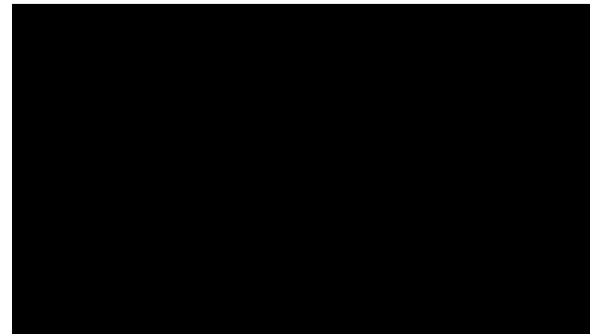
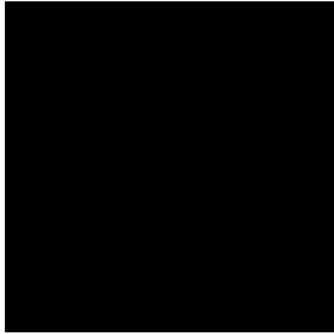


# **Ethical and Policy Issues in Using Psychedelics for Mental Health**

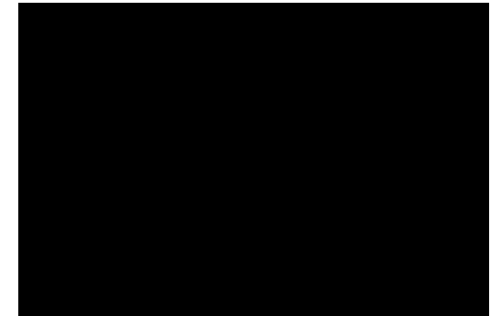
Amy McGuire, JD, PhD  
March 2023

**Psychedelics:** a subclass of hallucinogenic drugs whose primary effect is to trigger non-ordinary states of consciousness.

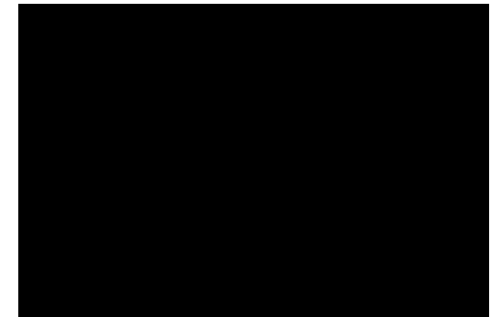
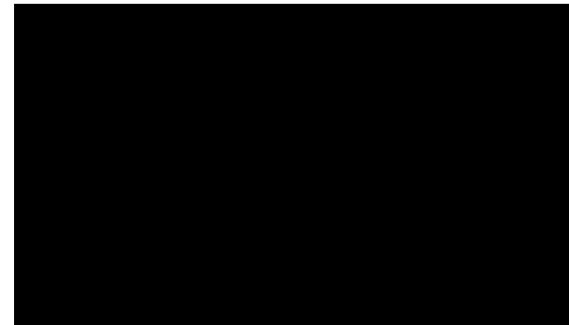
Classic psychedelics:  
hallucinogenic drugs  
that bind with  
specific serotonin  
receptors in the  
brain.



Entactogens: class of psychoactive drugs that  
produce experiences of emotional communion,  
oneness, relatedness, emotional openness.



