

**ALL THE BUZZ, LIMITED ACCESS:  
PRACTICAL CONSIDERATIONS FOR PRACTICING PSYCHOSOCIAL  
ONCOLOGY IN THE WORLD OF CANNABIS, KETAMINE, AND  
PSYCHEDELIC-ASSISTED THERAPIES**

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Academy of Consultation Liaison Psychiatry Annual Meeting, November 10 2023

**WE HAVE NO RELEVANT FINANCIAL  
DISCLOSURES.**

# Workshop outline

- Review the evolution in U.S. legal climate regarding cannabis, the medical community's approach to cannabis therapeutics, and medicinal cannabis lessons applicable to psychedelics
- Introduce the clinical and legal landscape in the U.S. of psychedelic-assisted therapies in the context of serious illness care
- Present three clinical cases with practical and ethical considerations around the use of psychedelic-assisted therapies
- Consider ethical principles in guiding conversation with patients about PAT
- Discussion

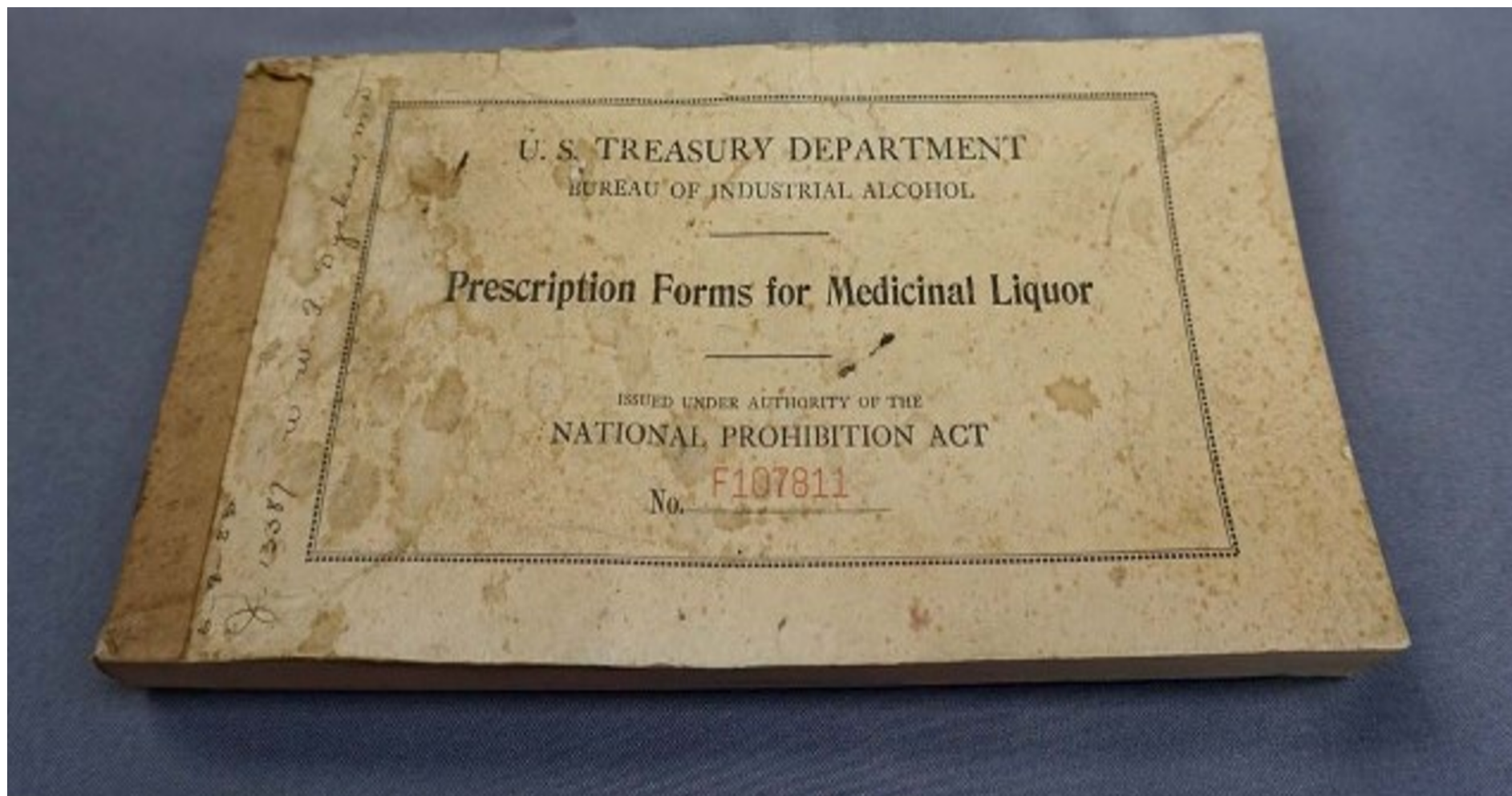
# MEDICAL CANNABIS: INSPIRATION OR CAUTIONARY TALE?

Ilana Braun, MD

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Dana-Farber Cancer Institute

Associate Professor in Psychiatry, Harvard Medical School

# 1920-1933: Alcohol prohibition

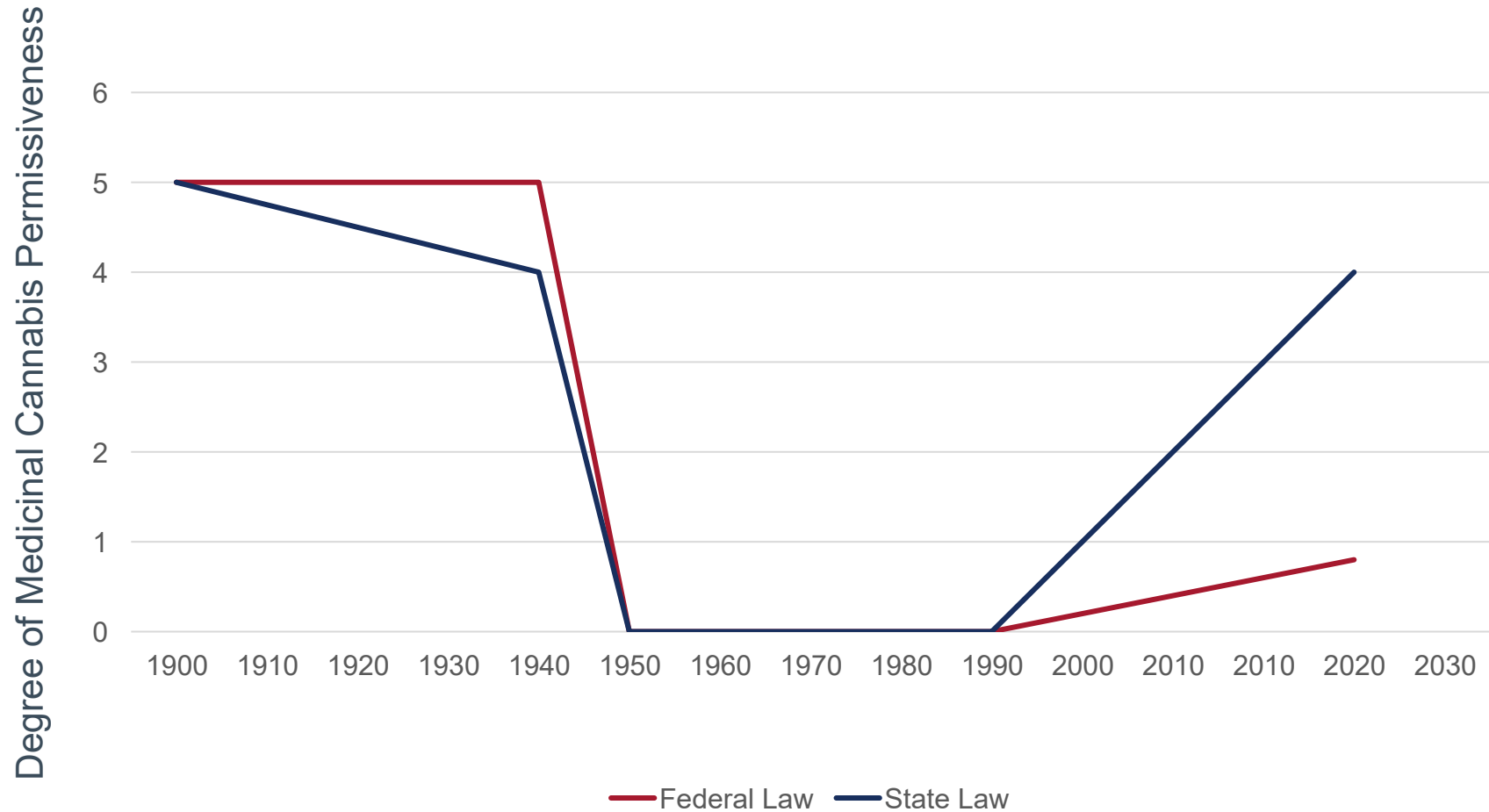


# Medicinal Cannabis

*Herbal cannabinoid products that individuals employ with therapeutic intent, sometimes in compliance with state law & with clinician authorization*



