REAGAN-UDALL FOUNDATION FOR THE FDA

Addressing the Public Health Effects of Opioid Medications

Hybrid Public Meeting
September 9, 2026 | 12:30-4:30pm (eastern)

This meeting is one of several engagement activities being conducted in collaboration with the FDA in partial fulfillment of Section 112 of the SUPPORT for Patients and Communities Reauthorization Act of 2025 (H.R. 2483), “Assessment of Opioid Drugs and Actions.”

This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of $117,983 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

REAGAN-UDALL FOUNDATION FOR THE FDA

WELCOME

Susan C. Winckler, RPh, Esq.

CEO, Reagan-Udall Foundation for the FDA

Housekeeping

REAGAN-UDALL FOUNDATION FOR THE FDA

Joining Online

Microphone and video will remain off during the meeting

Public Commenters: Make sure your Zoom name matches the name you used to register

Recording

This public meeting is being recorded

Slides, transcript, and video will be available at www.ReaganUdall.org

Agenda

All times listed in Eastern Time

REAGAN-UDALL FOUNDATION FOR THE FDA

12:30pm	Welcome
12:35pm	Opening Remarks
12:40pm	Federal Partner Panel
1:30pm	**Public Comment**
2:30pm	**Break**
2:45pm	Resume Public Comment
4:30pm	Adjourn

Public Comment

REAGAN-UDALL FOUNDATION FOR THE FDA

01 Scientific evidence regarding conditions of use, safety concerns, or benefit-risk assessment – including public health effects – of opioid medications

02 Input on FDA's regulation of opioid medications

03 Additional actions that could be considered to address the public health effects of opioid medications

REAGAN-UDALL FOUNDATION FOR THE FDA

Opening Remarks

Michael Davis, MD, PhD

Director, Center for Drug Evaluation & Research

U.S. Food and Drug Administration

Federal Partner Panel

REAGAN-UDALL FOUNDATION FOR THE FDA

Timothy J. Atkinson, PharmD

Acting Director, Opioid Safety
Specialty Care Program Office
U.S. Department of Veterans Affairs

Robert Baillieu, MD, MPH

Physician and Senior Advisor, Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration

Wilson M. Compton, MD, MPE

Deputy Director
National Institute on Drug Abuse

Kristine Schmit, MD, MPH

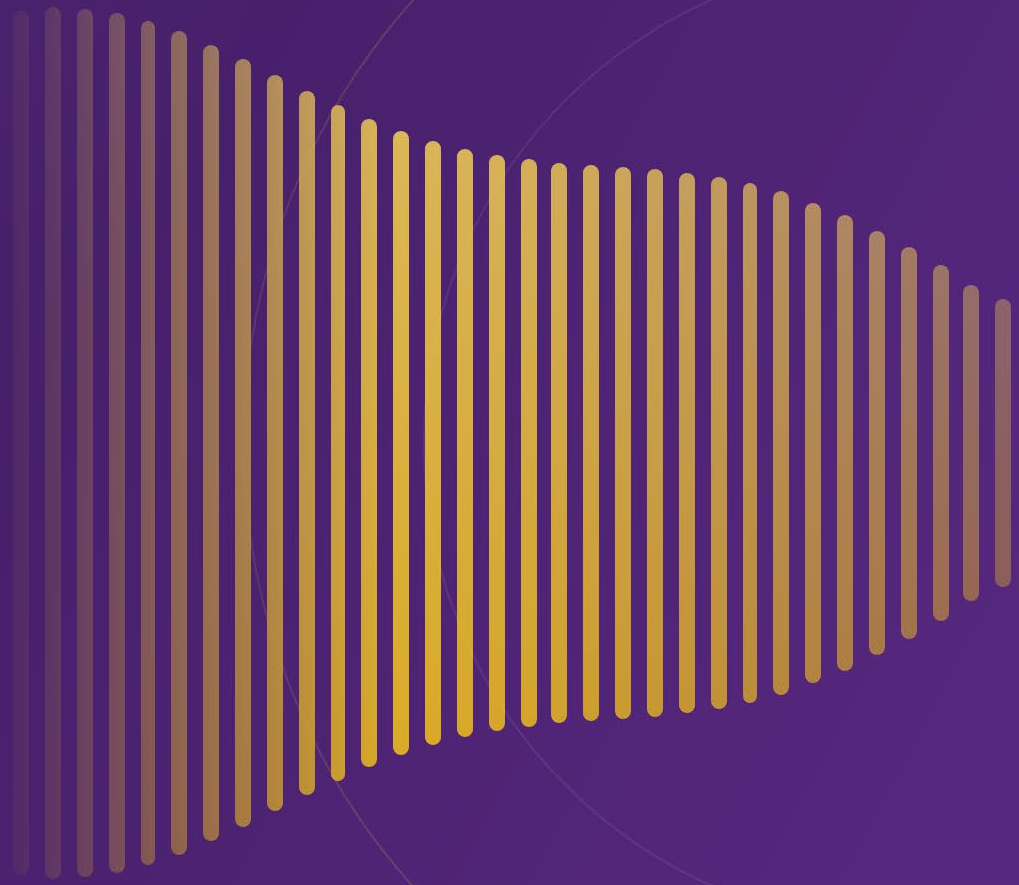
Medical Officer, Health Systems and Research Branch
Division of Overdose Prevention
U.S. Centers for Disease Control and Prevention

Marta Sokolowska, PhD

Deputy Center Director, Substance Use and Behavioral Health
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Public Comment

For those who signed up in advance during registration.



Public Comment Topics

REAGAN-UDALL FOUNDATION FOR THE FDA

1. Scientific evidence regarding conditions of use, safety concerns, or benefit-risk assessment—including public health effects—of opioid medications

2. Input on FDA's regulation of opioid medications

3. Additional actions that could be considered to address the public health effects of opioid medications

Virtual Public Comment Process

REAGAN-UDALL FOUNDATION FOR THE FDA

BEFORE THE MEETING BEGINS

- Make sure your Zoom name matches the name you used to register.
- Foundation staff will send you a Zoom chat in advance with a panelist invitation. Please watch for and accept that prompt.
- We will announce the commenters in sets of three, so you know when your slot is coming up.