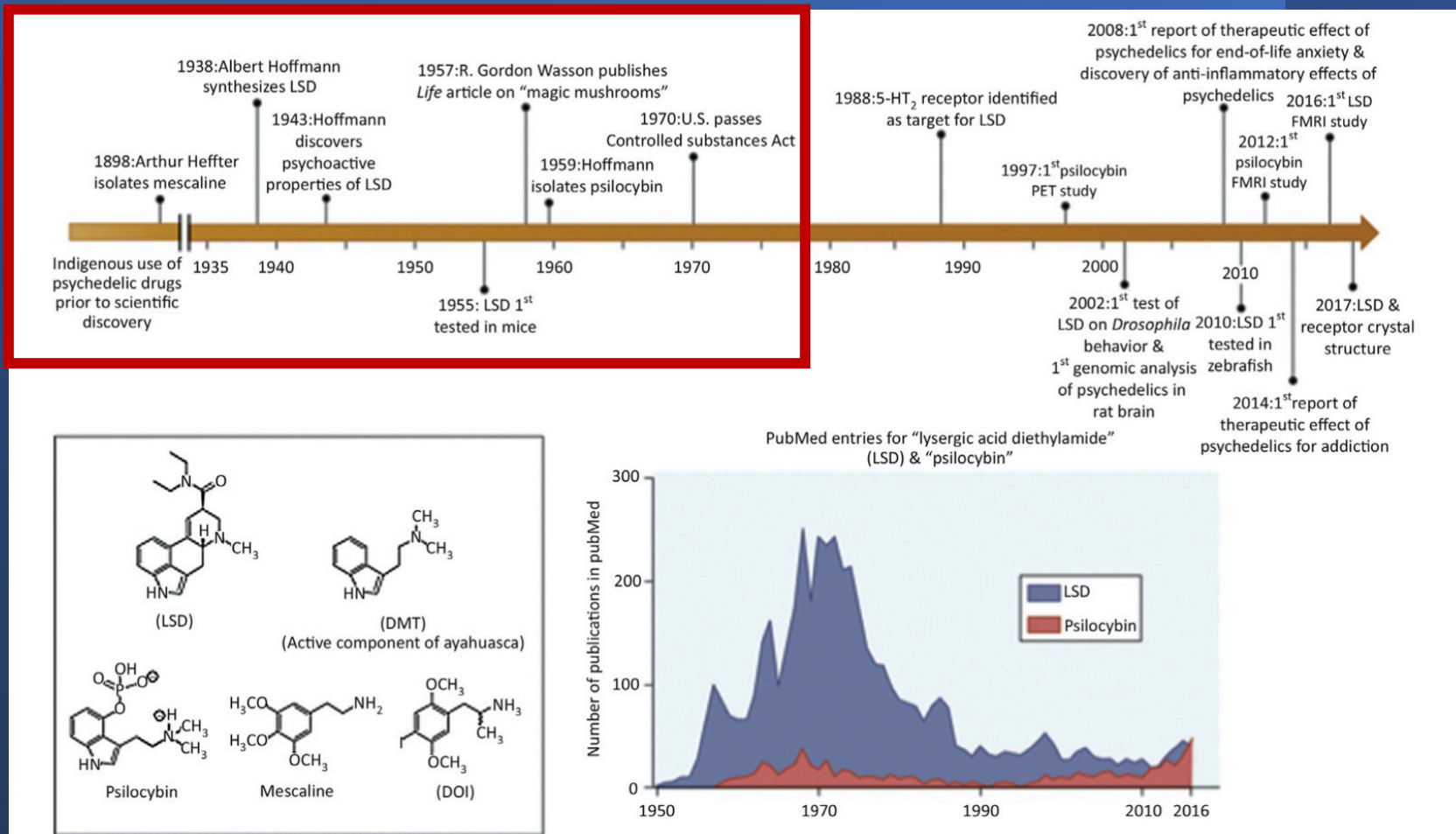
Other: TCH; Ketamine





# The history of psychedelic medicine





#### Trends in Pharmacological Sciences

**Figure 1. History of Psychedelic Research.** We present a brief timeline of psychedelic biomedicine in general (A) and PubMed entries for the terms LSD and psilocybin to illustrate the effect of the 1970 Controlled Substances Act on psychedelic research (B). Inset: chemical structures of major psychedelic drugs mentioned in this review including LSD, psilocybin, mescaline, DMT (principal component of ayahuasca), and DOI. Abbreviations: DMT, dimethyltryptamine; DOI, 2,5-dimethoxy-4-iodoamphetamine; fMRI, functional magnetic resonance imaging; LSD, lysergic acid diethylamide; PET, positron emission tomography.

# Nixon Calls War On Drugs

1242

PUBLIC LAW 91-513—OCT. 27, 1970

[84 STAT.

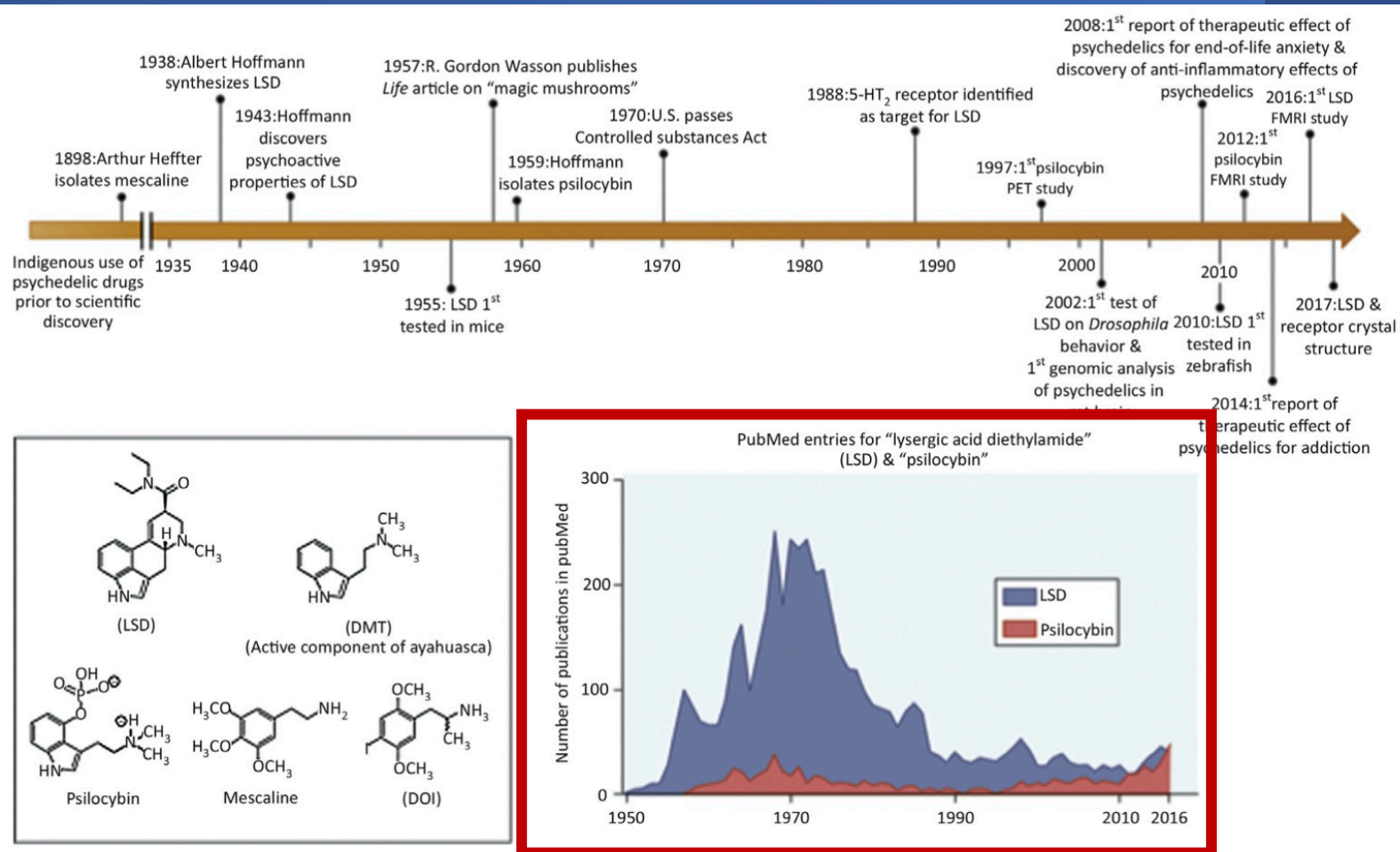
## TITLE II—CONTROL AND ENFORCEMENT

### PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

#### SHORT TITLE

Citation of  
title.