# Evolution in U.S. Legal Climate Regarding Cannabis



# 1850-1942: Cannabis in U.S. pharmacopeia

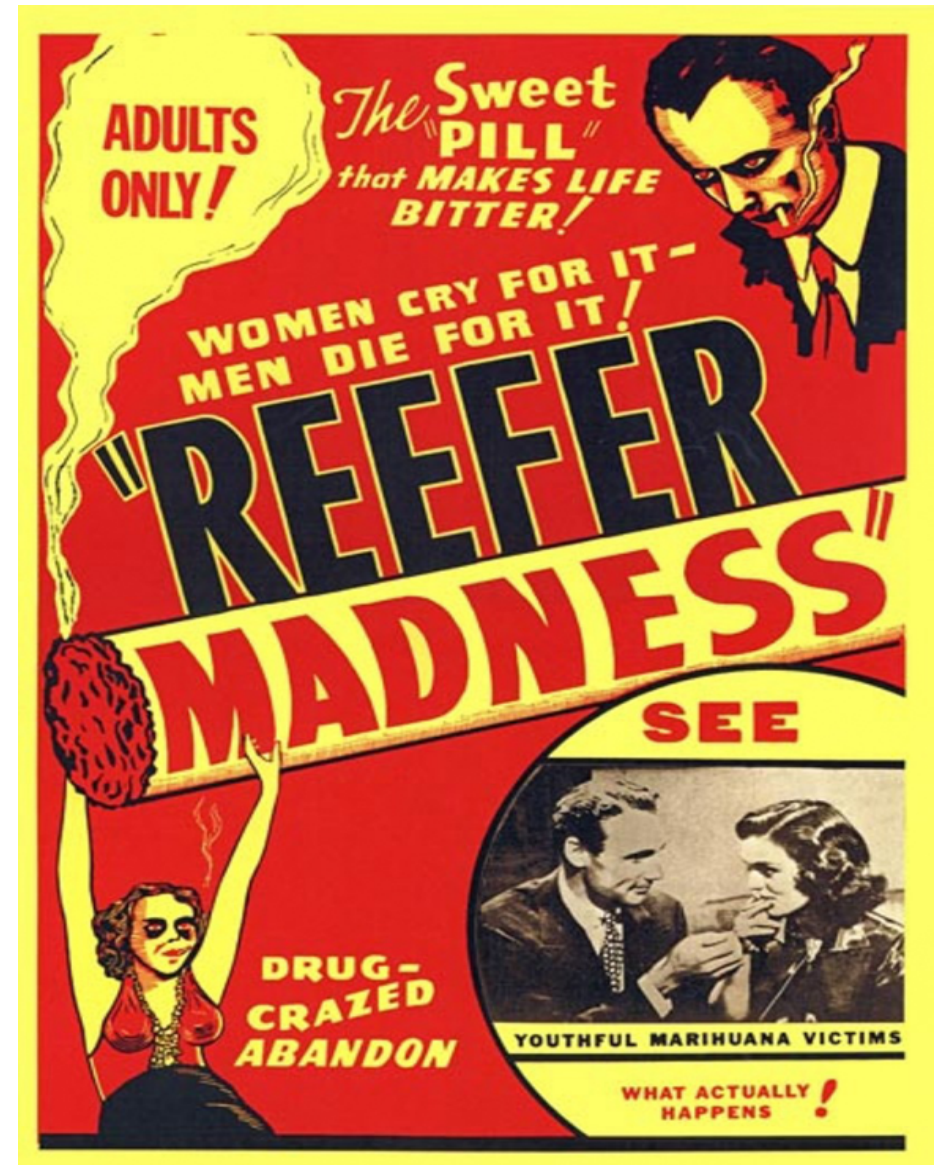
- \*analgesic
- \*antispasmodic
- \*sedative



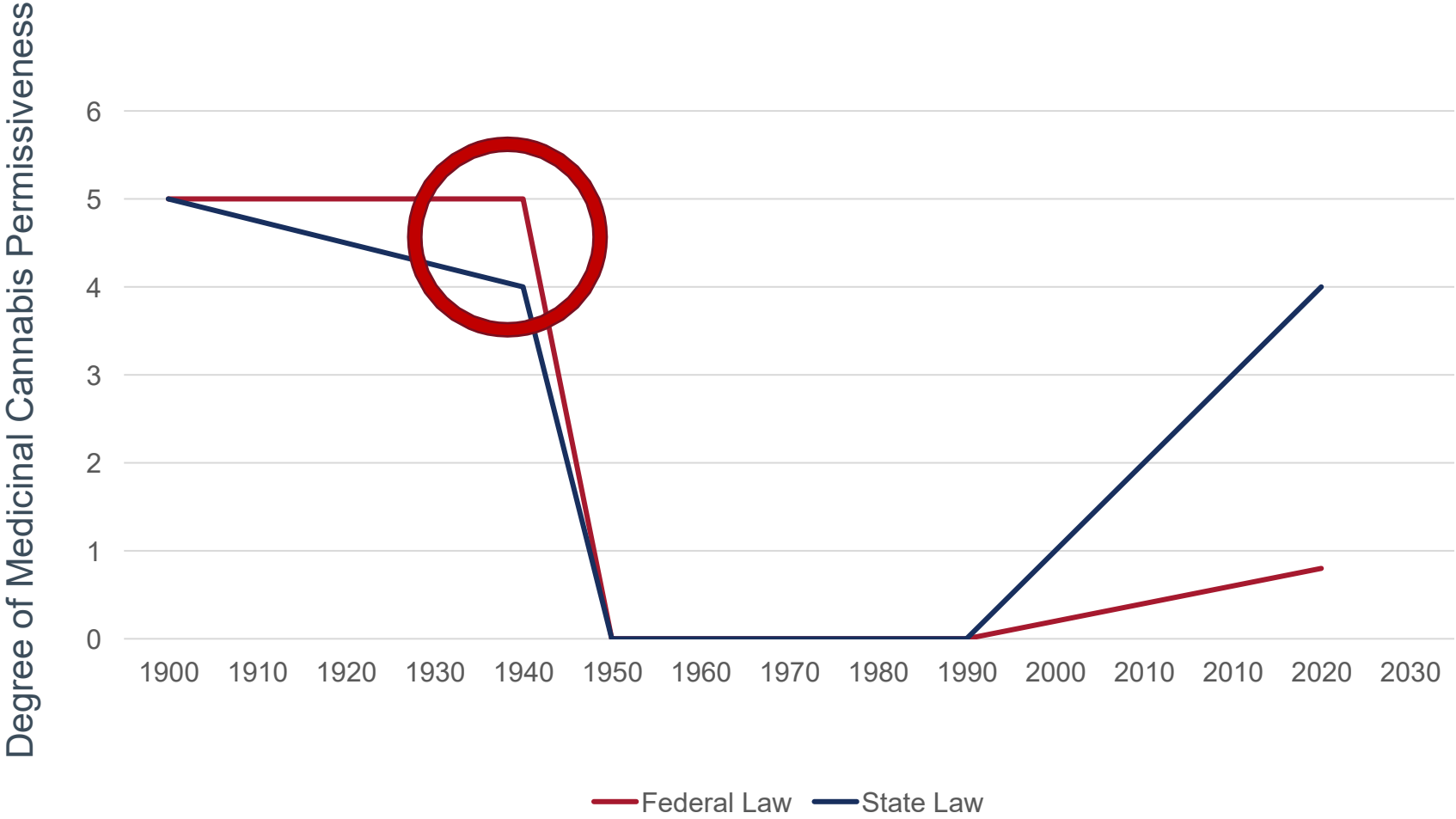


# Lead up to 1937

- \*Harry Anslinger, William Hearst link cannabis to insanity/criminality
- \*Several states restrict or ban