Open public comment forum: neither the Foundation nor the FDA will respond.

YOUR TURN TO SPEAK

1. First time your name is called:
   PREPARE TO SPEAK
2. Second time your name is called:
   STAND BY, CAMERA OFF
3. When introduced:
   TURN ON YOUR CAMERA, UNMUTE, AND BEGIN SPEAKING
4. You will have
   10 seconds to begin speaking

Commenters will have

2.5 minutes (150 seconds)

to speak. A countdown timer will be provided.

In-Person Public Comment Process

REAGAN-UDALL FOUNDATION FOR THE FDA

ORDER OF COMMENT

Virtual commenters will speak first. In-person commenters will then be called by last name, in alphabetical order.

- The moderator will provide a verbal cue when your turn is coming up.
- A staff member will direct you to the appropriate podium.

Open public comment forum: neither the Foundation nor the FDA will respond.

YOUR TURN TO SPEAK

1. First time your name is called:
   MOVE TO THE STAGE STAIRS
2. Second time your name is called:
   MOVE TO THE PODIUM
3. When introduced:
   SPEAK FROM THE PODIUM

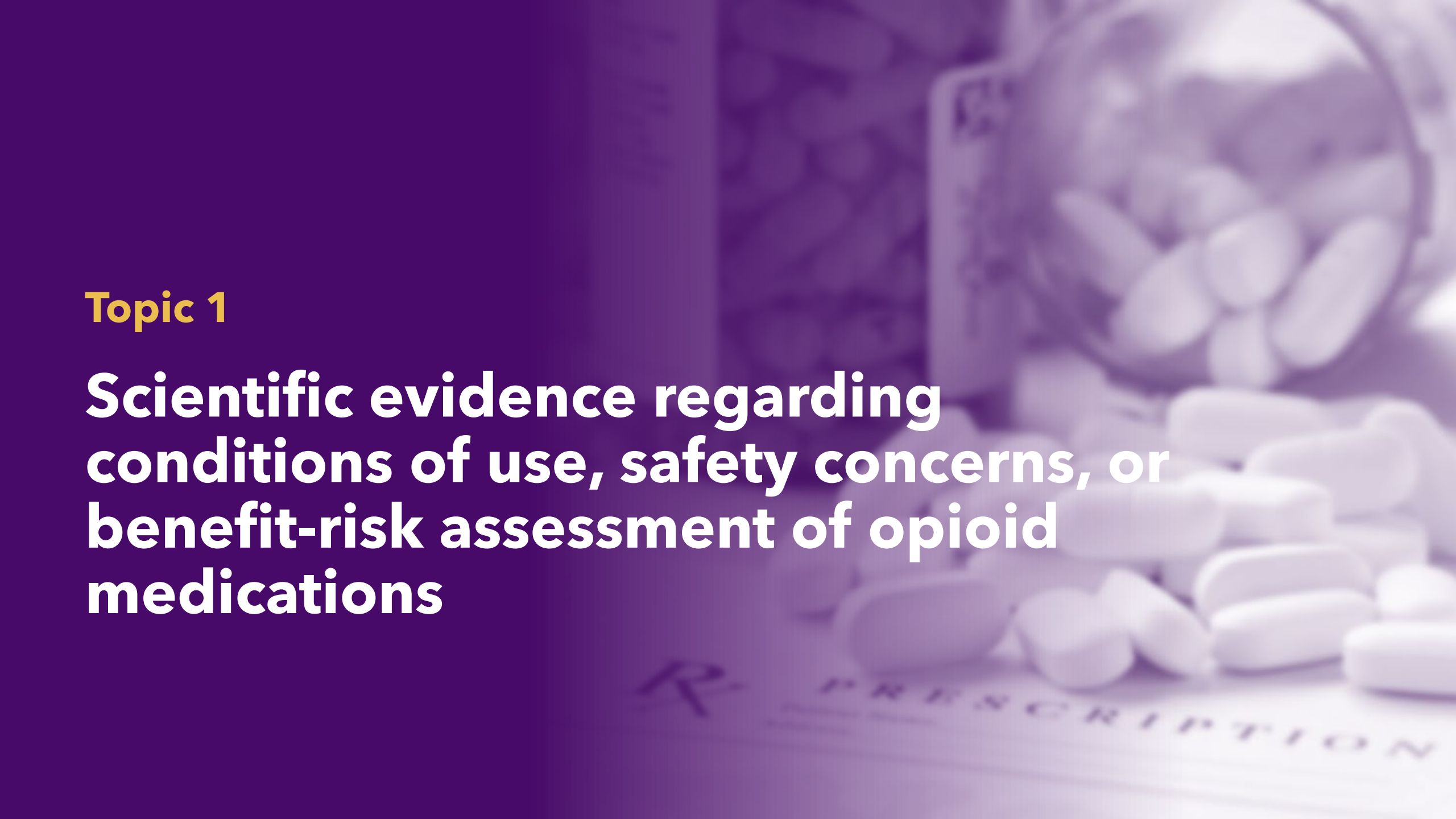
Commenters will have

2.5 minutes (150 seconds)

to speak. A countdown timer will be provided.

Topic 1

Scientific evidence regarding conditions of use, safety concerns, or benefit-risk assessment of opioid medications



Amy Applebaum

Public Comment

Ashley Berryessa

Public Comment

Kailyn Bower

Public Comment

Chronic Pain Patients Need Evidence-Based Access

A patient perspective from living with stage 4 endometriosis

MY REALITY

Stage 4 endometriosis

Severe, debilitating pain.

Other treatments failed.

My prescribed opioid works.

Effective treatment lets me live.

ADDICTION RISK IS NOT UNIFORM

0.19% No prior/current abuse or addiction.

3.3% Overall chronic-pain group in review.

<8% Carefully diagnosed addiction in cited studies.

THE EPIDEMIC CHANGED

2012–2024

Prescription opioid dispensing ↓↓↓

Overdose deaths ↑ through 2022

Synthetic opioids / fentanyl drove the rise

2023–2024: deaths ↓ 26%

CDC: prescription opioids are not a primary driver of overdose today.