SEC. 100. This title may be cited as the “Controlled Substances Act”.



#### Trends in Pharmacological Sciences

**Figure 1. History of Psychedelic Research.** We present a brief timeline of psychedelic biomedicine in general (A) and PubMed entries for the terms LSD and psilocybin to illustrate the effect of the 1970 Controlled Substances Act on psychedelic research (B). Inset: chemical structures of major psychedelic drugs mentioned in this review including LSD, psilocybin, mescaline, DMT (principal component of ayahuasca), and DOI. Abbreviations: DMT, dimethyltryptamine; DOI, 2,5-dimethoxy-4-iodoamphetamine; fMRI, functional magnetic resonance imaging; LSD, lysergic acid diethylamide; PET, positron emission tomography.

CONSUMER TECH

# FDA Designates MDMA As 'Breakthrough Therapy' For Post-Traumatic Stress

**Janet Burns** Senior Contributor @  
*I cover labor, culture, drugs, AI, and more.*

Follow

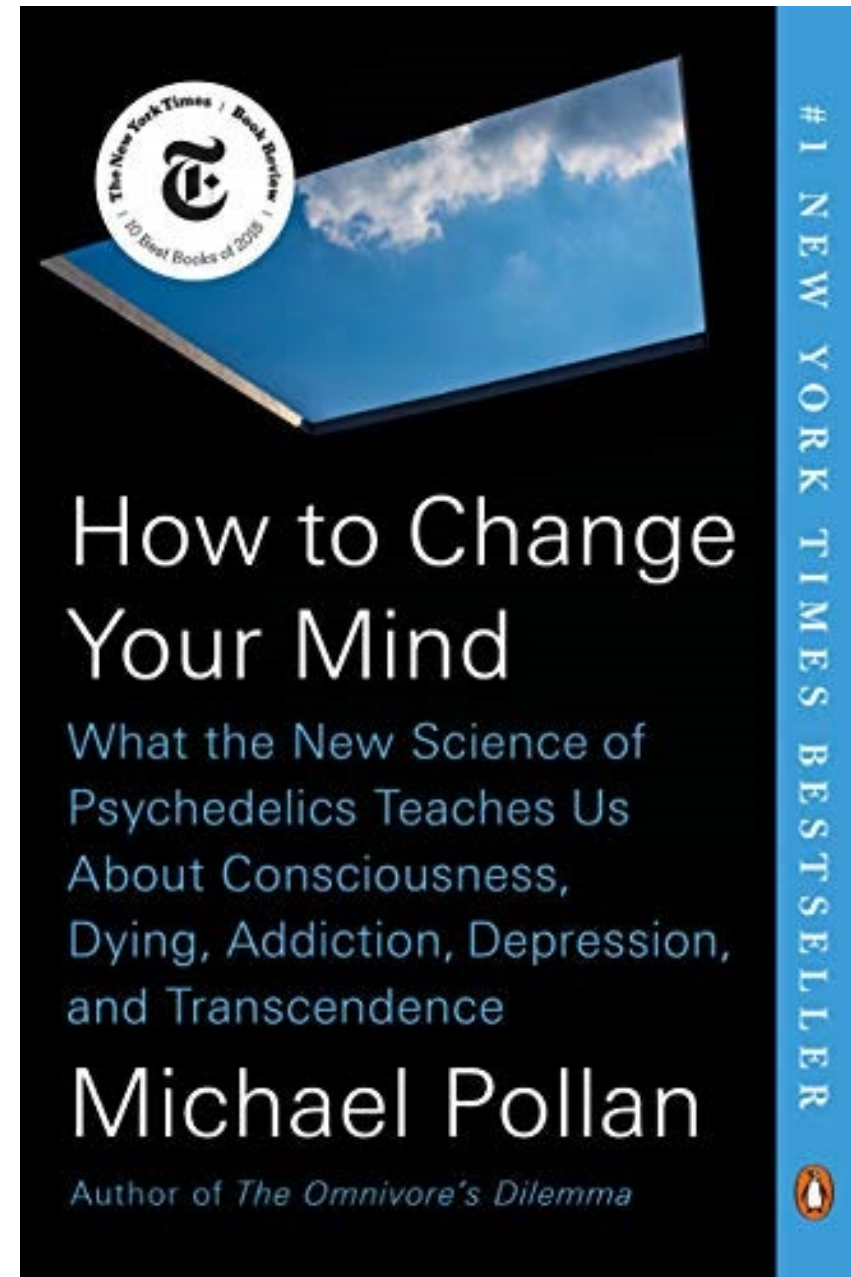
Aug 28, 2017, 03:58pm EDT

# FDA Calls Psychedelic Psilocybin a 'Breakthrough Therapy' for Severe Depression

By [Yasemin Saplakoglu](#) published November 25, 2019