# Evolution in U.S. Legal Climate Regarding Cannabis



# 1937: Marihuana Tax Act

\*AMA opposes

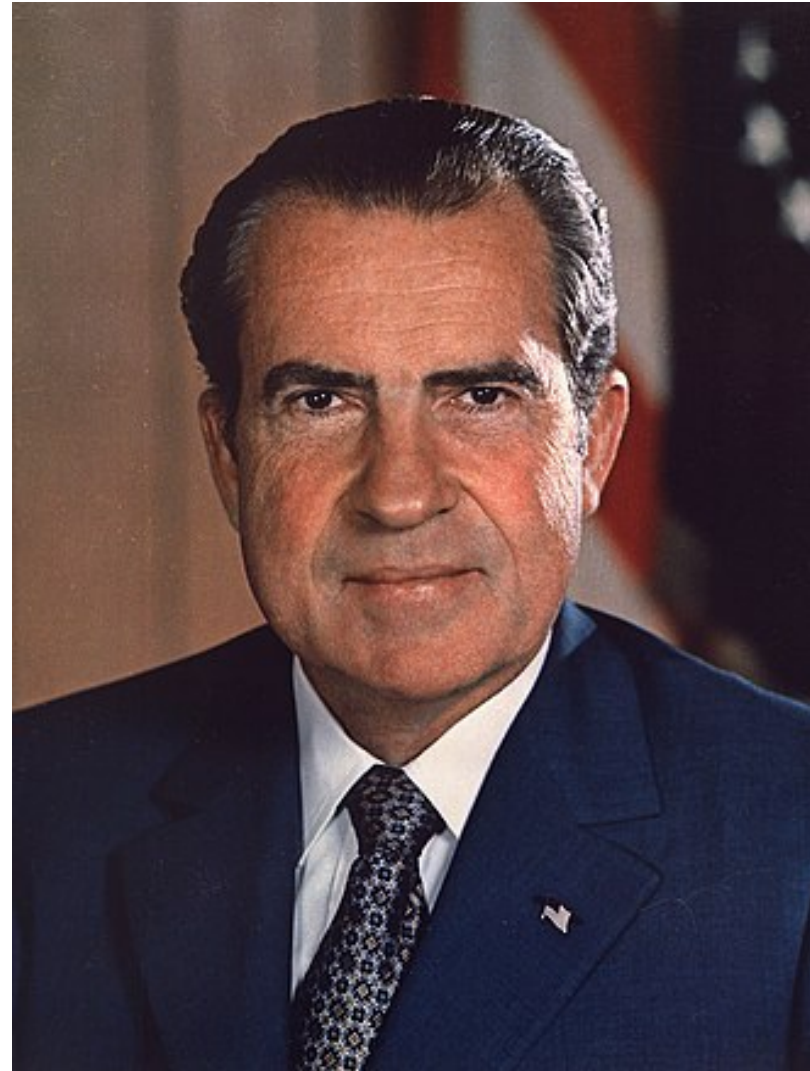


# 1968: Federal cannabis grower identified

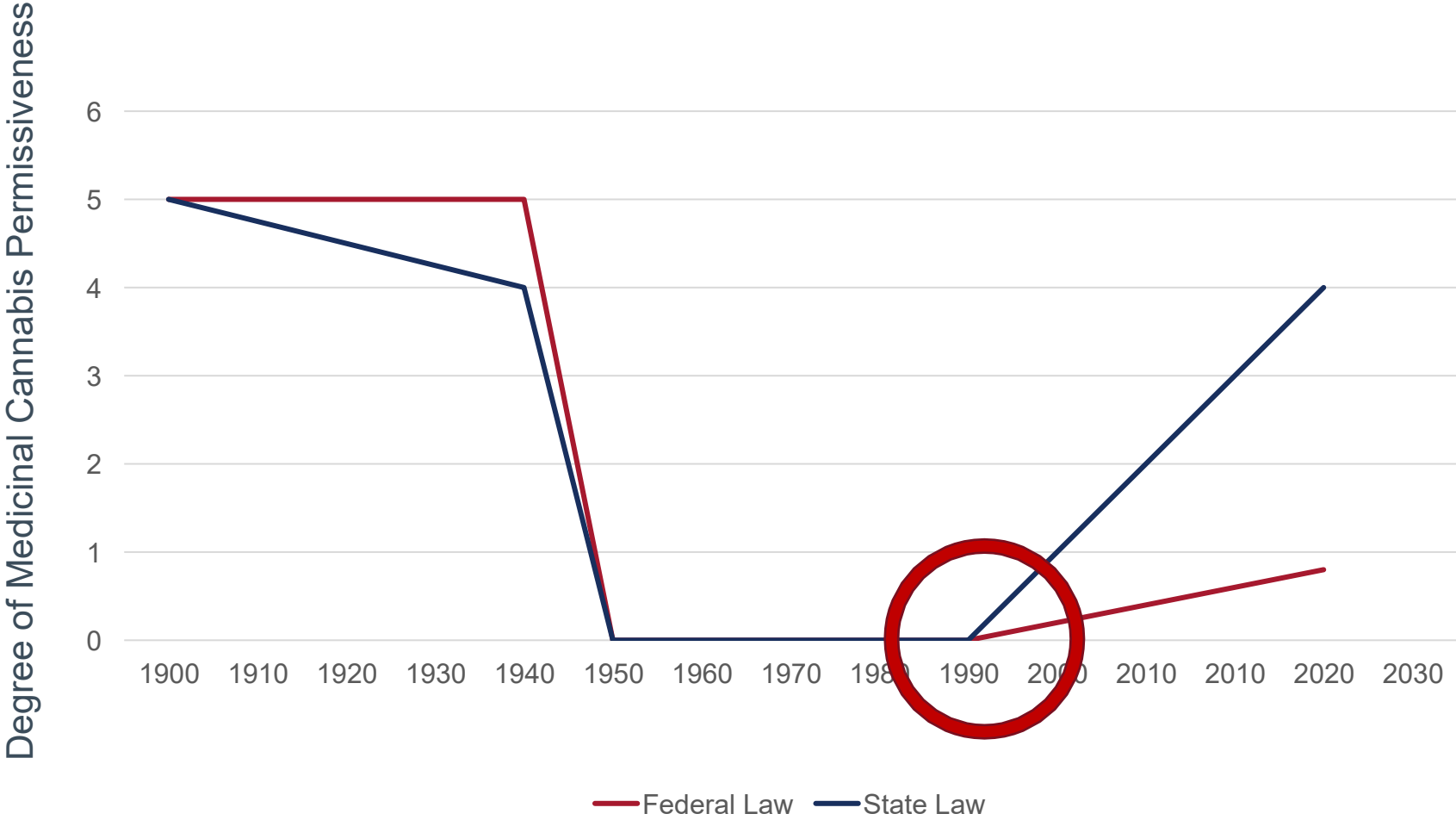


# 1970: Controlled Substances Act

- \*Cannabis, schedule I
- \*Cocaine, schedule II



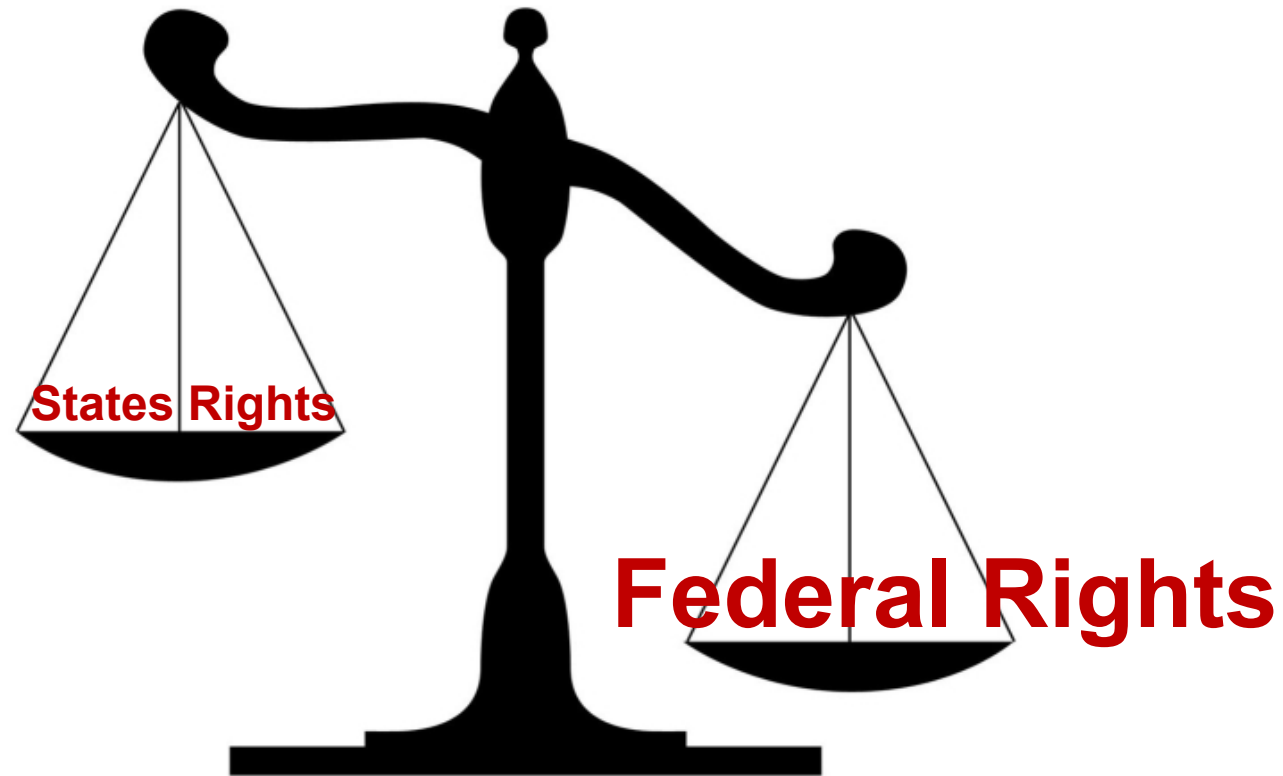
# Evolution in U.S. Legal Climate Regarding Cannabis



# 1996: California legalizes medicinal cannabis



# 2004: U.S. Supreme Court says Feds may prosecute patients lawfully using medicinal cannabis





# 2012: CO & WA legalize cannabis for adult use



# 2013-2015

\*DOJ's Cole Memorandum:  
prosecutors, medical cannabis  
cases not priority

\*Rohrabacher-Farr budget  
amendment: prohibits DOJ \$  
from interfering in state medicinal  
cannabis implementation



# 2017-2019

Most THC  
assays do not  
measure  
levels



- \*1st herbal cannabinoid FDA-approved & rescheduled
- \*Farm Bill legalized cultivation/sale of high CBD, extremely low THC (<0.3%) cannabis- but federal, state, local regulatory uncertainties persist.

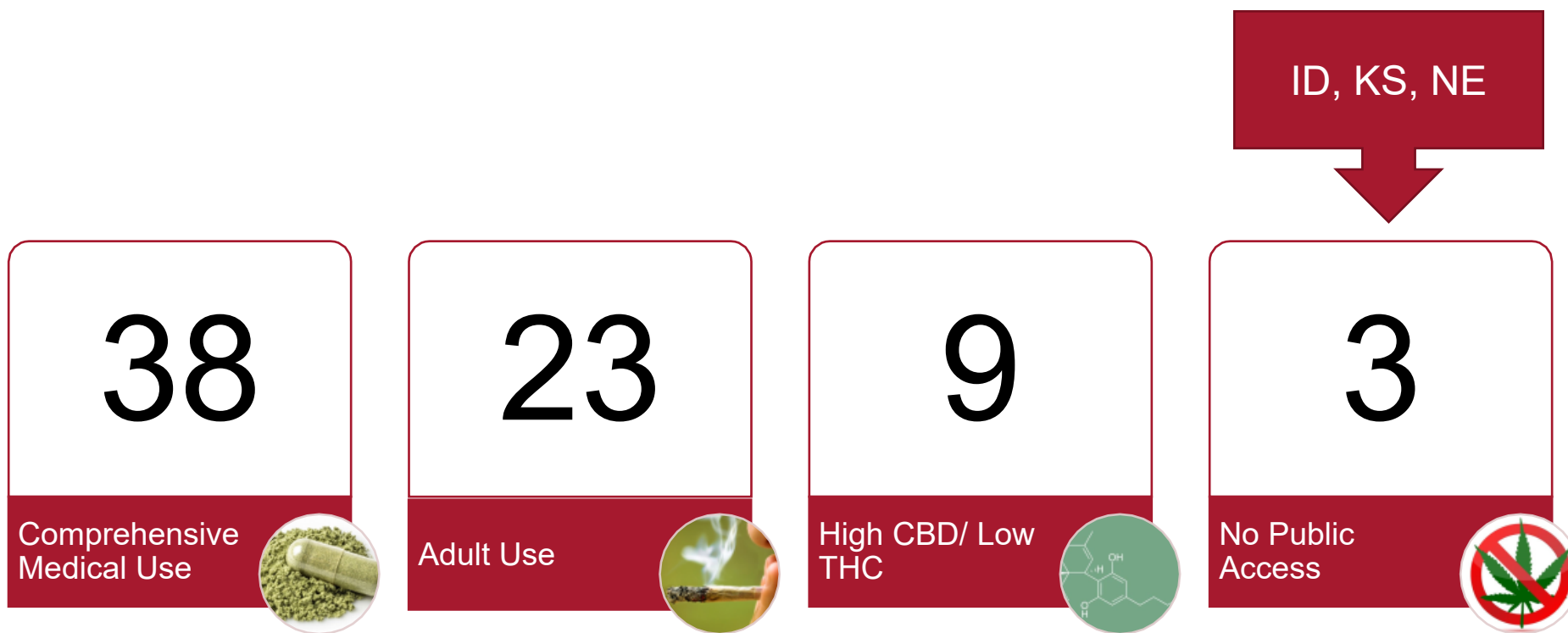
# “Grandmother sues after she was arrested at Disney with CBD oil in her purse” **CNN**

August 6, 2020

“Disney & uniformed local law enforcement officials... arrested & detained, processed as a narcotics felon and strip-searched a harmless, entirely blameless American great-grandmother, whose only ‘crime’ was her desire to lessen crippling osteoarthritic pain with a doctor-recommended hemp-based oil.”

-7/2020 filed complaint

# 2023 State Cannabis Laws



# Typical Medicinal Cannabis Dispensaries

- \*Non-pharmaceutical preparations:  
chemical purity standard does not  
ensure stability, safety, efficacy
- \*Highly regulated in many ways
- \*Often un-regulated in important ones:
  - \*ratios of active ingredients
  - \*potencies
  - \*types of products
- \*Non-medical intermediaries advise on  
products, delivery methods, dosing



# Prescription vs Recommendation

Cannabis = >300  
active ingredients!