Carolyn Concia

Public Comment

Todd Davies

Public Comment

MEASURING LONG-TERM SUCCESS IN OPIOID REGULATORY SCIENCE

REGULATORY CHALLENGE

Opioid public health effects are influenced by medication, formulation, and treatment setting.

EVIDENCE GAP

Common endpoints often fail to distinguish meaningful long-term benefit from meaningful long-term harm.

FDA OPPORTUNITY

Develop validated, clinically actionable measures that support benefit-risk decisions.

Before significant changes are made to conditions of use, dosing expectations, or benefit-risk frameworks, FDA should prioritize development of clinically actionable long-term outcome measures.

Todd H. Davies, PhD
Associate Professor & Director of Research | Division of Addiction Science
Joan C. Edwards School of Medicine | Marshall University
daviest@marshall.edu

Raoul Estrada

Public Comment

Chad Kollas

Public Comment

Correctly Contextualizing Benefits & Risks of Long-term Opioid Therapy

Virtual Testimony - Chad D. Kollas, MD, FACP, FAAHPM

References:

- Kollas CD, Ruiz K, Laughlin A. Effectiveness of Long-Term Opioid Therapy for Chronic Pain in an Outpatient Palliative Medicine Clinic. J Palliat Med. 2024 Jan;27(1):31-38. doi: 10.1089/jpm.2023.0251.
- Kollas CD, Kollas BB. Chapter 15: Laws and Policies Affecting Pain Management in the United States. Bonica's Management of Pain, 6th Edition (James P. Rathmell JP, Edwards RR, Gilligan CJ). Wolters Kluwer, September 2026. ISBN: 9781975222369.

Disclosures:

- Facilitator, American Academy of Hospice & Palliative Medicine (AAHPM) Pain Care Discussion Page
- Member, American Medical Association (AMA) House of Delegates (AAHPM Delegate)
- Chair, AMA Pain & Palliative Medicine Specialty Section Council
- Member, AMA Substance Use & Pain Care Task Force (AAHPM Representative)

Sara Lewis

Public Comment

ARE WE MEASURING BOTH SIDES OF OPIOID BENEFIT–RISK?

Patient story + national evidence: benefit–risk must include consequences of losing effective treatment.

24.3%
U.S. adults had chronic pain
CDC/NCHS, 2023

−70%
Anesthesiology applicants to Pain Medicine fellowships
351 → 106 | 2019–2025

−21.6%
Retail opioid prescriptions
153.6M → 120.4M | 2019–2024

FDA + HHS
WARN AGAINST RAPID TAPER / ABRUPT STOP
Withdrawal • worse pain • distress • suicide

OPIOID-RELATED HARMS WE TRACK

- Overdose / respiratory depression
- Misuse, diversion & OUD
- Adverse events & mortality
- Prescribing rates / dosage metrics

OUTCOMES AFTER TREATMENT DISRUPTION

- Uncontrolled pain & withdrawal
- Lost function / quality of life
- Hospitalization & psychological crisis
- Unsafe self-treatment & suicide

A MEDICATION HAS RISKS. LOSING EFFECTIVE TREATMENT HAS RISKS TOO.

Are BOTH being captured and weighed with the same rigor?

Sara Lewis • Arachnoiditis United

Sources: CDC/NCHS Data Brief 518 (2024) • CDC Opioid Dispensing Data (2026)
CDC Guideline (2022) • HHS Tapering Guide (2019) • Wright et al., Pain Medicine (2026)

Denise Zecca-George

Public Comment

Risk-Benefit Evaluation is Individual, not Categorical

~18 million Americans live with moderate-to-severe chronic pain.[1]

Opioid risk varies w/ dose, comorbidities, Rx history, and patient context.[2]

The Numbers on Opioid Use Disorder (OUD)

2.1% of 91.8 million Rx-opioid users met criteria for prescription-OUD.[1,3]

Among >4.3 million chronic pain patients, 9.3% had dependence and/or OUD[4]

Restriction Carries Substantial Public Health Risk

Opioid pain treatment disruption is associated w/ poorer mental outcomes, including ↑ suicide attempts, withdrawal, and hospital/ED visits.[5,6]

WHAT RESTRICTION OVERLOOKS

- **~18 million** Americans live with moderate-to-severe chronic pain[1]
- **Quality of life** comparable to patients dying with cancer[1]
- **~$600 billion/year** healthcare costs + lost productivity[1]

1. Nadeau, S. E., Wu, J. K., & Lawhern, R. A. (2021). Opioids and Chronic Pain: An Analytic Review of the Clinical Evidence. Frontiers in Pain Research, 2(721357). https://doi.org/10.3389/fpain.2021.721357
2. Cordero-Pérez, F. J., Pérez-Baena, M. J., Pina-Ruviralta, N., Fernández-Testa, A., & Holgado-Madruga, M. (2026). Optimizing Opioid Use in Pain Management: A Comprehensive Review of Clinical Benefits, Risks, and Dependence. *Healthcare (Basel, Switzerland), 14*(4), 457. https://doi.org/10.3390/healthcare14040457
3. Han, B., Compton, W. M., Blanco, C., Crane, E., Lee, J., & Jones, C. M. (2017). Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health. *Annals of Internal Medicine, 167*(5), 293–301. https://doi.org/10.7326/m17-0865
4. Thomas, K. H., Dalili, M. N., Cheng, H. Y., Dawson, S., Donnelly, N., Julian, & Hickman, M. (2024). Prevalence of problematic pharmaceutical opioid use in patients with chronic non-cancer pain: A systematic review and meta-analysis. *Addiction*, *119*(11). https://doi.org/10.1111/add.16616
5. Sabety, A. H., Neprash, H. T., Gaye, M., & Barnett, M. L. (2024). Clinical and healthcare use outcomes after cessation of long term opioid treatment due to prescriber workforce exit: quasi-experimental difference-in-differences study. *BMJ*, *385*, e076509. https://doi.org/10.1136/bmj-2023-076509
6. Ramachandran, S., Kertesz, S., Gravlee, E., Prajapati, P., Bentley, J. P., & Yang, Y. (2025). Development of the barriers to opioid access scale among individuals with chronic pain. *Exploratory Research in Clinical and Social Pharmacy*, *18*, 100580. https://doi.org/10.1016/j.rcsop.2025.100580