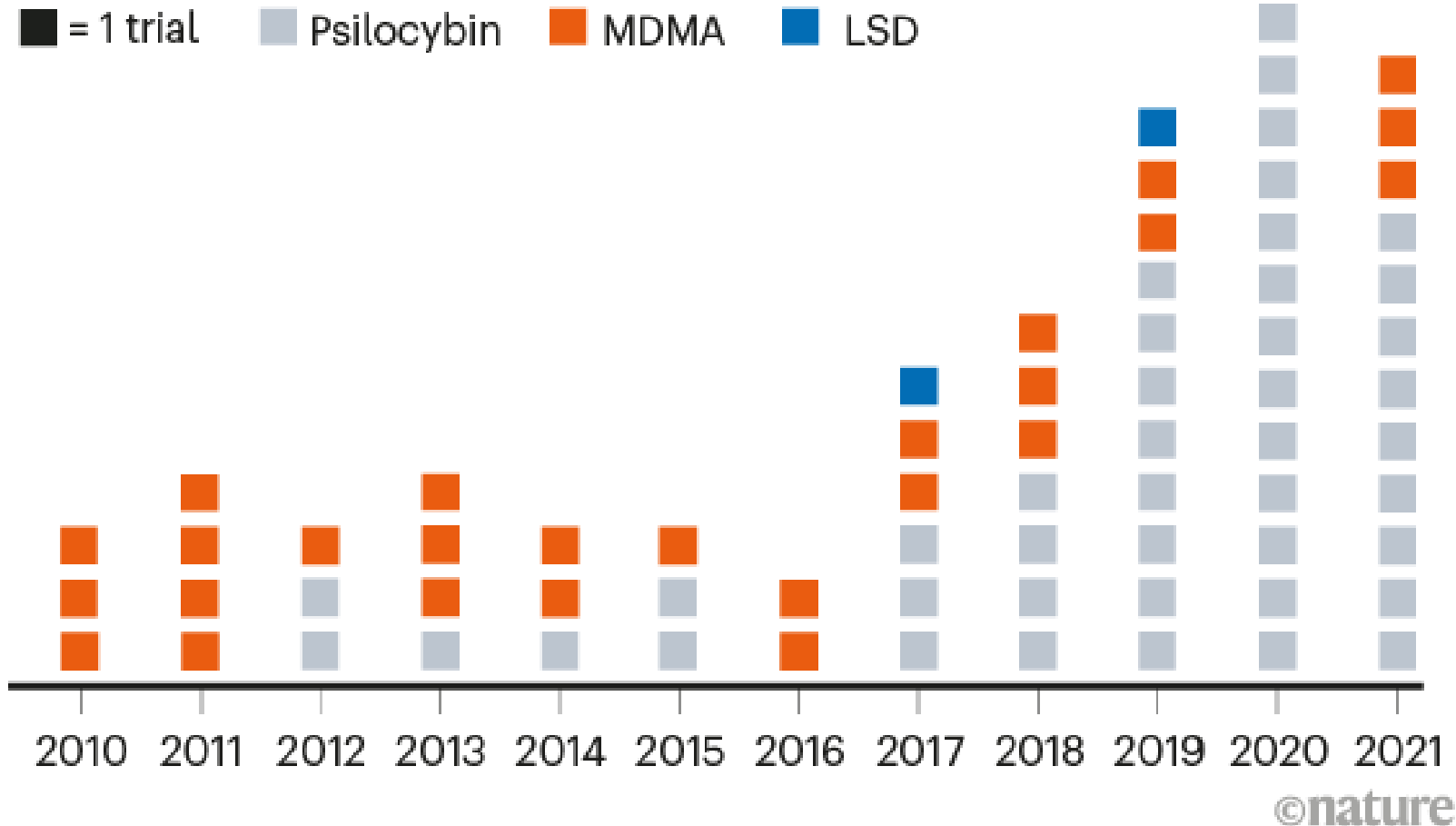


Comments (10)



# PSYCHEDELICS TAKE FLIGHT

Over the past decade, there has been an increase in clinical trials testing psilocybin, MDMA and LSD for use in psychiatric conditions, including depression, drug dependency and anorexia nervosa.



- Noticeable uptick in clinical trials since 2017
- 169 ongoing registered studies testing psychedelic interventions

*Nature* **589**, 506-509 (2021)

doi: <https://doi.org/10.1038/d41586-021-00187-9>



# The 11 Best Luxury Psychedelic Wellness Retreats

TRAVEL

DESTINATIONS

HOTELS + RESORTS

By **Jill Ettinger** February 21, 2022

NATIONAL

## Thousands of moms are microdosing with mushrooms to ease the stress of parenting

September 13, 2022 · 5:48 PM ET

Heard on [All Things Considered](#)

ALLISON SHERRY

FROM  **CPR News**

FORBES > LEADERSHIP > CAREERS

EDITORS' PICK

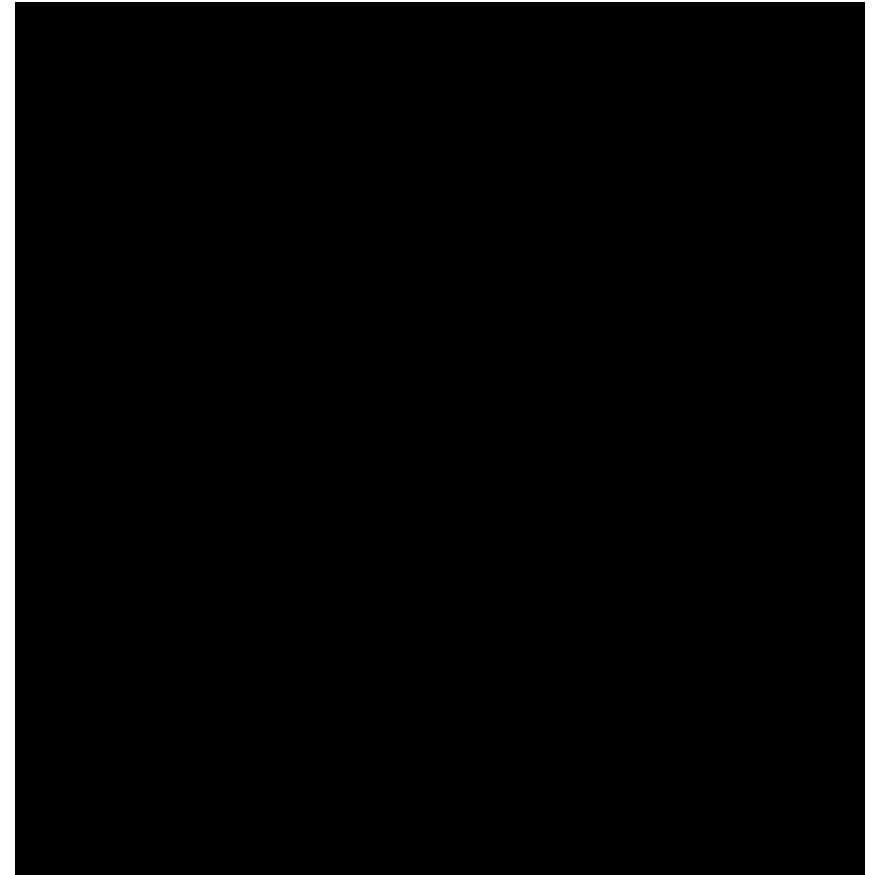
## Silicon Valley Is Micro-Dosing 'Magic Mushrooms' To Boost Their Careers

