



State Regulation of Psilocybin Therapy

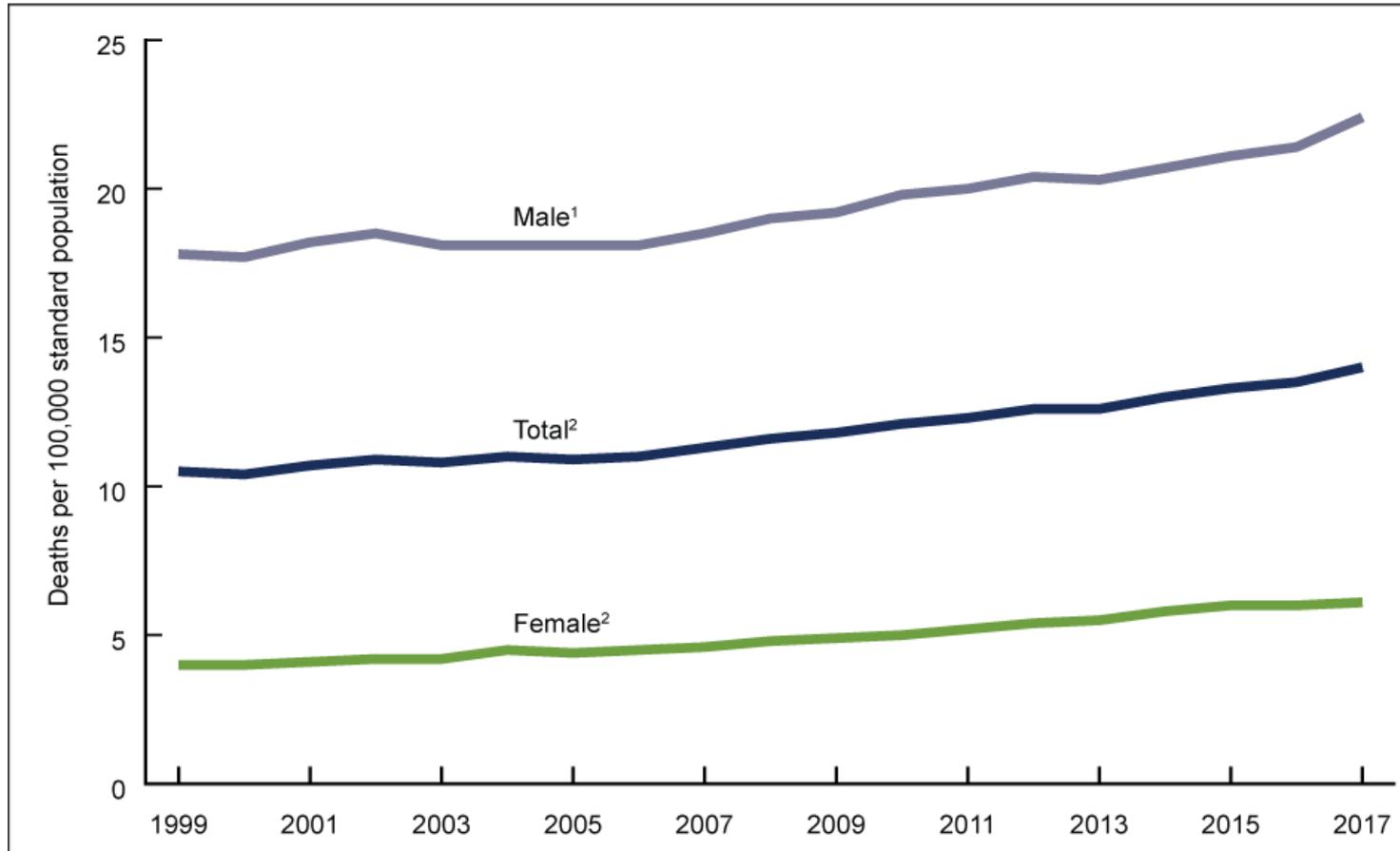
Mason Marks, MD, JD

Assistant Professor of Law, Gonzaga University
Fellow-in-Residence, Harvard Law School, Petrie-Flom Center

masonmarks@fas.harvard.edu

U.S. Suicide Trends (1999 – 2017)