Adriane Fugh-Berman

Public Comment

PharmedOUT.ORG

Adriane Fugh-Berman MD

Professor, Department of Pharmacology and Physiology
& Department of Family Medicine
Director, PharmedOut
Georgetown University Medical Center
pharmedout@gmail.com

- **Inappropriate prescribing** of opioids is still a major public health problem.
- Overprescribing opioids **contributes substantially** to the epidemic of opioid use disorder.
- Opioids are **generally ineffective** for chronic pain, and **overused** for acute pain.
- With continued use, opioids become **less effective** and escalating doses increases harms.

Dr. Fugh-Berman is a paid expert witness at the request of plaintiffs in litigation regarding pharmaceutical marketing practices. Dr. Fugh-Berman is also an advisory board member of Physicians for Responsible Opioid Prescribing

Douglas Smith, MD

Public Comment

Role of plasma catecholamines in eliciting cardiovascular changes seen during naloxone-precipitated withdrawal in conscious, unrestrained morphine-dependent rats

A P Chang et al. J Pharmacol Exp Ther. 1990 Sep.

"After removal of adrenal glands from morphine-dependant rats, naxolone injection produced no change in the BP or plasma Epi."

Regional changes in sympathetic nerve activity and baroreceptor reflex function and arterial plasma levels of catecholamines, renin and vasopressin during naloxone-precipitated morphine withdrawal in rats

M Delle et al. J Pharmacol Exp Ther. 1990 May.

"Although renal SNA was inhibited by approximately 50%, adrenal SNA and lumbar SNA increased by approximately 400 and 80%, respectively. Splanchnic SNA did not change significantly."


ANESTHESIOLOGY

ARTICLE NAVIGATION

Clinical Science | May 1998

Profound Increase in Epinephrine Concentration in Plasma and Cardiovascular Stimulation after [micro sign]-Opioid Receptor Blockade in Opioid-addicted Patients during Barbiturate-induced Anesthesia for Acute Detoxification FREE

Peter Kienbaum, MD; Norbert Thurauf, MD; Martin C. Michel, MD; Norbert Scherbaum, MD; Markus Gastpar, MD; Jurgen Peters, MD

+ Author and Article Information

Anesthesiology May 1998, Vol. 88, 1154–1161.

"Concentration of epinephrine in plasma increased 30-fold (15 +/- 9 to 458 +/- 304 pg/ml)."

Increased OPRM1 DNA methylation in lymphocytes of methadone-maintained former heroin addicts

David A Nielsen et al. Neuropsychopharmacology. 2009 Mar.

" Direct sequencing of bisulfite-treated DNA showed that the percent methylation at two CpG sites was significantly associa with heroin addiction."

" Increased DNA methylation in the OPRM1 gene is associated with opioid dependence. Hypermethylated CpG sites located in OPRM1 promoter may potentially block the binding of Sp1 and other transcription activators, thus leading to OPRM1 silencing. "

Elevated levels of DNA methylation at the *OPRM1* promoter in blood and sperm from male opioid addicts

Vesselin M. Chorbov, PhD, Alexandre A. Todorov, PhD, [...], and Theodore J. Cicero, PhD

Epigenetic Variation in the Mu-opioid Receptor Gene in Infants with Neonatal Abstinence Syndrome

Elisha M Wachman, MD, Marie J Hayes, PhD, [...], and Jonathan M Davis, MD

"Increased methylation within the OPRM1promoter is associated with worse NAS outcomes, consistent with gene silencing."

Epigenetic variation in OPRM1 gene in opioid-exposed mother-infant dyads

E M Wachman et al. Genes Brain Behav. 2018 Sep.

"These results suggest an association of higher levels of OPRM1 methylation at specific CpG sites and increased NAS severity, replicating prior findings."

Effect of short-term prescription opioids on DNA methylation of the *OPRM1* promoter

Jose Vladimir Sandoval-Sierra, Francisco I. Salgado García, [...]Khyobeni Mozhui

Clinical Epigenetics **12**, Article number: 76 (2020) | Cite this article

"The present study provides evidence that the hypermethylation of the OPRM1promoter is in response to opioid use and that epigenetic differences in OPRM1 and other sites are associated with a short-term use of therapeutic opioids."

Topic 2

Input on FDA's regulation of opioid medications

Toni Collins

Public Comment

WHEN FEDERAL OPIOID POLICY MEETS THE REAL WORLD

PROTECT PATIENTS FROM INAPPROPRIATE PRESCRIBING & INAPPROPRIATE RESTRICTION.

Individual patients require individualized care.

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1 GUIDANCE ≠ HARD LIMITS

MME is a tool, not a treatment ceiling. Policies should assist clinical judgment, not overtake it.

2 RISK-BENEFIT MUST WORK BOTH WAYS

Undertreatment has risks too. Consider stability, function, untreated pain, and the risks of alternative treatments.

3 REGULATORY FEAR HAS CONSEQUENCES

Fear should not dictate care. Clinicians and pharmacists need room to exercise professional judgment.

TONI COLLINS | Patient Advocate

Anne Fuqua

Public Comment

Nazia Fyazi

Public Comment

Joseph Hermosillo

Public Comment

Tina Kanak

Public Comment

Kristin McGarity

Public Comment

NATIONAL COUNCIL ON INDEPENDENT LIVING

The nation's longest-running organization run by and for people with disabilities

In policies and legislation addressing opioid prescribing, NCIL supports these principles:

No arbitrary or blanket prescribing limits that override individualized, medically necessary treatment as determined by an individual and their healthcare provider

Ensure access to the full range of pain treatments with no undue access burdens—such as excessive appointment frequency, invasive procedures or unproven treatments required before prescribing opioids, restrictive refill rules, or "opioid taxes"

Prohibit forced or involuntary treatment or institutionalization without patient consent, including involuntary tapering without effective alternative pain management

Protect individuals in pain taking prescription opioid medication from stigma, bias, and discrimination in media, healthcare, employment, and community life.