**Jack Kelly** Senior Contributor ©

# Ethical and Policy Issues

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- Explanatory models and their implications for administration, training, and licensure
- Boundary issues and concerns about abuse
- Informed consent and the transformative experience
- Regulating the therapeutic context
- State vs federal law
- Developing natural psychedelic drugs

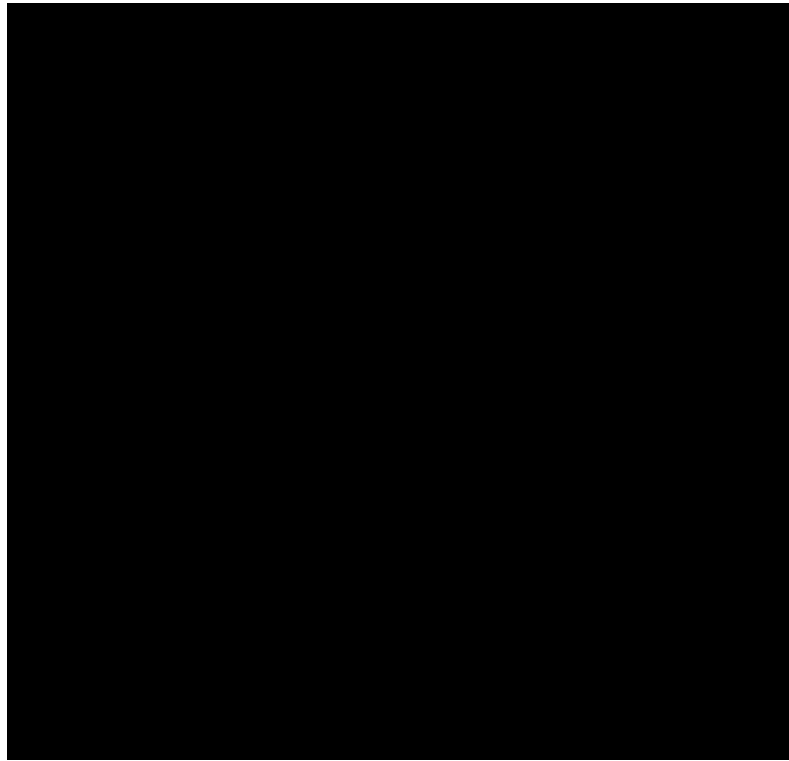


# Explanatory models and their implications for administration, training, and licensure

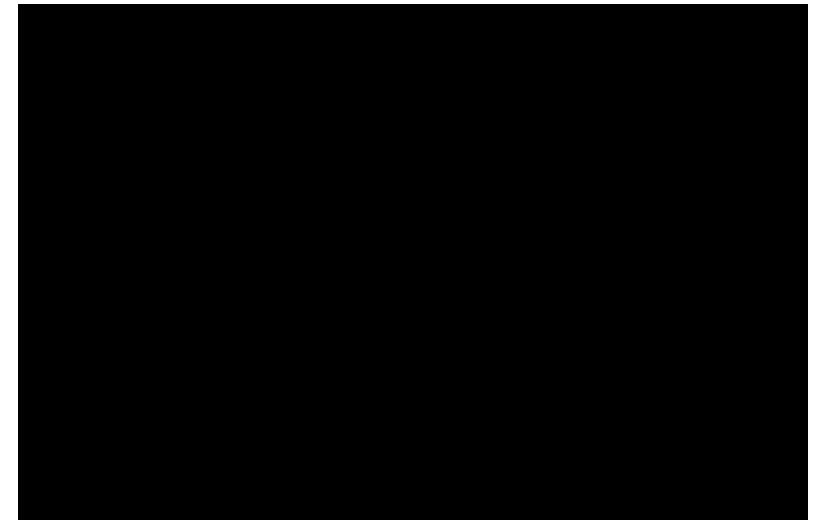
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Bio



Psycho



Spiritual

# Boundary issues and concerns about abuse



An image from a video recording of Meaghan Buisson's MDMA therapy during clinical trials to treat PTSD, showing Dr Dryer and Mr Yensen in bed with her. (*Four Corners*)

Opinion

## VIEWPOINT

### Studying Harms Is Key to Improving Psychedelic-Assisted Therapy—Participants Call for Changes to Research Landscape

**Sarah McNamee, MSW, MScA**  
School of Social Work,  
McGill University,  
Montreal, Quebec,  
Canada.

**Neşe Devenot, PhD**  
Institute for Research in  
Sensing, University of  
Cincinnati, Cincinnati,  
Ohio.

**Meaghan Buisson, BSc**  
Independent  
researcher, Winnipeg,  
Manitoba, Canada.

Although psychedelic drugs generally have good safety profiles, a recent systematic review<sup>1</sup> concluded that adverse events in psychedelic trials are poorly defined, not systematically assessed, and likely underreported. In the past year there have been multiple reports of serious adverse events (SAEs), and long-lasting harms to participants in clinical trials of psychedelic-assisted therapy (PAT) have emerged.<sup>2,3</sup> We draw attention to a unique and overlooked category of risk in PAT stemming from the interactions between therapists and patients receiving high doses of psychedelics. In our view, the understudied therapeutic component of PAT presents the most serious risks. Addressing it requires interdisciplinary approaches by researchers free from conflicts of interests.