Specify	Prescription	Recommendation
Active ingredient(s)	✓	
Medical condition or symptoms		✓
Quantity	✓	✓
Route	✓	
Dose	✓	
Frequency	✓	
Duration	✓	✓

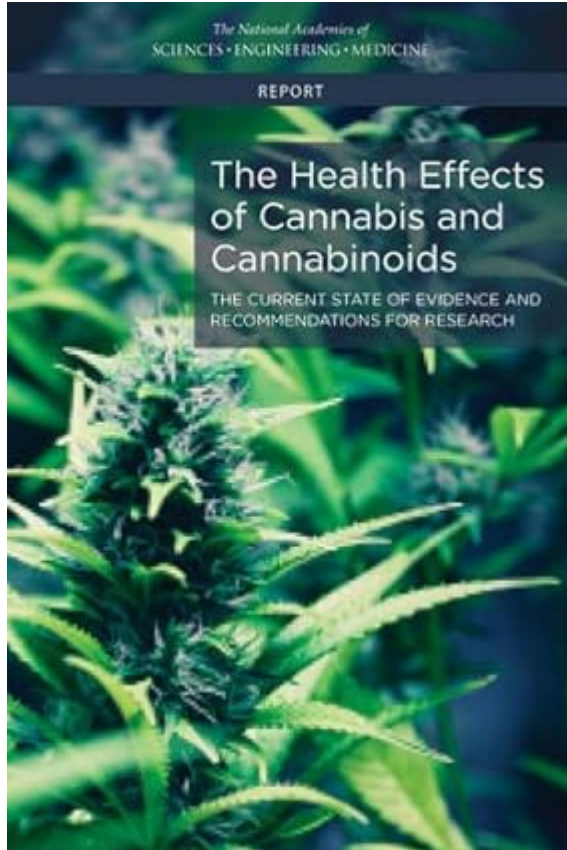
# Research Challenges Posed by Schedule I Designation

- \*Accessing federal funding
- \*Sourcing study drug
- \*Negotiating red tape
- \*Managing personal financial & criminal liability





# Scientific Evidence to Support Medicating with Cannabis



- 468 pages
- Conclusive/substantial evidence cannabis effective against chronic pain in adults
- Conclusive/substantial evidence cannabinoids effective for:
  - chemotherapy-induced nausea & vomiting
  - multiple sclerosis spasticity

# Medical Community's Contradictory Stance Toward Cannabis

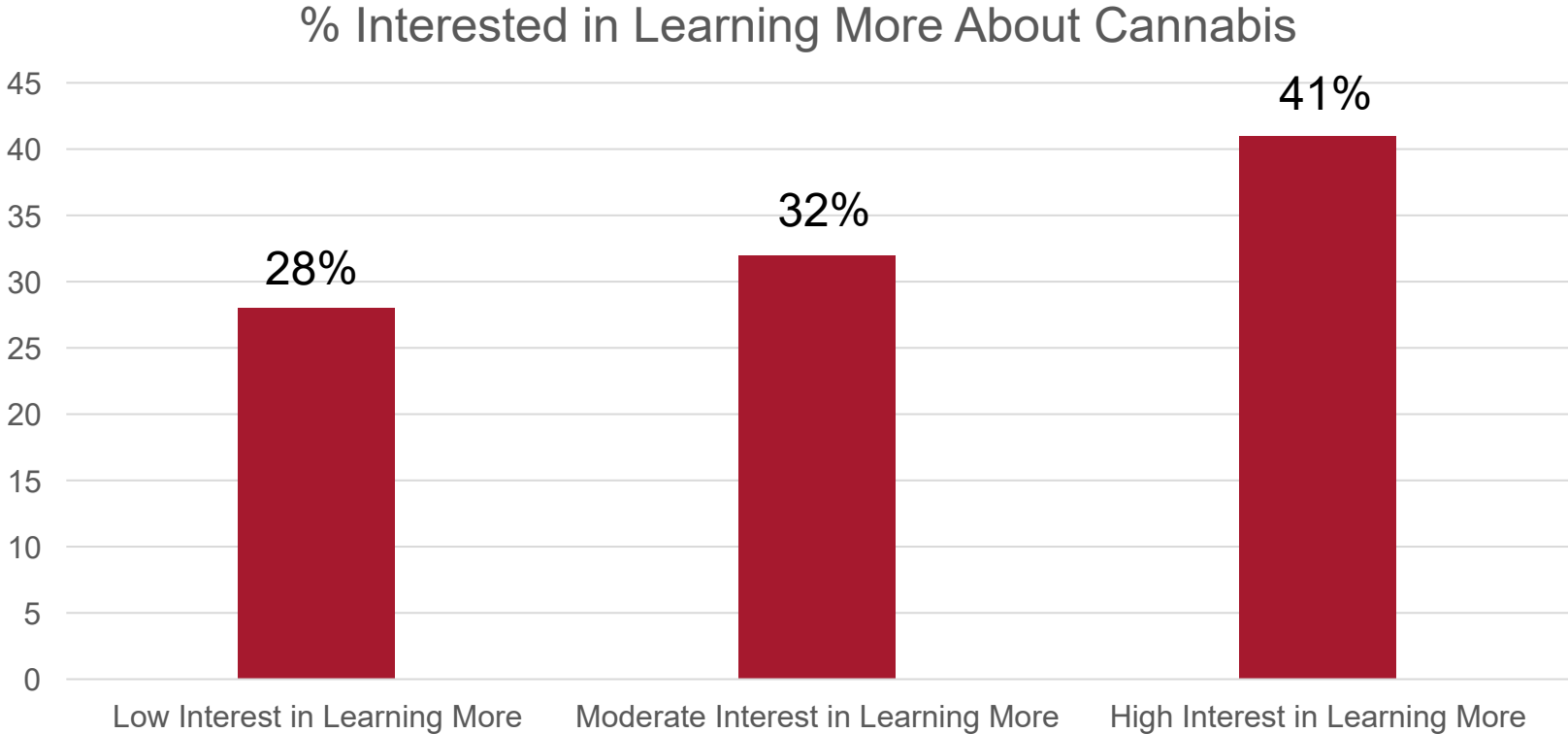
## Key Takeaways

- \*Healthcare providers turn to cannabis clinically
- \*Some recommending clinicians acknowledge they do not understand cannabis well enough
- \*Some adults who medicate with it perceive lack of clinical oversight



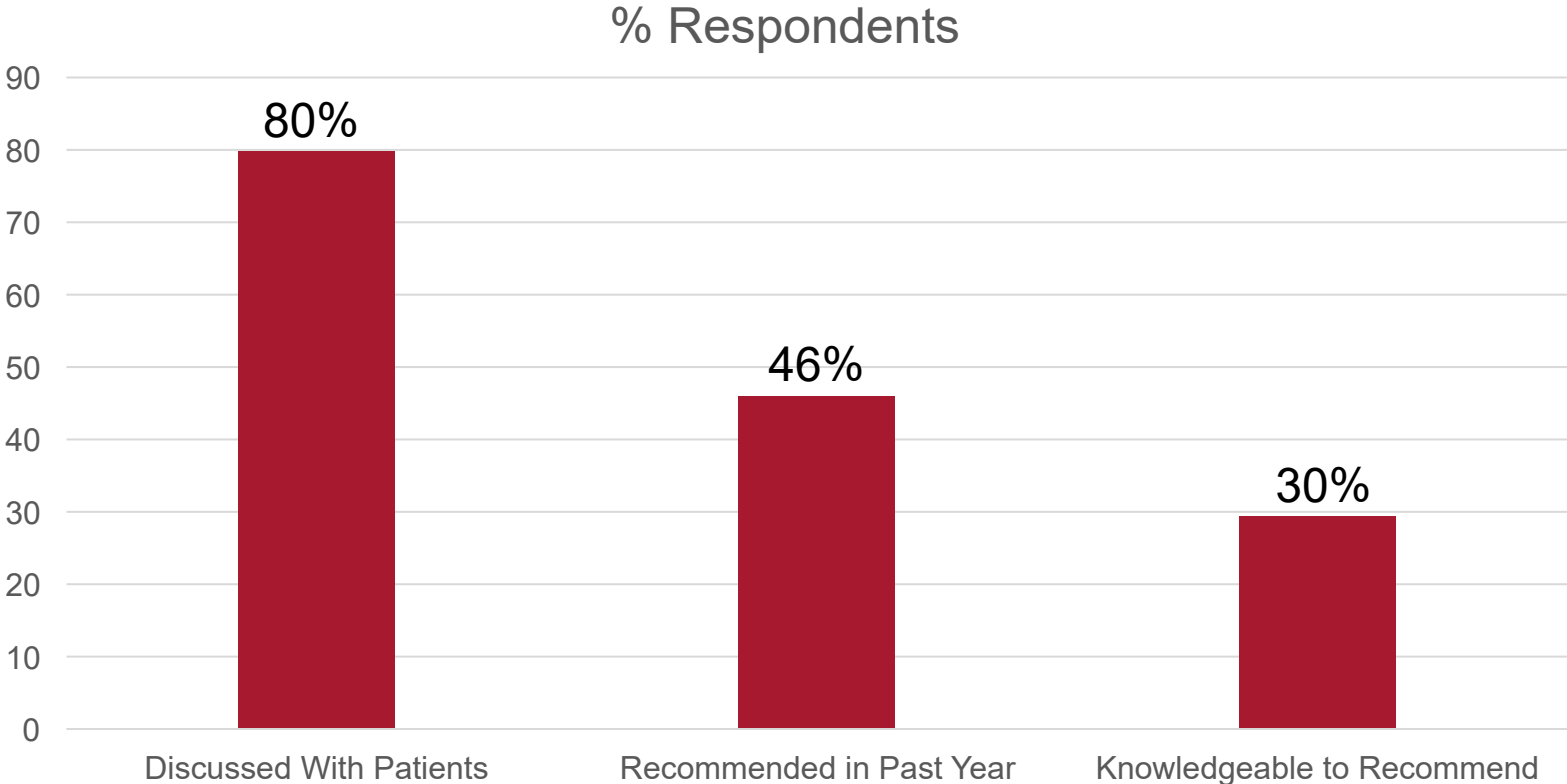
# Comprehensive cancer center patient survey (N=926)

**Only 12% received cannabis information from their cancer doctor or nurse while 74% wished they had**



# Survey of national oncologists (N=400) (Braun, 2018)

**56% of cannabis recommenders did not consider themselves sufficiently knowledgeable**



# Across 8 states, interview with cancer patients using medicinal cannabis (N=24) (Braun, 2020; Nayak, 2022)

## Lack of medicinal cannabis integration into medical care

- Most received certifications from professionals new to their care through brief, transactional encounters.
- **ALL** disclosed medical cannabis use but medical teams offered startlingly little clinical guidance.
- Stigma perceived in all domains, medical > personal
- Participants relied on personal experimentation &/or commercial information sources.
- Adults with cancer used cannabis for symptom management &- for half of participants-- as cancer-directed therapy, sometimes in lieu of traditional treatments.