Include people with lived experience of chronic pain in developing laws, policies, and philosophies concerning pain care, with a meaningful "seat at the table" in discussions and decision making.

Enabling people with disabilities to work, parent, and participate in community life is a public health BENEFIT

Carmen Orlowski

Public Comment

Erica Ro

Public Comment

Bev Schechtman

Public Comment

FDA Measured Addiction Risk. Now Measure Patient Outcomes After Opioid Reduction.

Bev C. Schechtman | VP, The Doctor Patient Forum

DPF receives no pharmaceutical or government funding.

Table 4: Unweighted 12-Month Cumulative Incidence Using Different OUD-P Thresholds for Defining Opioid Use Disorder in 3033-1 – Prospective Study

OUD Criteria	12-Month Comulative Incidence (95% CIs)	
	ER/LA Initiators (N = 978)	LToT Initiators (N = 1,244)
Pain-Adjusted[6] DSM-5 Measure		
OUD-H and/or ≥ 2 pain-adjusted OUD-P criteria (any OUD)	8.4% (6.8, 10.2)	5.8% (4.4, 7.7)
Prespecified primary analysis: OUD-H and/or ≥ 4 pain-adjusted OUD-P criteria (moderate-to-severe OUD)	1.4% (0.9, 2.3)	1.6% (0.9, 2.9)
OUD-H and/or ≥ 6 pain-adjusted OUD-P criteria (severe OUD)	0.4% (0.1, 1.7)	0.9% (0.4, 1.9)
DSM-5[6] Measure		
OUD-H and/or ≥ 2 DSM-5 OUD-P criteria (any OUD)	22.5% (19.0, 26.5)	14.8% (13.0, 16.8)
OUD-H and/or ≥ 4 DSM-5 OUD-P criteria (moderate-to-severe OUD)	5.8% (4.5, 7.3)	3.4% (2.3, 5.1)
OUD-H and/or ≥ 6 DSM-5 OUD-P criteria (severe OUD)	1.1% (0.6, 1.7)	1.5% (0.8, 3.1)

Source: Briefing Document for AADP and DSARM Advisory Committees, May 5, 2025

- **"However, the impact of these prescribing limits on the patient, their pain level, their quality of life, and other important health outcomes has not been well studied…"**
- **"Most importantly, most of the current literature does not sufficiently evaluate patient outcomes in a rigorous manner, and many other important patient outcomes are not evaluated at all."**

Source: HHS, *Report to Congress on Opioid Prescribing Limitations* (2020)

Christine Wallace

Public Comment


Luke Taylor's Story
THE FACE OF
ADHESIVE ARACHNOIDITIS
UNTREATED PAIN KILLS!
MX69.com

Gail Groves Scott

Public Comment

Marketing of opioid medications requires stronger regulation

Why? Controlled medications for pain & addiction: vulnerabilities & policy gaps

Clarify public health requirements: industry RX surveillance, mandated reports

More transparency: FDA "Sunshine" database, marketing & education material

Require independent CE for marketers & sales reps

Ban industry gifts

health policy network

Gail@HealthPolicyNetwork.com

Gail Groves Scott, MPH, PhD candidate in Health Policy

- Former 16-year pharma sales rep. Sold opioids for pain, addiction
- Whistleblower & fact witness: illegal marketing of opioids
- Director, Health Policy Network, LLC, Lancaster, PA, independent research & advocacy organization. No outside funding.