Figure 1. Age-adjusted suicide rates, by sex: United States, 1999–2017

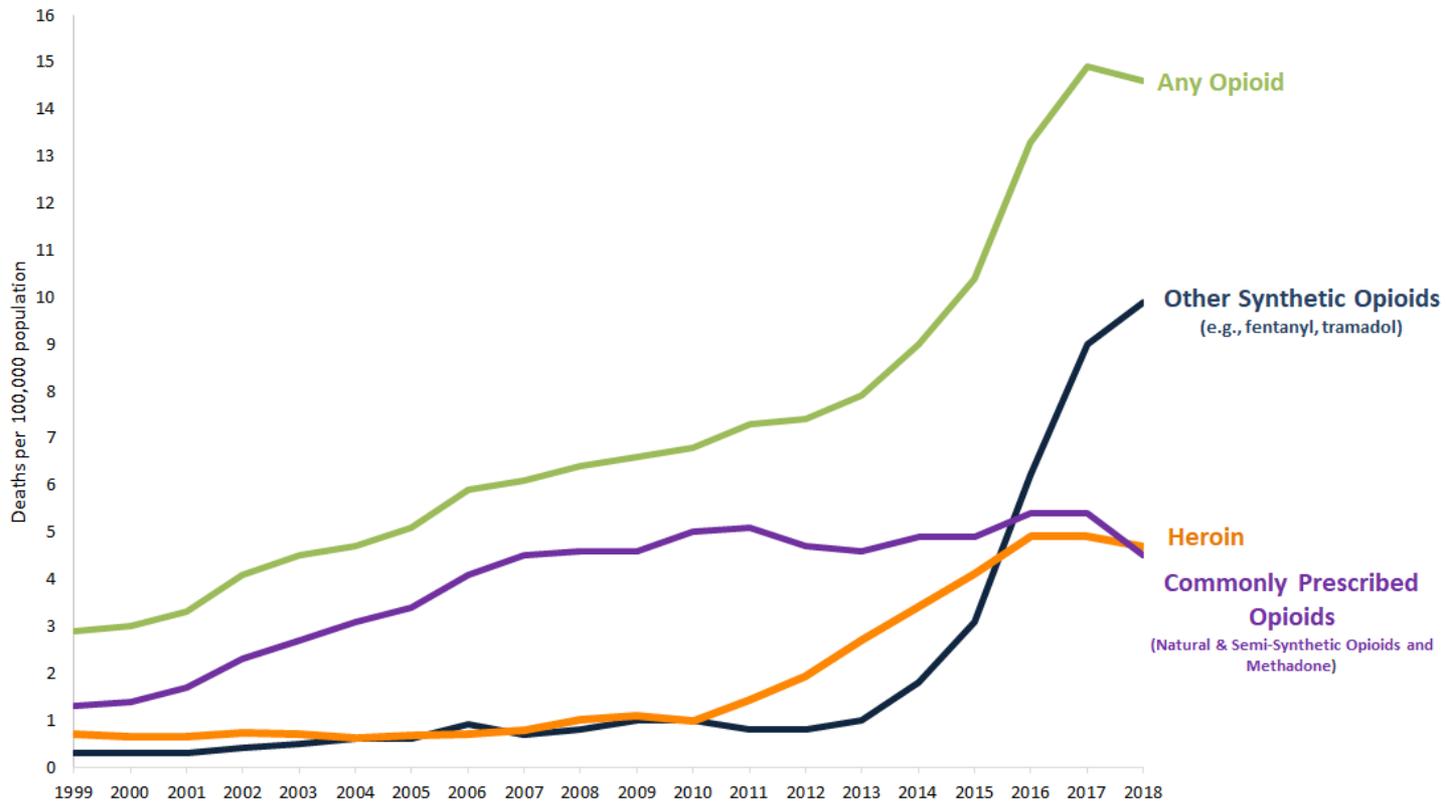


¹Stable trend from 1999 through 2006; significant increasing trend from 2006 through 2017, $p < 0.001$.