#### Attending to the Therapy in PAT

Psychedelic-assisted therapy combines 2 psychoactive components: drugs and psychotherapy. This innova-

psychotherapy is controversial and understudied, even without adding psychedelics.

Fundamentally, psychotherapy requires active, ongoing, and dynamic consent. In PAT, patients are under the influence of substances that may enhance suggestibility and impair capacity for consent and withdrawal (which is also restricted by protocol), potentially increasing overcompliance with therapist suggestions. The use of conventional psychotherapy approaches, which require active, ongoing, and dynamic consent, poses unique risks and problems. Even psychotherapy practices with an existing evidence base need to be reevaluated for safety and efficacy in PAT.

#### SAEs and Harms

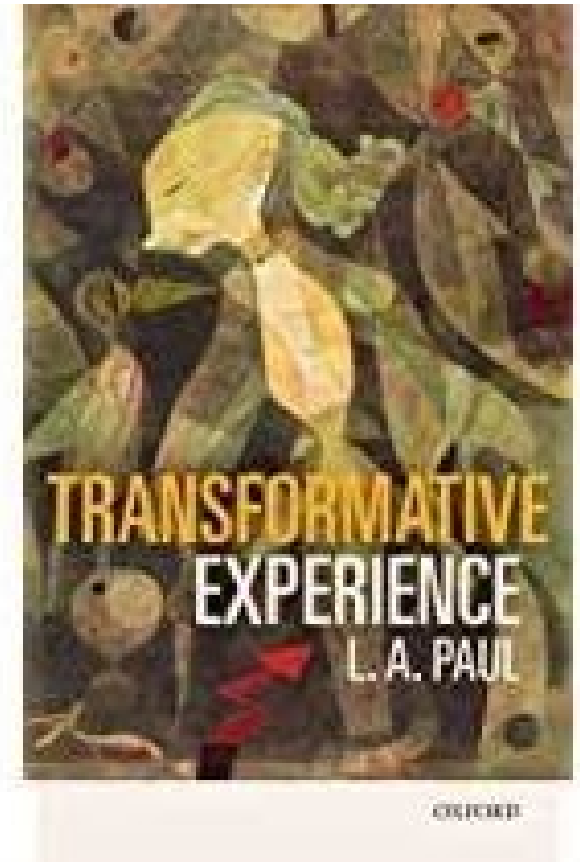
In the past year, media stories have identified SAEs and harms—including suicidality, sexual abuse, and psychotic symptoms—in trials sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS) of



# Informed consent and the transformative experience

---

- A transformative experience has two components:
  - Epistemically transformative – giving you new information in virtue of your experience
  - Personally transformative – changing how you experience being who you are
- Problem: to make a decision about whether to have a TE you need to know the values of the relevant outcomes and to be able to weigh them against each other, but in the case of a decision involving a TE, you cannot know what it is like to have that kind of experience until you've had it.
- Paul's response: choose based on whether we want to discover who we'll become
- Can one give valid informed consent to participate in PAT given the potential for it to be a TE?



# Regulating the therapeutic context



The  
Intercept\_



## **BIDEN ADMINISTRATION PLANS FOR LEGAL PSYCHEDELIC THERAPIES WITHIN TWO YEARS**

A letter from the Health and Human Services Department discloses the anticipated FDA approval of MDMA and psilocybin treatments.

Mattha Busby

July 26 2022, 2:07 p.m.

- “Set and setting” are thought to be critical for therapeutic effect, but FDA only regulates drug products.
- FDA can’t regulate “conditions of use” - may veer into the practice of medicine, which is left to state regulation