James Hackworth

Public Comment

Adneuris THERAPEUTICS

First-in-class Dual-NMR agonist

An investigational new pain medicine to potentially replace opioids

INPUT ON FDA'S REGULATIONS ON OPIOID MEDICATIONS

September 9, 2026

James Hackworth, PhD

Corey Whetzel

Public Comment

REAGAN-UDALL FOUNDATION FOR THE FDA

Break

The meeting will resume at 2:45pm Eastern

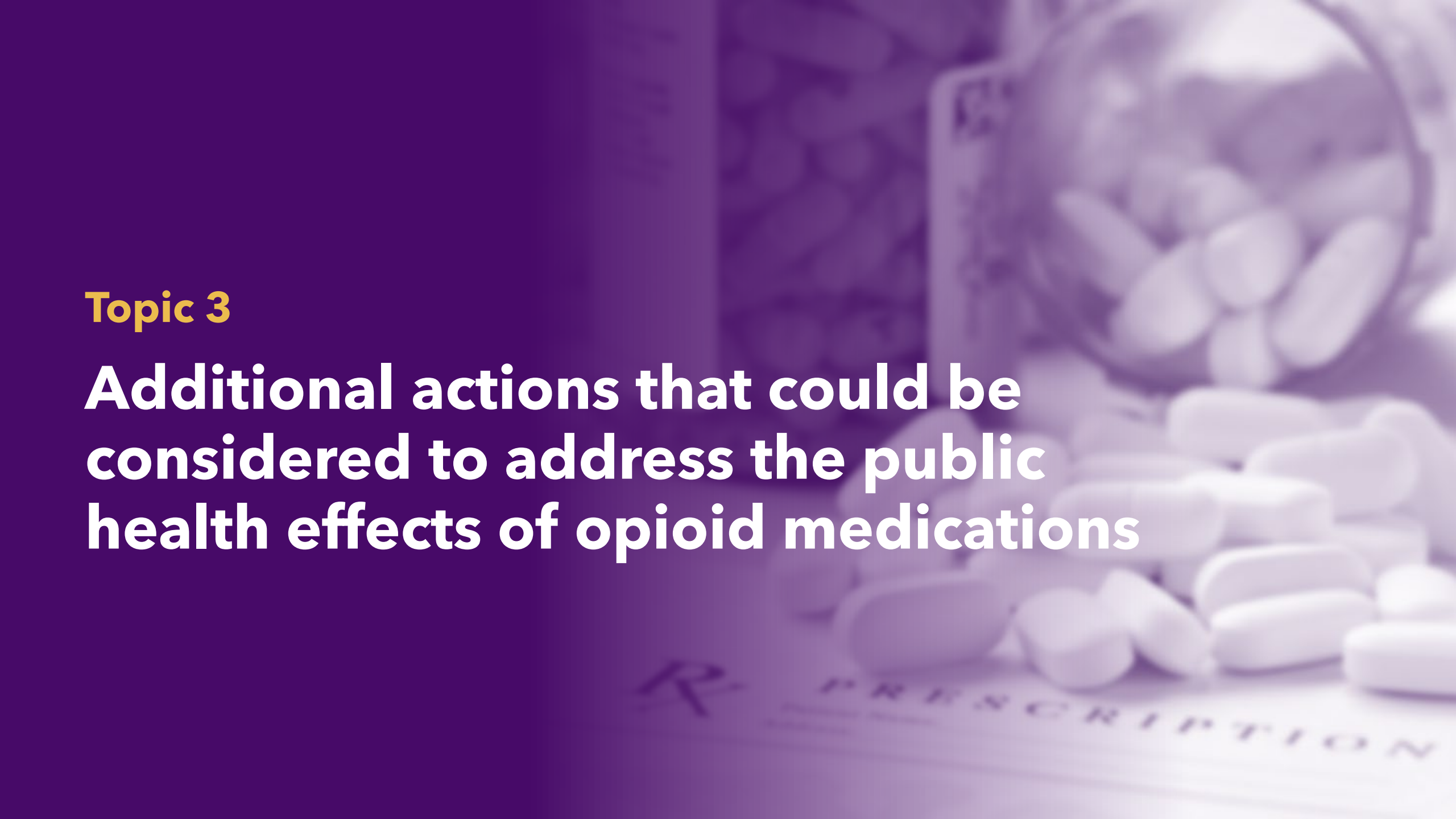
REAGAN-UDALL FOUNDATION FOR THE FDA

Public Comment

CONTINUED

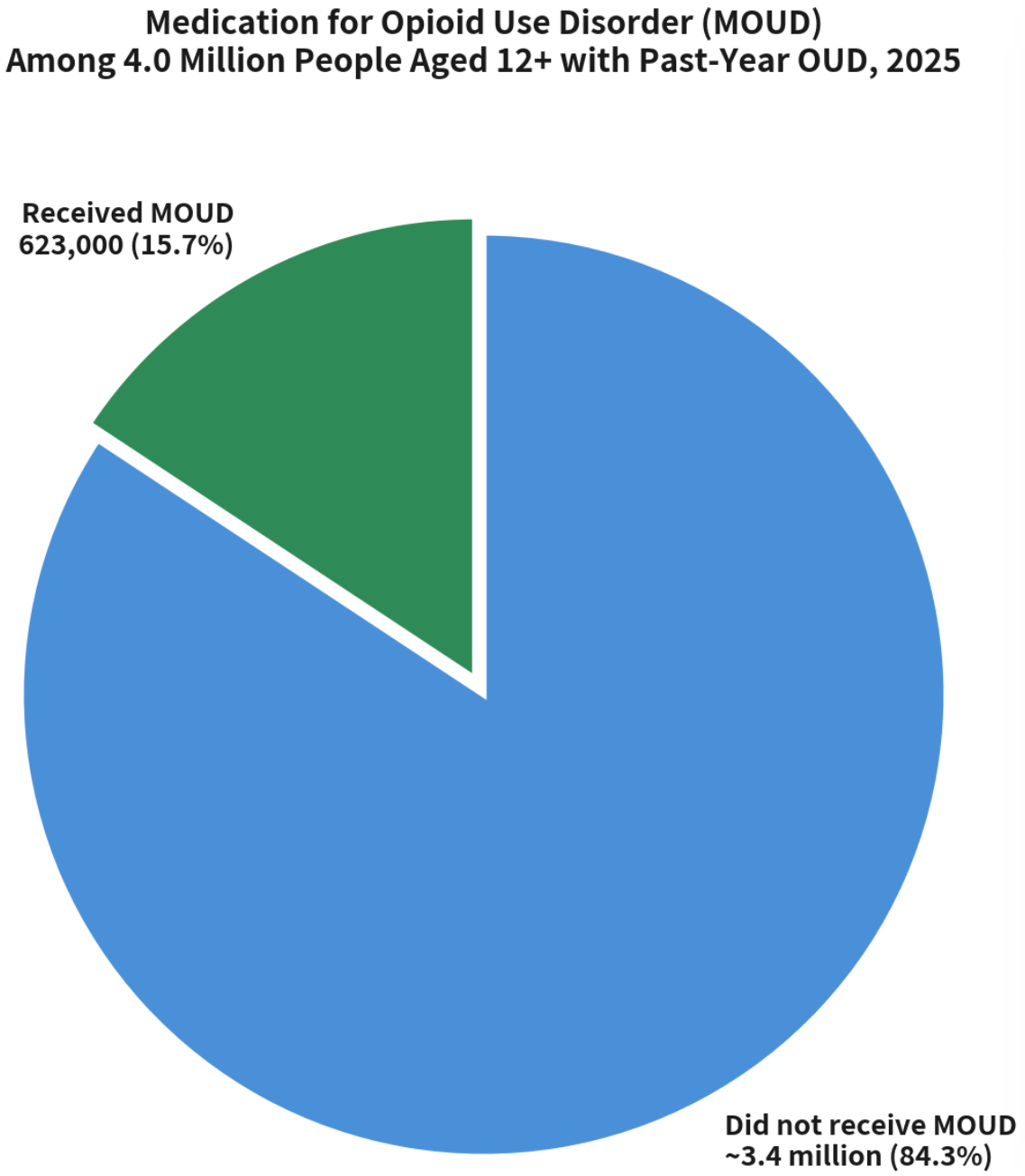
Topic 3

Additional actions that could be considered to address the public health effects of opioid medications



Kevin Roy

Public Comment



Data Summary

- **4.0 million** people aged 12+ had a past-year opioid use disorder
- **15.7%** (623,000) received medication for OUD in the past year
- **84.3%** (~3.4 million) did not receive it