# Across 8 states, interview with cancer patients using medicinal cannabis (N=24) (Braun, 2020; Nayak, 2022)

“Most doctors-- you mention cannabis: They shut right up. They don't say two words to you. They don't give you an opinion: Nothing. They just shut right up.”



# Across 8 states, interview with cancer patients using medicinal cannabis (N=24) (Braun, 2020; Nayak, 2022)

“I vaped in front of my doctor the other day and he didn't even know what I was doing.”

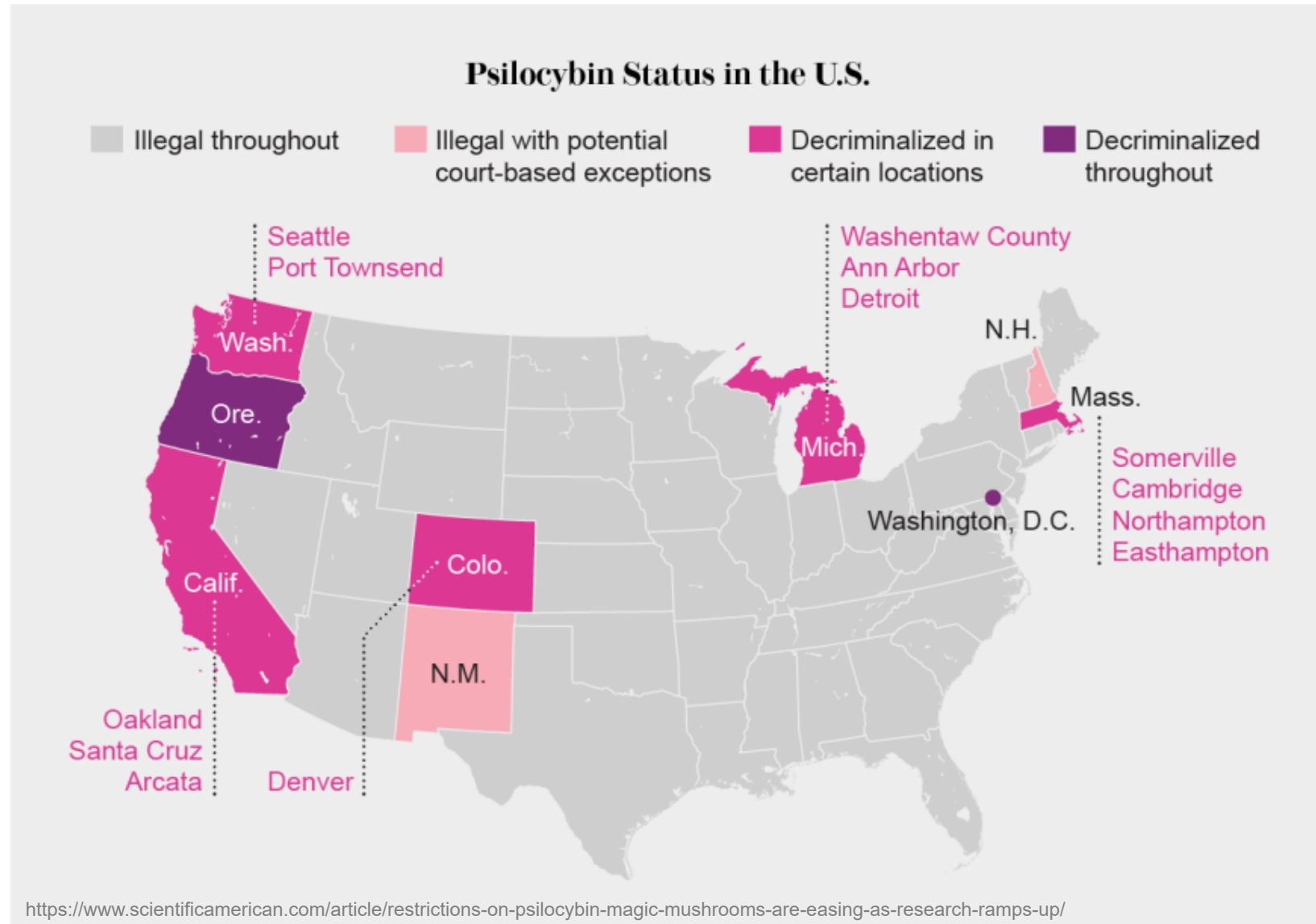


# THE MORAL IS...





# Psychedelic-assisted therapies: Medical Cannabis as Inspiration versus Cautionary Tale



# Psychedelic-assisted therapies: Medical Cannabis as Inspiration versus Cautionary Tale



## Medicinal psychedelic assisted therapies action plan:

- Check biases
- Keep the suffering patient front of mind
- Conduct rigorous scientific research
- Arrive at evidence-based, standardized institutional guidelines/policies... & share them
- Educate through medical education, CME & patient-facing materials
- Guide the conversation in the media
- Guide the conversation in the clinic

# PSYCHEDELIC-ASSISTED THERAPIES IN SERIOUS ILLNESS CARE: A (RE)EMERGING FIELD

Roxanne Sholevar, MD

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Dana-Farber Cancer Institute  
Instructor in Psychiatry, Harvard Medical School

# The scope of suffering

**People with serious illness experience distress over and above the physical symptoms of their specific condition**

**62%**

feel anxious, confused, or helpless

**48%**

have emotional or psychological problems caused by their condition

**32%**

reported feeling left out, lacking in companionship, or isolated from others



The New York Times



**HARVARD**  
**T.H. CHAN**  
SCHOOL OF PUBLIC HEALTH



# The scope of suffering

- Distress extends beyond traditional psychiatric diagnoses:
  - Existential distress
  - Demoralization
  - Spiritual well-being
  - Desire for hastened death

*Psycho-existential well-being affects...*

Quality of life

Survival

Adherence to treatment

Bereaved loved ones

## Multidimensional palliative care needs

Hui et al 2018



# Limited efficacy of available treatments

## Psychotherapies

Supportive  
Behavioral  
Existential  
Expressive

## Pharmacotherapies

Antidepressants  
Anxiolytics  
Antipsychotics  
Mood stabilizers

## Palliative Care

Symptom management  
Communication  
Caregiver support  
Multidimensional  
patient-level targets

## Integrative Therapies

Body work  
Meditation  
Creative therapies  
Nutrition

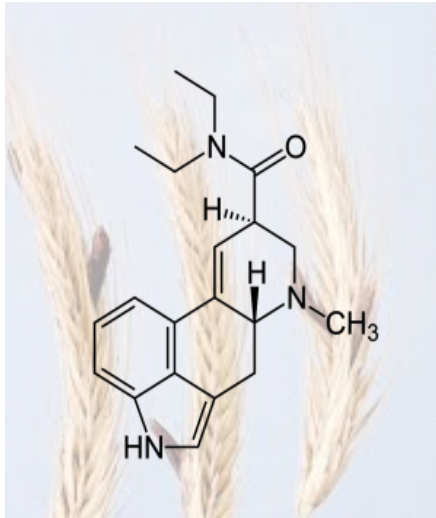


## Psychedelic-assisted therapies

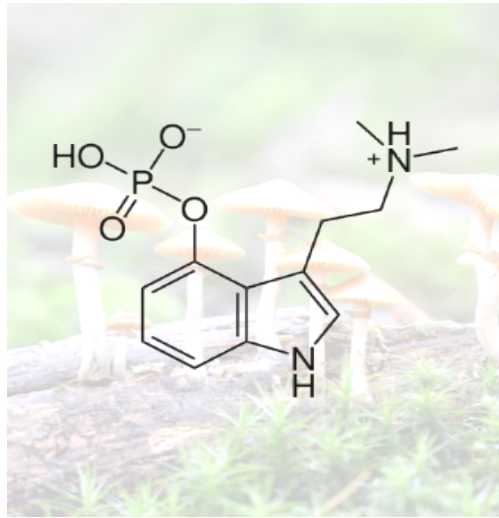
# psychedelics: "mind manifesting" or "soul revealing"

"Psychedelics are to the study of the mind what the microscope is to biology and the telescope is to astronomy." **Stanislav Grof**

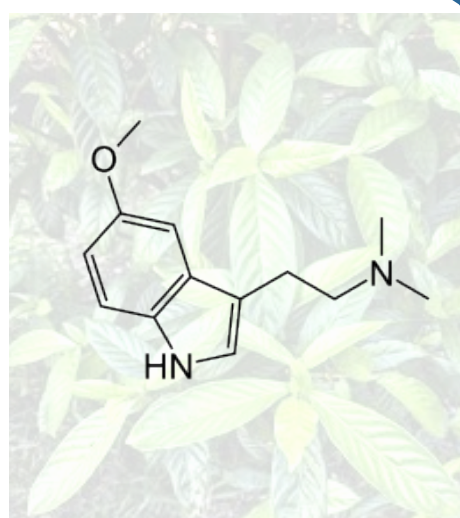
**Classic Psychedelics** (*naturally occurring or synthesized from natural compounds*)