U.S. Overdose Death Trends (1999 – 2018)

Overdose Death Rates Involving Opioids, by Type, United States, 1999-2018



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2020.
<https://wonder.cdc.gov/>.

www.cdc.gov
Your Source for Credible Health Information



Psilocybin-Assisted Therapy



- ▣ Supervised administration
- ▣ Up to eight hours duration
- ▣ Sustained decrease in depression and anxiety
- ▣ Mystical experiences
- ▣ Increased life satisfaction
- ▣ Increased acceptance of mortality

Griffiths et al., *Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial*, 30 *Journal of Psychopharmacology* 1181 (2016).



Psilocybin-Assisted Therapy

- ❑ Schedule I controlled substance (state and federal law)
- ❑ No clear evidence for physical or psychological dependence
- ❑ The Netherlands allows over the counter sales
- ❑ FDA breakthrough therapy for depression
- ❑ Ongoing Phase II clinical trials
- ❑ Canada allows treatment through compassionate use
- ❑ US advocates failed to gain access through right to try
- ❑ In 2020, Oregon voters passed Measure 109, creating statewide industry for psilocybin-assisted therapy



State Regulation

- Oregon Measure 109
- Florida HB 549
- Hawaii SB 738
- Iowa HF 480
- Connecticut HB 6296
- Texas HB 1802
- Massachusetts HD 3829
- California SB 519
- Iowa HF 459



Unresolved Questions

- ❑ What form should state regulation take?
- ❑ What is the relationship between state and federal law?
- ❑ How can regulators ensure equal access to care?
- ❑ What are best practices for psilocybin research and therapy?
- ❑ What are ideal screening criteria?
- ❑ What training should psilocybin therapy facilitators complete?
- ❑ How can researchers access federal funding for research?

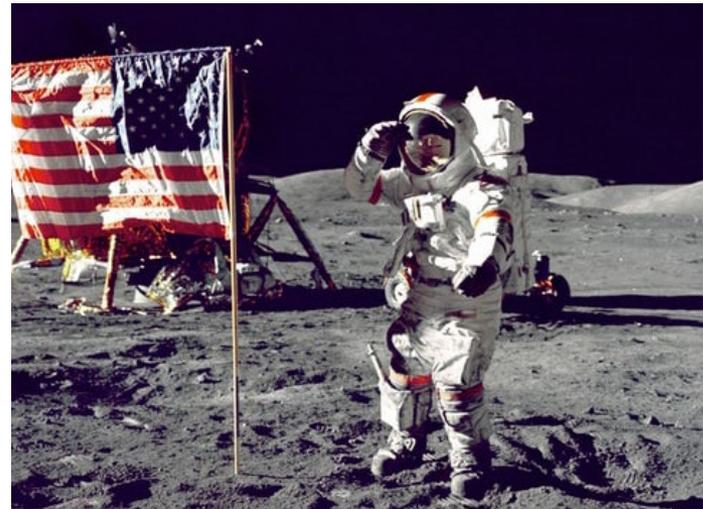


Petrie-Flom Center Events

**Addressing the
Overdose Epidemic:
Substance Use Policy for
the Biden Administration,**
March 24, noon – 1pm
EST



**Mental Health Moonshot:
Unlocking Federal Funds
for Psychedelics
Research,** April 12, noon
– 1pm EST



Register at <https://petrieflom.law.harvard.edu/>





Thanks!

Mason Marks, MD, JD
masonmarks@fas.harvard.edu