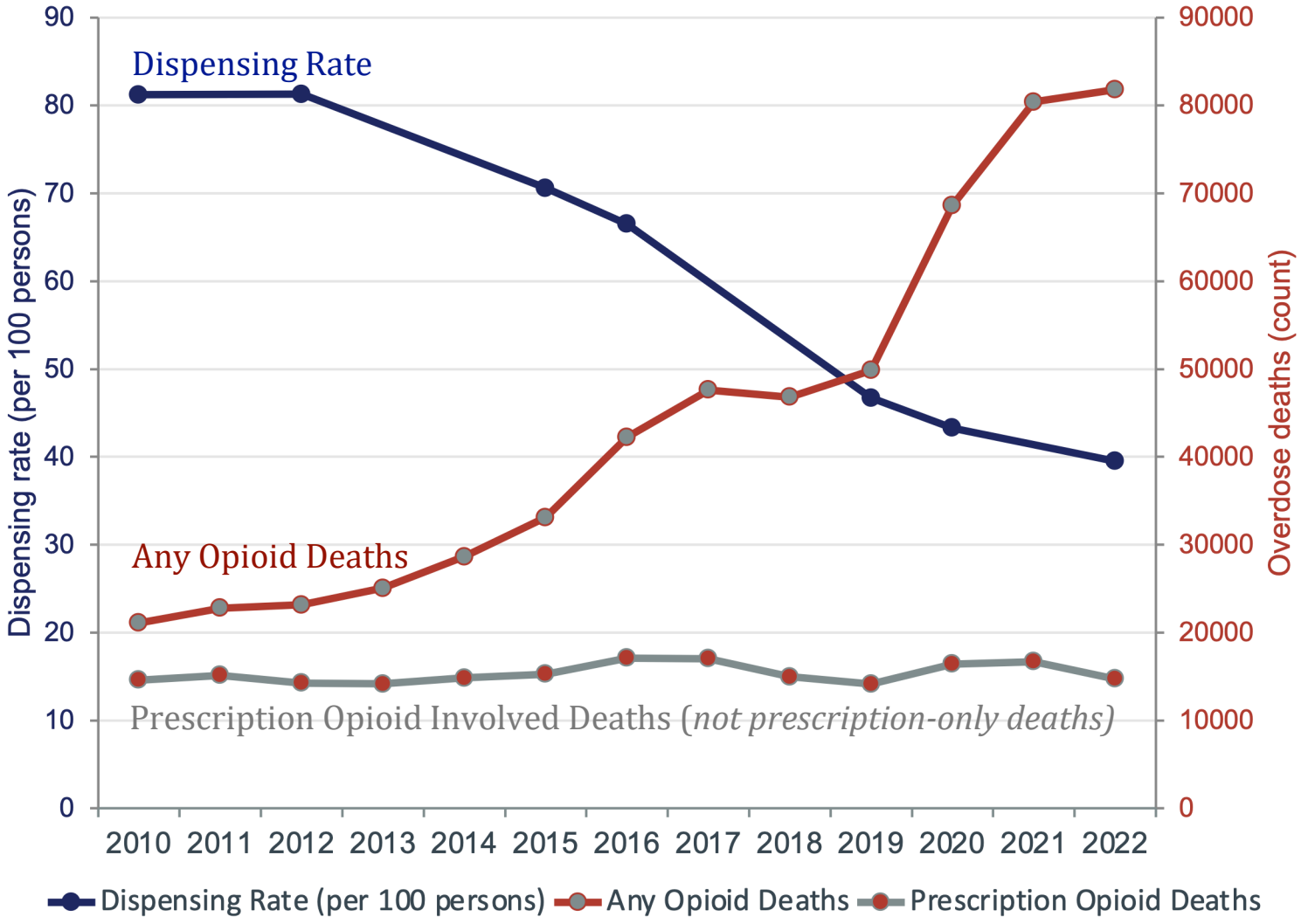
Presented by Kevin Roy on behalf of Center for Addiction, Science, Policy and Research (CASPR)

Source: Substance Abuse and Mental Health Services Administration. Key Substance Use and Mental Health Indicators in the United States: Results from the 2025 National Survey on Drug Use and Health. HHS Publication No. PEP26-07-001. Rockville, MD: SAMHSA, 2026 — samhsa.gov

Sara Batchelder

Public Comment

Opioid Dispensing Rates vs. Deaths, 2010-2022



"Actions [derived from the 2016 Guideline]…have contributed to patient harm, including untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose, and suicidal ideation and behavior."

—CDC, Clinical Practice Guideline for Prescribing Opioids for Pain, 2022

Dispensing rate: CDC/IQVIA, verified years shown (gaps = years without a published national rate).
Overdose deaths: CDC WONDER, every year verified. Sources: cdc.gov/overdose-prevention; nida.nih.gov.

Lisa Bright

Public Comment

Jessamyn Butler

Public Comment

Terecita Elizabeth Carrion Zavaleta

Public Comment

2024 Update and Measures to Reduce the Impact

Measures to Reduce the Impact of Opioids on Public Health

- Rational use
- Education
- Active pharmacovigilance
- Shared responsibility

Australia has strengthened the concept of opioid stewardship, aimed at balancing pain relief with the prevention of respiratory depression, dependence, overdose, and unnecessary prolonged use.

Canada (2024)

- Harm reduction.
- Education on overdose prevention.
- Access to naloxone.

European Union (2024)

Maintains risk minimization measures as part of its good pharmacovigilance practices.

Paul Giacinto

Public Comment

Mark Ibsen, MD

Public Comment

San Irving

Public Comment

Neil Jackson

Public Comment

Richard Lawhern

Public Comment

Q3: Actions to address public health effects of opioid medications

- **Facts:**
  - Iatrogenic Substance Abuse Disorder occurs in <1% of patients treated by a clinician for severe chronic pain
  - "Over-Prescribing" did not create the "US Opioid Crisis."
  - Addiction is demand driven, unrelated to supply.
  - US CDC acknowledges 2022 Guidelines have harmed patients
- **Actions Required:**

- Immediately repudiate and withdraw CDC and VA guidelines and FDA REMS for use of opioids

- FDA schedule listening sessions for patient advocates

- Open inter-agency discussions on correction of public health policy for treatment of pain and addiction.