# State vs. federal law

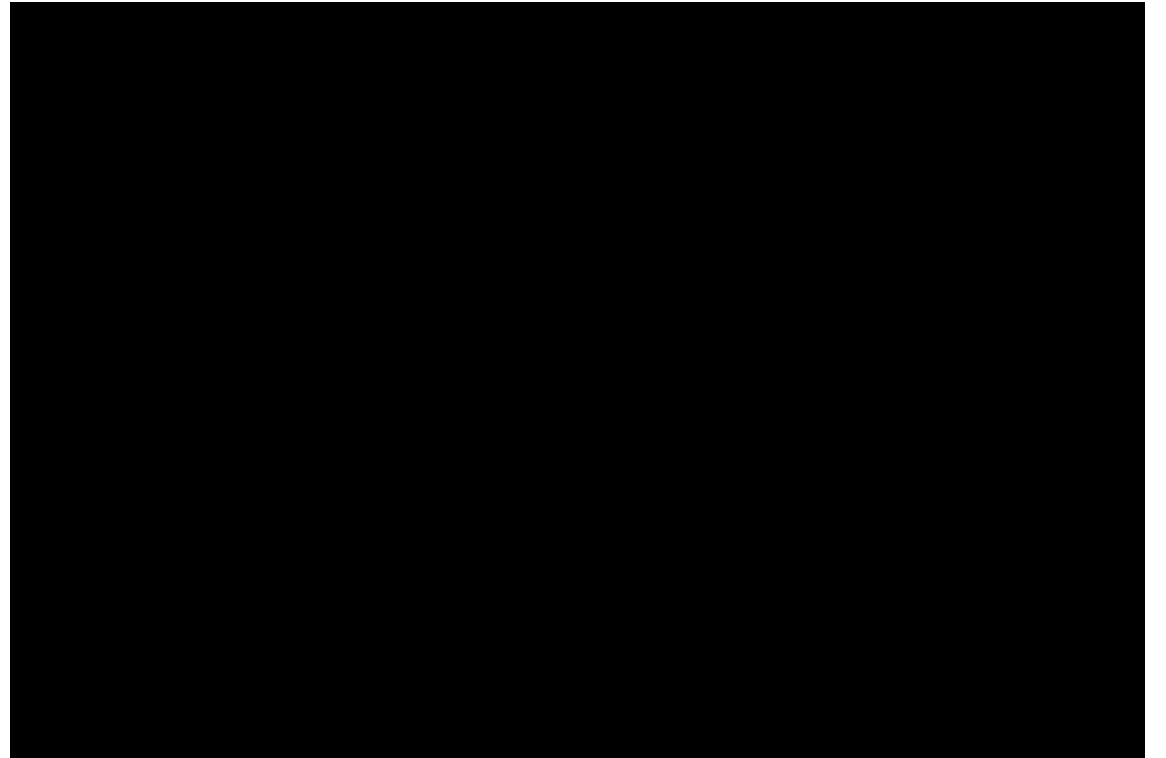
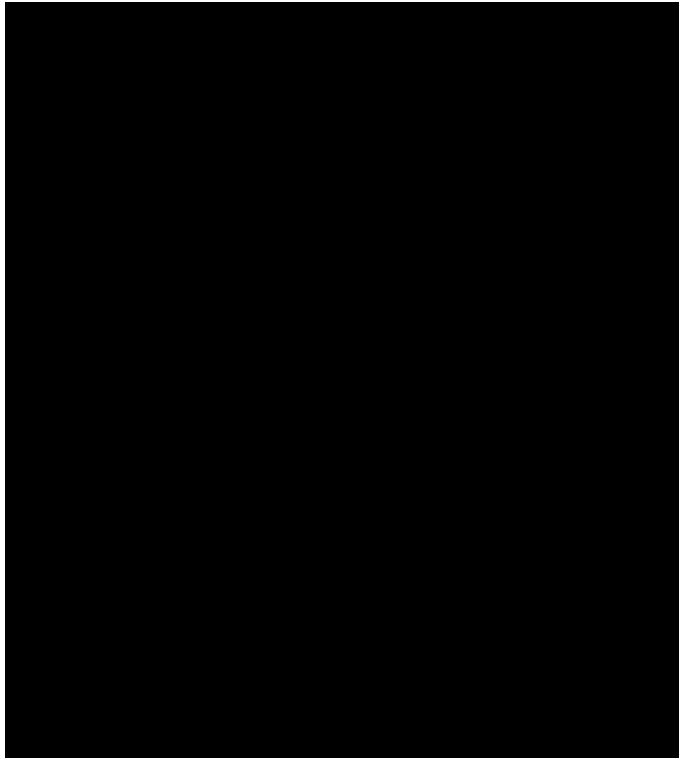
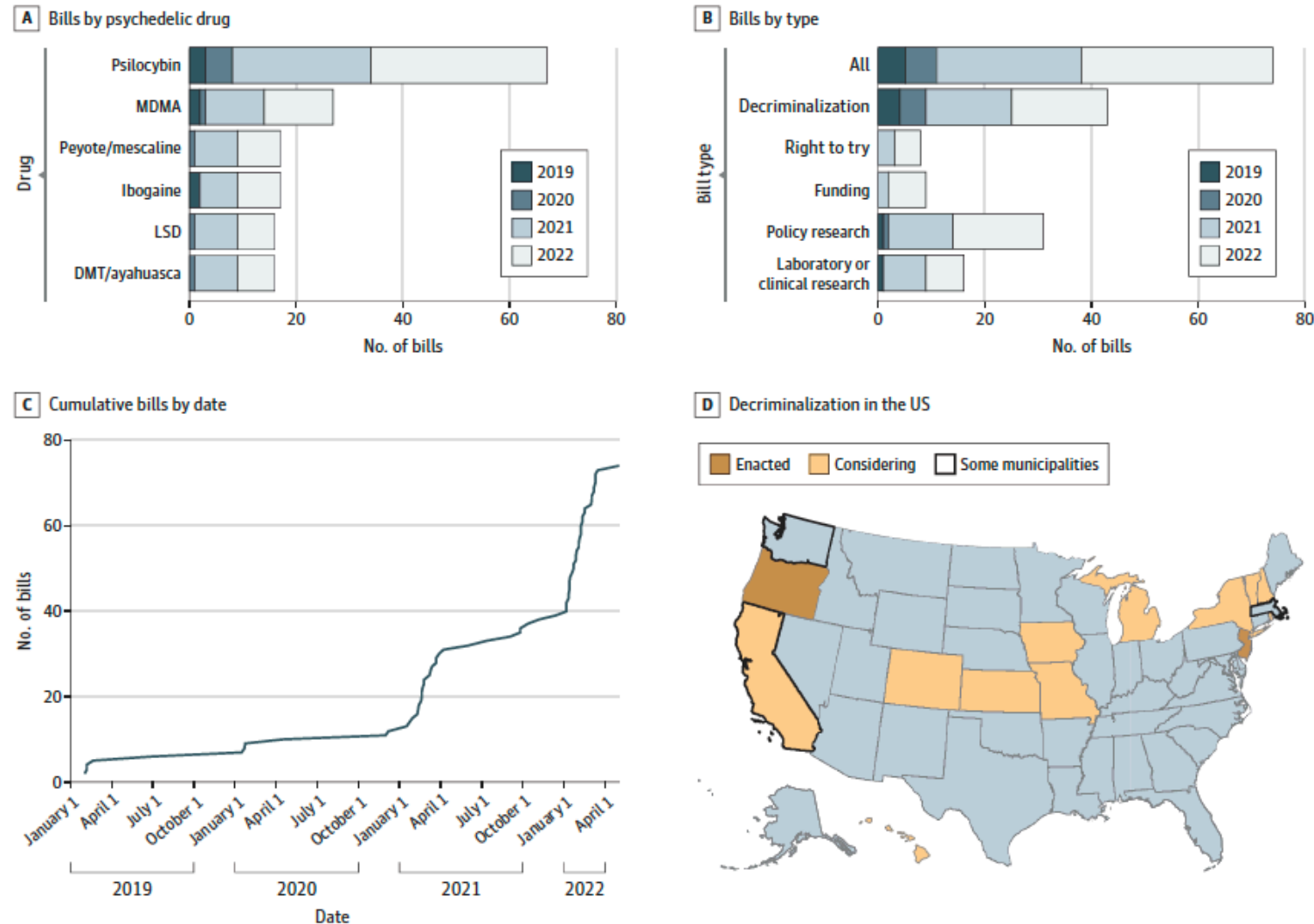
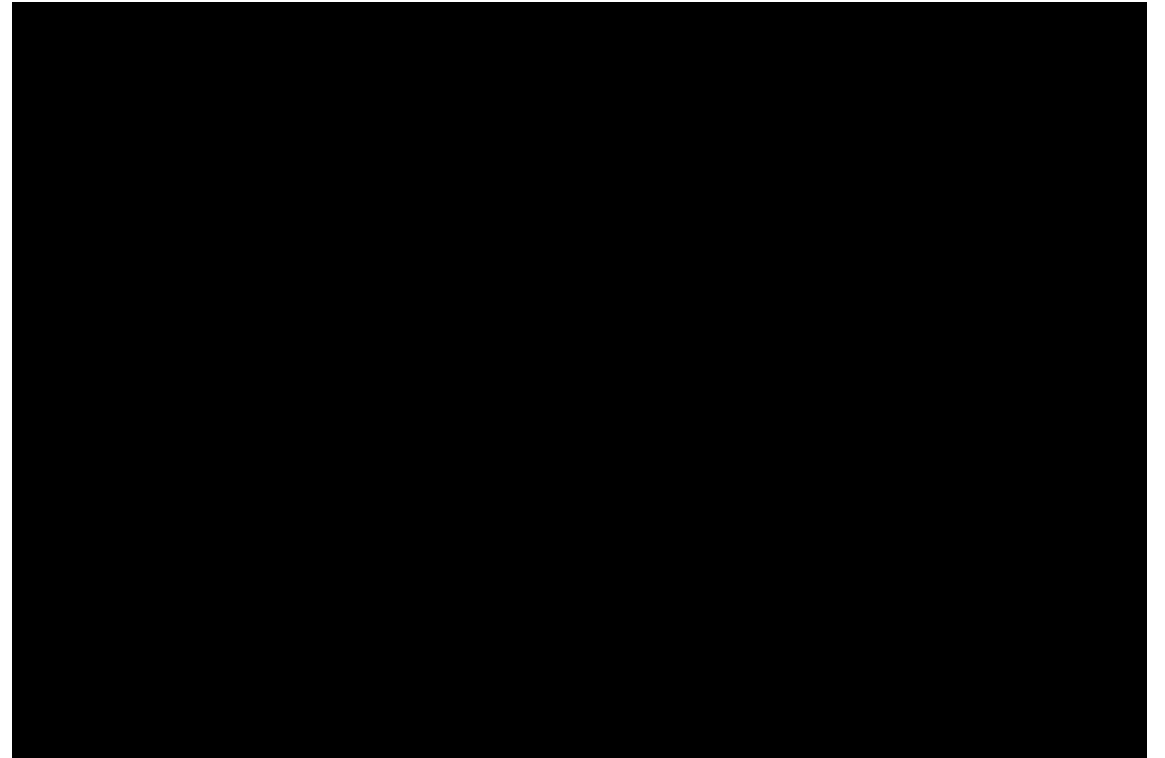