LSD-25

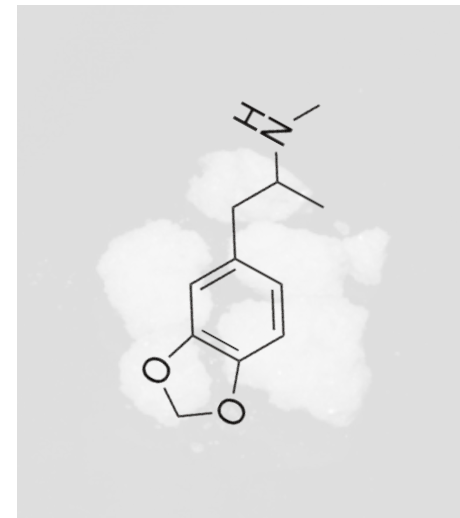


Psilocybin

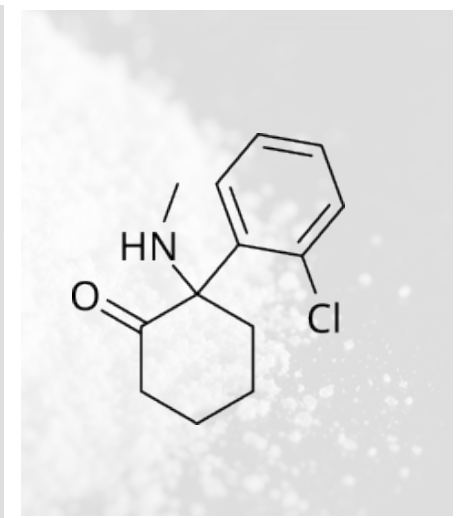


DMT

**Non-Classic Psychedelics** (*not naturally occurring synthetic compounds*)

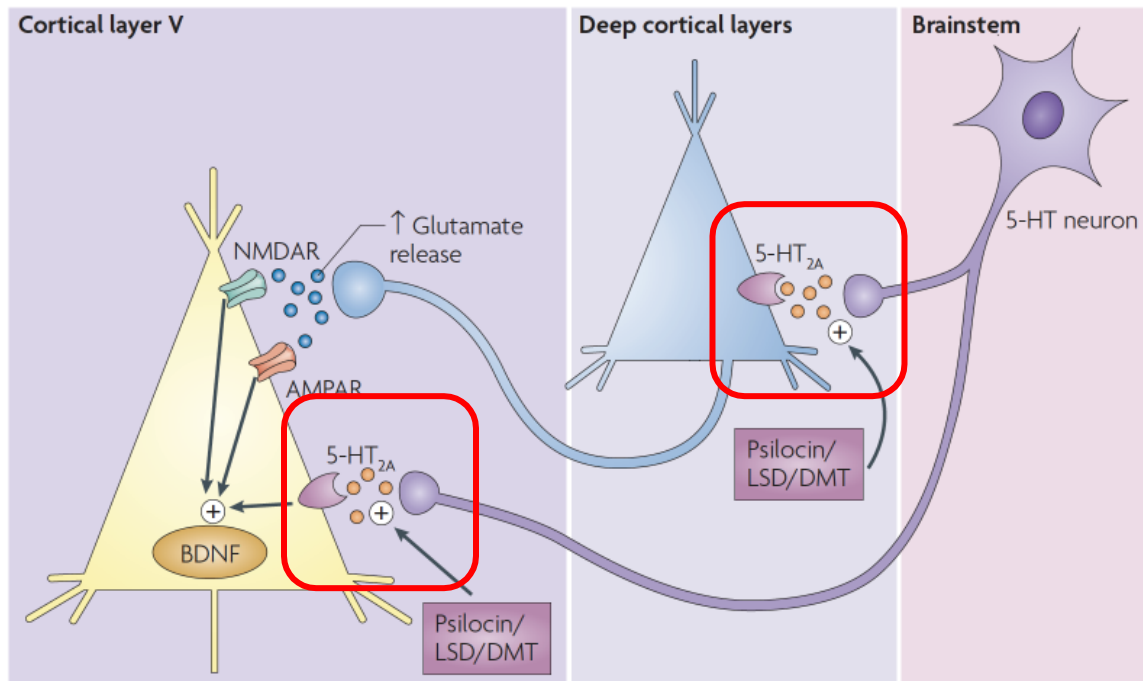


MDMA



Ketamine

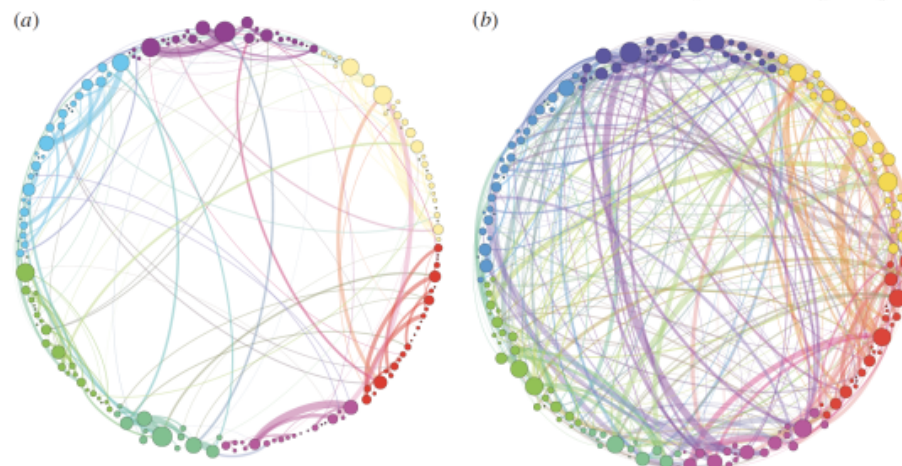
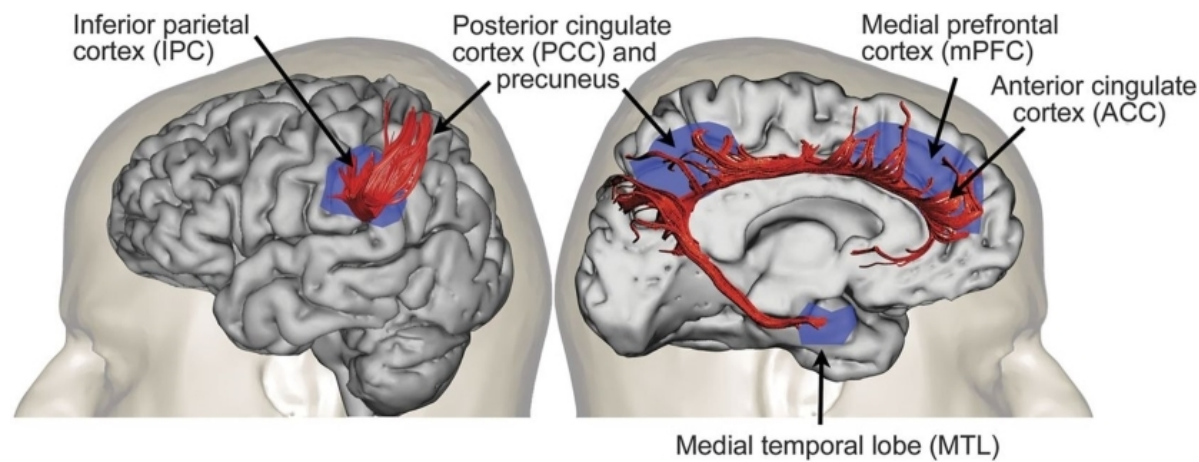
# Pharmacology & neurobiology



(Vollenweider et al., 2010)

- 5HT<sub>2A</sub> agonism
- Glutamate-driven neuroplasticity
- Reopening the social reward learning critical period

The default mode network: intra-network connectivity --> wide extra-network connectivity



(Petri et al, 2014; Carhart-Harris et al., 2014)



# Psychedelics as medicine



Life magazine publishes Gordon R. Wasson's account of 1955 Mazatec mushroom ritual with curandera Maria Sabina

Early wave of studies using LSD-assisted psychotherapy in terminal illness



Psychedelics listed as Schedule 1 under Controlled Substances Act



Usona receives Breakthrough Therapy Designation. NYU and JHU publish cancer studies in 2016

Resurgence of pre-clinical and clinical academic research



~1,500 BC

1957

1959

1960s

1970

1980s

2010s

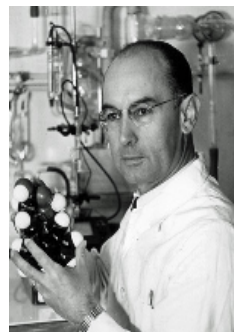
2019

2020s

Ceremonial use of *psilocybe* mushrooms in Mesoamerica



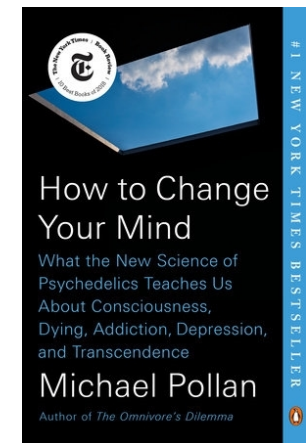
Albert Hofmann synthesizes psilocybin, after isolating and identifying the compound in 1957



Dame Cecily Saunders & the birth of the hospice movement



Advances in cancer care, patients living longer, psychosocial oncology and palliative care increasingly recognized



Increasing public interest in psychedelic-assisted therapies

# There has been enduring clinical and research interest in applications of PAT for patients at end of life

## Early psychedelic research in patients with serious illness 1964 – 1977

### Early therapeutic signals on cancer pain → QOL / psycho-existential distress

- Kast, E.C. and Collins, V.J. (1964). **Study of Lysergic Acid Diethylamide as an Analgesic Agent.** *Anesthesia & Analgesia.*
- Kast, E.C. (1966). **LSD and the dying patient.** *Chicago Medical School Quarterly.*
- Kast, E.C. (1967). **Attenuation of anticipation: A therapeutic use of lysergic acid diethylamide.** *Psychiatric Quarterly.*

### Psychotherapeutic process / set & setting; mystical experience; death anxiety / psycho-existential distress

- Pahnke W. et al. (1969). **LSD-assisted psychotherapy with terminal cancer patients.** *Psychedelic Drugs.*
- Grof, S. et al. (1973). **LSD-assisted psychotherapy in patients with terminal cancer.** *Int. Pharmacopsychiat.*
- Richards, W.A. et al. (1977). **The Peak experience variable in DPT-assisted psychotherapy with cancer patients.** *Journal of Psychedelic Drugs.*



# There is strong preliminary evidence showing PAT may help patients cope with serious illness and manage anxiety, depression, and existential distress

## Contemporary psychedelic research in patients with serious illness 2011-

Grob, C. et al. (2010) **Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer.** *Archives of General Psychiatry.*

Gasser, P. et al. (2014). **Safety and efficacy of lysergic acid diethylamide-assisted psychotherapy for anxiety associated with life-threatening diseases.** *Journal of Nervous and Mental Disease.*

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

Ross, S. et al. (2016) **Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial.** *Journal of Psychopharmacology.*

Anderson BT et al. (2020) **Psilocybin-assisted group therapy for demoralized older long-term AIDS survivor men: An open-label safety and feasibility pilot study.** *EClinical Medicine*

Wolfson PE et al. (2020) **MDMA-assisted psychotherapy for treatment of anxiety and other psychological distress related to life-threatening illnesses: a randomized pilot study.** *Sci Rep*