Richard A Lawhern Ph.D.

Vanessa Mareno

Public Comment

Oral health is imperative in addressing the public health effects of opioid medications

1. Design an **1115 Medicaid Demonstration Waiver** that supports **comprehensive dental benefits** for at risk individuals with OUD and those on **sublingual buprenorphine**

2. Include **oral healthcare** in the **SAMHSA Certified Community Behavioral Health Clinic** (CCBHC) Medicaid expansion program

Taye McCord-Amasis

Public Comment

Fanesse Muyah

Public Comment

Regina Sën

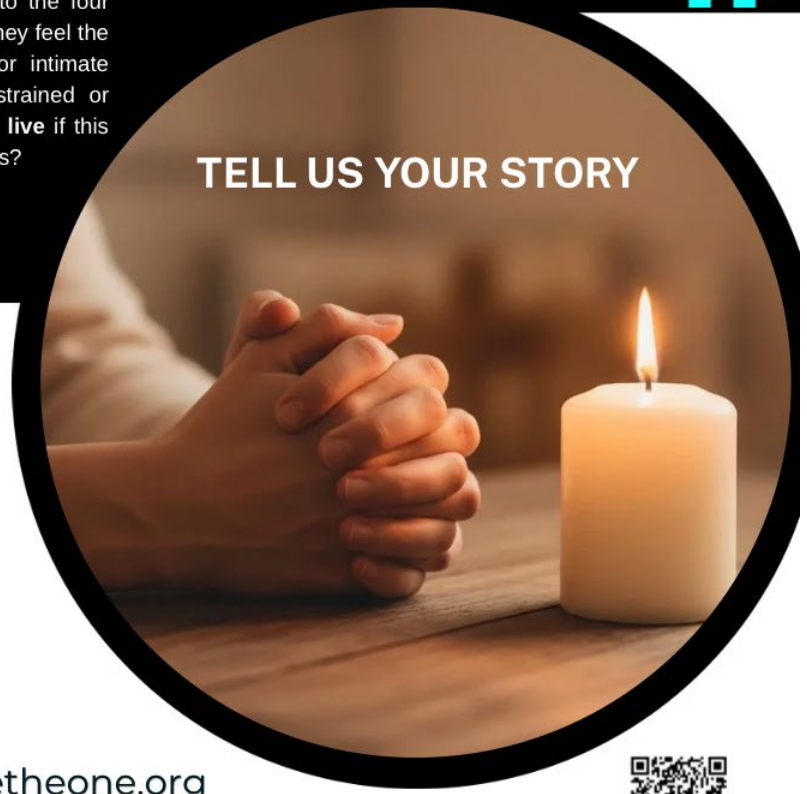
Public Comment

Emily's Place
THE ONE

Is Your Loved One In Pain, *Life Altering?*

HAVE THEY FELT ABANDONED OR UNHEARD by the medical community? See NationalPain.org. Life-sustaining medicine withheld, no safe haven for care? **Has life shrunk** to the four corners of their bed? In perpetual survival mode? Do they feel the grief of a lost career? Autonomy? Lost marriage or intimate relationship? Has their emotional regulation been strained or tattered by all-consuming pain? Do they wonder **why live** if this high level of pain continues? If they can't be themselves?

We Need **Your Eye Witness**



DOES YOUR LOVED ONE HAVE AN UNDIAGNOSED OR LIFELONG CONDITION

- Mostly Bedbound or Housebound?
- Pain Level 6 or Higher Everyday?
- For A Year Or More?

CONTACT

emilysplacetheone.org

Artrsenlove@gmail.com

David Smith

Public Comment

Tamera Stewart

Public Comment

A COMPLETE BENEFIT / RISK ASSESSMENT COUNTS ALL THREE

Benefits of treatment … and the risks of losing it … cannot remain outside the analysis. It belongs front and center.

01

BENEFITS OF TREATMENT

- Pain relief
- Function
- Quality of life
- Independence

02

RISKS OF TREATMENT

- Adverse effects
- Misuse
- Addiction
- Overdose

03

RISKS OF UNDERTREATMENT & LOST CARE

- Functional decline
- Mental-health crisis
- Illicit substitution
- Suicide and/or Death

SUPPORT Act §112 requires FDA's plan to address public-health effects as part of the benefit / risk assessment. In prior FDA actions involving benefit / risk assessment, meaningful outcome measures were required to protect the public. This action must not omit the outcomes that matter most to patients who have repeatedly warned of harms caused by widespread reductions in opioid prescribing.

OUTPUTS	VS	OUTCOMES
Prescriptions • MME • Tapers • Trainings Measures administrative actions		Pain • Function • Access • Mental health • Survival Measures what happened to patients

Tamera Stewart Impact2HEAL by P3Alliance

Sarah Tompkins

Public Comment

Tyler Varisco

Public Comment

Chris Fox

Public Comment

Peter Lee

Public Comment

Susan Ousterman

Public Comment

RESTORING PUBLIC TRUST

Requires structural reform

After nearly three decades, the crisis is no longer about opioid prescribing, it is the loss of public trust.

1 Restore regulatory independence

Address the FDA's dependence on industry user fees and make public accountability unmistakable.

2 Protect clinical judgment

Medical decisions should be guided by medical standards; not fear of law-enforcement.

3 Remove commercial influence

End direct pharmaceutical solicitation of prescribers and direct-to-consumer drug advertising.

4 Make policy accountable

Measure unintended harms. Acknowledge failures. Change course when policies cause harm.

Public health requires public trust.

Susan Ousterman | Executive Director, Vilomah Foundation

Charles Stillings

Public Comment

REAGAN-UDALL FOUNDATION FOR THE FDA

Addressing the Public Health Effects of Opioid Medications

Thank you!

Slides, transcript, and recording will be available at **www.ReaganUdall.org**

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