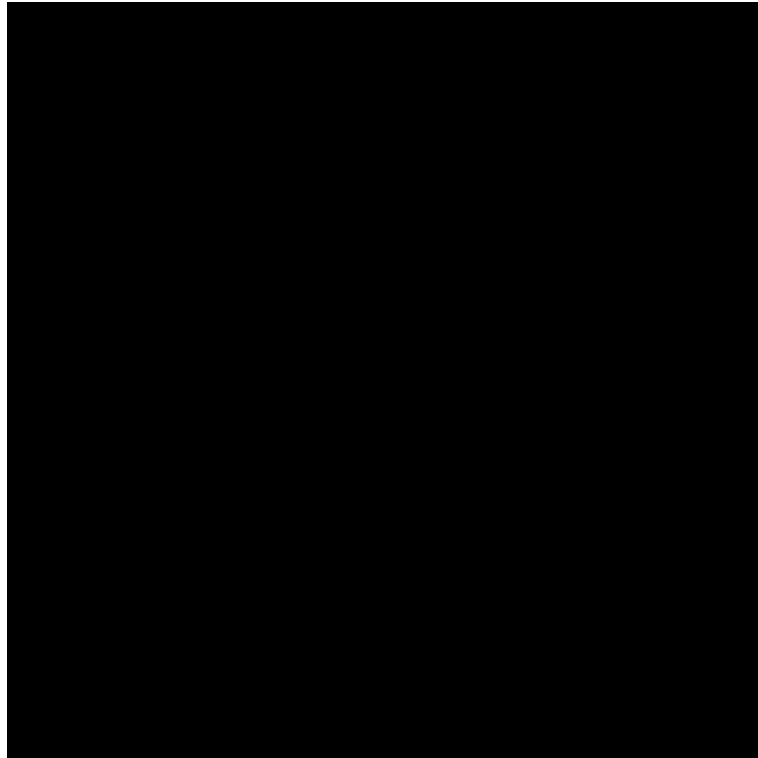


Figure 1. Trends in Psychedelic Drug Reform Bills





# Developing natural psychedelic drugs





# ELIP SIS

ETHICAL LEGAL IMPLICATIONS  
OF PSYCHEDELICS IN SOCIETY