Agrawal et al. (2023) **Psilocybin-assisted Group Therapy in Patients with Cancer Diagnosed with a Major Depressive Disorder.** *Cancer*

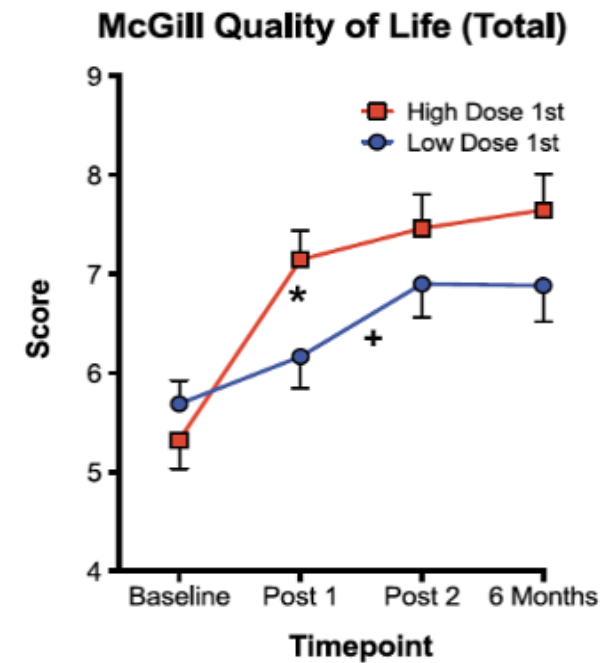
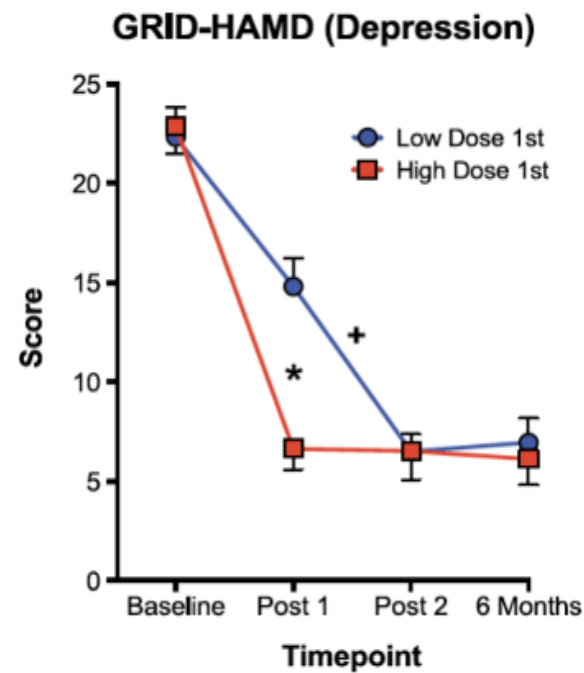
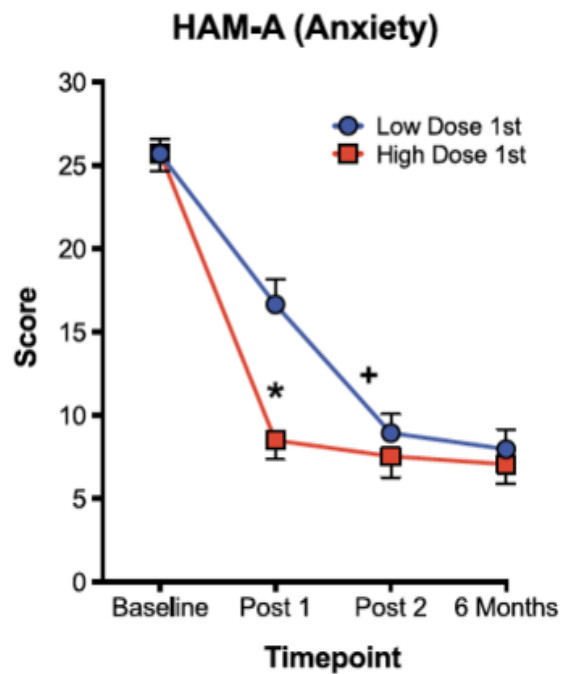
Lewis et al. (2023) **HOPE: A Pilot Study of Psilocybin Enhanced Group Psychotherapy in Patients with Cancer.** *Journal of Pain and Symptom Management* 2023



# PAT results in significant reductions in anxiety, depression, and improved QoL

n = 51, psilocybin 25mg, cancer + anxiety and/or depression

Griffith et al., 2016



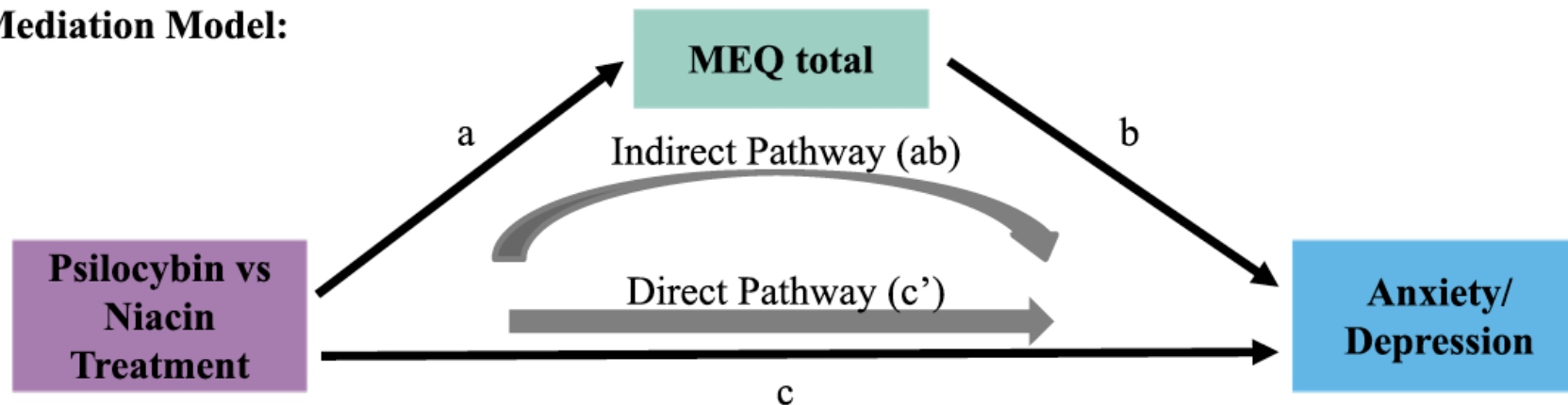
80% significant reduction in anxiety and depression at 6 months  
70% remission

# PAT results in significant reductions in anxiety, depression, and improved QoL

Effect is mediated by subjective experience

n = 29, cancer + anxiety and/or depression Ross et al, 2016

Mediation Model:



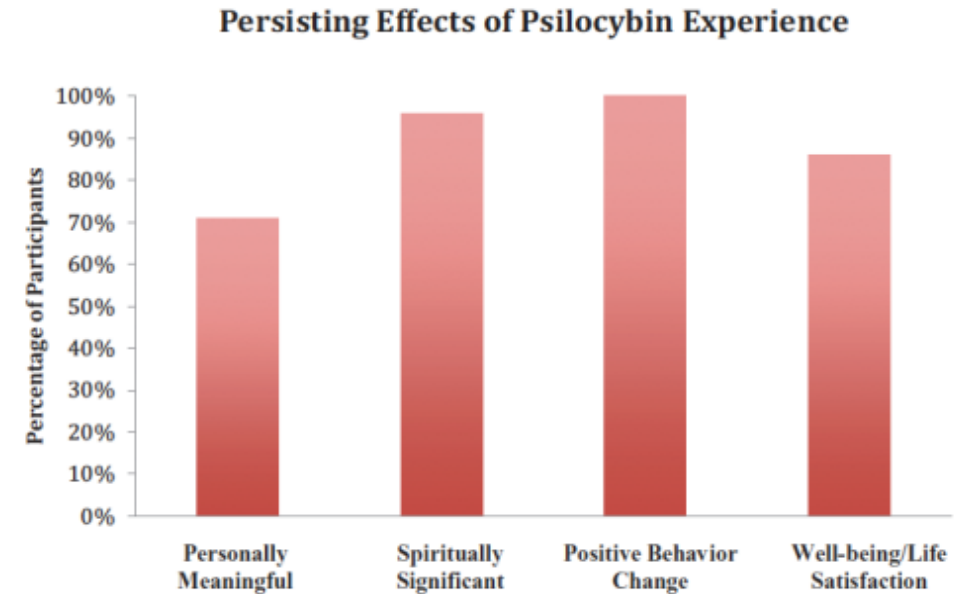
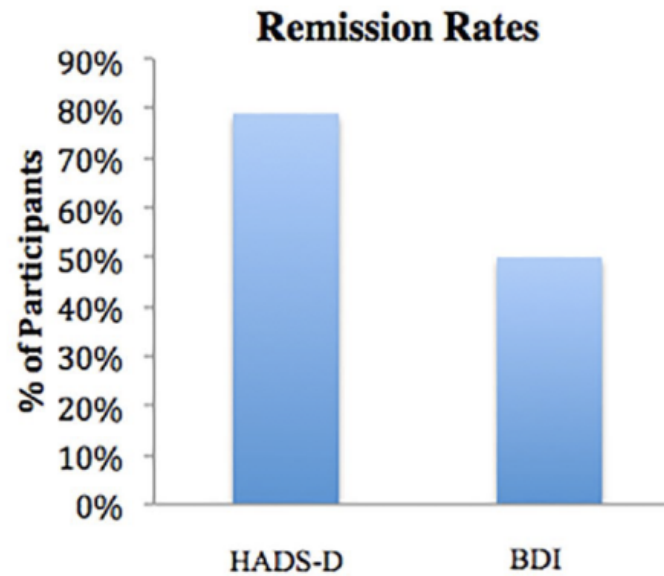
**ab** = Indirect effect of psilocybin on anxiety/depression *mediated by mystical experience*  
**c'** = Direct effect of psilocybin on anxiety/depression *not mediated by mystical experience*

Mystical  
Interpersonal  
Psychodynamic (grief, trauma...)

# PAT results in significant reductions in anxiety, depression, and improved QoL

## Effect is sustainable

n = 15, long term effect follow-up study (3.2 and 4.5 years) Agin-Liebes et al, 2020



60–80% continued response  
and > 50% remission.

100% endorsed their experience as  
spiritually significant and having had  
positive changes

# An evidence-based psychedelic treatment involves medication and therapy—the psychedelic agent is not a “stand-alone” intervention

Medication (psychedelic) administered to induce a non-ordinary state of consciousness embedded in a **framework of support**



Pre-treatment psychotherapy  
(preparation)



Psychological/spiritual  
support during administration  
(dosing)



Post-treatment psychotherapy  
(integration)

All classical psychedelics (psilocybin, LSD, DMT) and MDMA are **schedule I substances** and are not permissible for use outside research and certain religious settings.

## Current Status of Regulatory Approval:

FDA Phase II  
Clinical Trials

Psilocybin: major depressive disorder, treatment-resistant depression, substance use disorder, **distress related to serious illness**

Ketamine: alcohol use disorder, suicidal ideation and behavior, **distress related to serious illness**

LSD: cluster headaches, anxiety disorders, **distress related to serious illness**

MDMA: anxiety disorders, social anxiety in autistic adults, **distress related to serious illness**

Projected approval  
2025-2026

FDA Phase III  
Clinical Trials

MDMA: PTSD, TRD **Projected approval  
2024**



American Medical Association to Issue  
First New Code for Psychedelic Therapies

PUBLIC HEALTH DIVISION  
<http://Public.Health.Oregon.gov>



Oregon Psilocybin Services





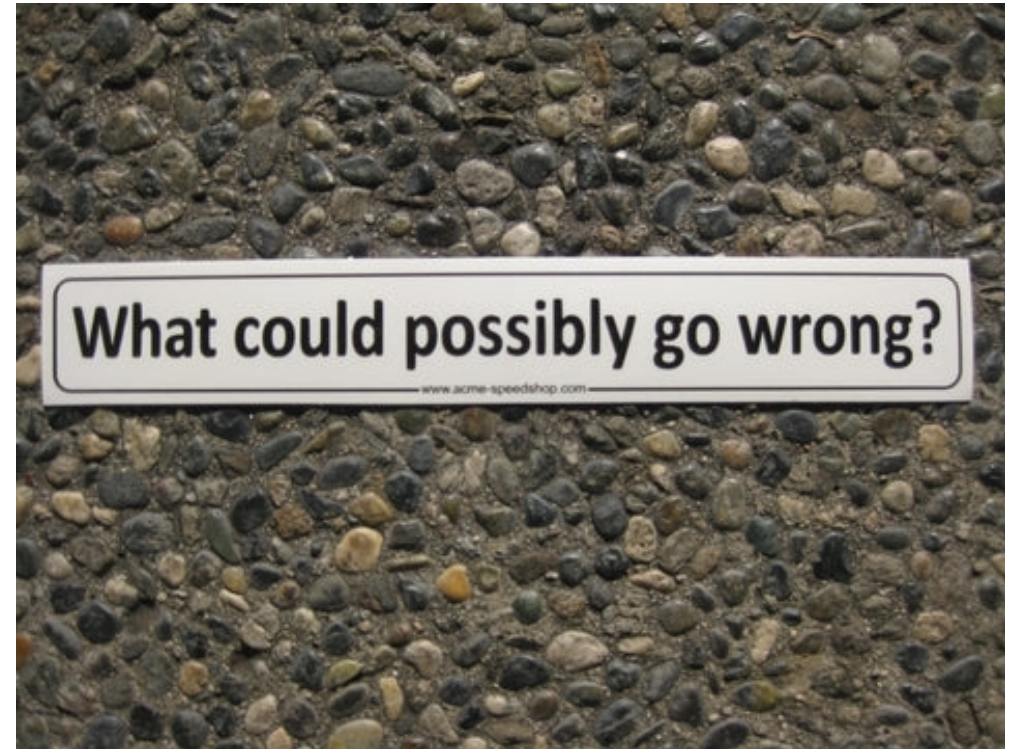
# Facing integration: current studies of PAT in patients with serious illness

A Phase 2b, Randomized, Double-blind, Placebo-controlled, multi-center Study of the Effects of Psilocybin-assisted Psychotherapy on Psychiatric and Existential Distress in Advanced Cancer	NYU Langone Health	Psilocybin
Psilocybin Combined With Multidisciplinary Palliative Care in Demoralized Cancer Survivors With Chronic Pain	Emory University	Psilocybin
Pilot Study of Psilocybin-Assisted Therapy for Demoralization in Patients Receiving Hospice Care	Dana-Farber Cancer Institute	Psilocybin
Feasibility Phase 2 Study of Psilocybin-Assisted Therapy for Opioid-Refractory Cancer Pain in Patients with Advanced Cancer	Dana-Farber Cancer Institute	Psilocybin
The Safety and Efficacy of Psilocybin in Cancer Patients With Major Depressive Disorder	Maryland Oncology Hematology	Psilocybin
MDMA-assisted Therapy for Adjustment Disorder (AD) in Dyads of Patients With Cancer and a Concerned Significant Other	Sunstone Medical	MDMA
Study of Psilocybin Enhanced Group Psychotherapy in Patients With Cancer	University of Utah	Psilocybin
Pragmatic Trial of Psilocybin Therapy in Palliative Care (PT2PC): A Multi-center Triple-blind Phase 2 Randomized Controlled Trail of Psilocybin Therapy for Demoralized Adults Near the End of Life	UCSF	Psilocybin, Ketamine
Ketamine-Assisted Psychotherapy Viability in Treating Cancer-Related Emotional Distress	Northwell Health	Ketamine

# Psychedelics still carry significant stigma and serious illness care experts have concerns about their safe and ethical implementation

*Beaussant et al 2020*

- **Association to drugs of abuse**
- **Vulnerable patients**
  - Somatic risk: delirium, epilepsy, cardio
  - Psychosocial risk: exacerbation of distress, disruption of patient/family relationships, behavioral issues/accidents, abuse of patients
- **Risk related to scaling/commercialization**
  - Lowering the amount of psychosocial and spiritual support
- **Lack of access, diversity and recognition of indigenous heritage**



# Psychedelic-assisted therapies are viewed by patients and providers as demanding and potentially disruptive

Research has shown how **powerful** the psychedelic experience can be, and how support is critical to both **reduce harm** and **optimize effect**

## Acceptability of the psilocybin experience: patient perspectives

- Intensity and demandingness of the effect – seen as integral to the healing process
- Tension between resistance and surrender
- Vulnerability, dependence, and suggestibility felt towards the setting

*Beaussant et al 2023*

## Disruptive potential of the psychedelic experience: experts' perspectives

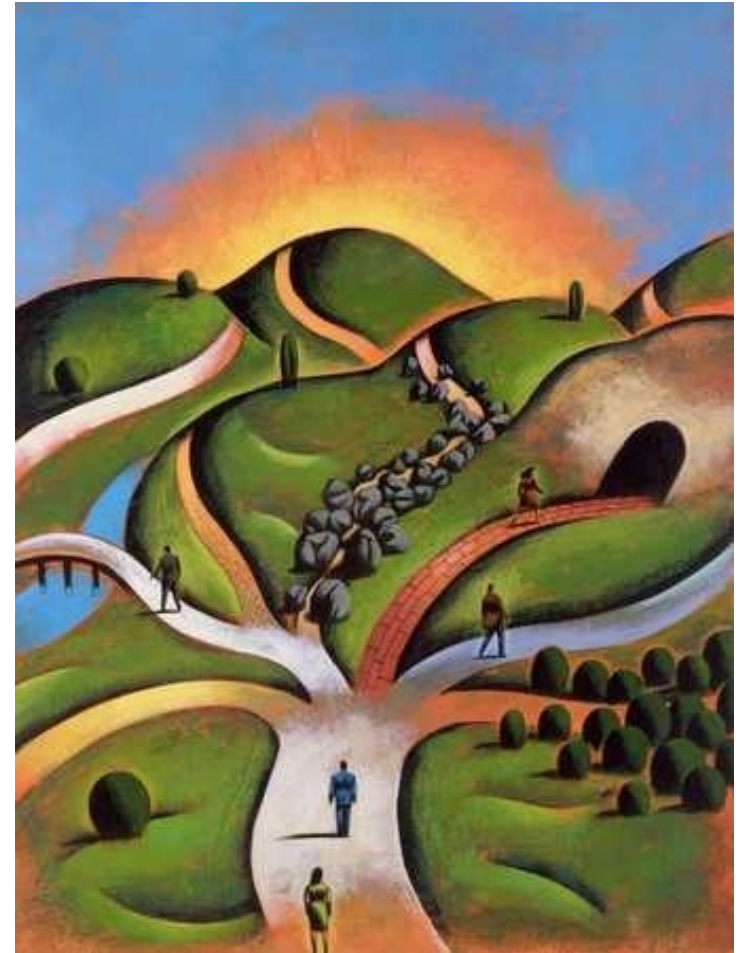
- Serious illness care experts had divergent perspectives on the role of PAT and identified potential points of disruption at the individual, relational, clinical, and societal levels
- Whether this disruptive potential was viewed as a therapeutic opportunity or harmful risk depended on adequate structures in place to contain and leverage this disruptive potential

*Sholevar et al 2023*

# Although classic psychedelics are not yet clinically available, significant public interest results in **increasingly frequent patient inquiries**

What are the available routes for patients to pursue psychedelic-assisted therapies?

- Through a registered clinical trial
- Legal public models (Oregon psilocybin service model for guided adult use in dedicated facilities)
- Ketamine-assisted therapies (schedule II, widely available in both infusion and KAP model)
- "Underground" access
- Personal cultivation and self-guided use



# CLINICAL CASES

# A Request for Advice

- A 32 year old entrepreneur being treated with FOLFOX chemotherapy for metastatic rectal cancer requested help with anxiety during weekly infusions
- His anxiety and self-described PTSD began after he was involuntarily detained by staff at his previous hospital when he was perceived as threatening toward his oncologist
- His history included a turbulent relationship with his father, working 90 hours a week in a medical mushroom start-up, and using psilocybin for both anti-neoplastic and anti-anxiety effects
- He requested advice on his use of psychedelics for his PTSD

# Should I See a Shaman?

- 69 year old divorced, female engineer with recurrent advanced, low grade serous ovarian cancer s/p surgical debulking, 5 cycles of carbo/taxol. She developed progression of disease on anastrozole, now on a MEK-inhibitor.
- She has a history of longstanding depression, one previous suicide attempt and numerous medication trials for depressed mood. She has also tried CBT and is currently in supportive psychotherapy discussing demoralization around her cancer diagnosis. She discusses loneliness and difficulty with decision making about retirement and transitions in her life.
- She shares that a family member suggested she "go see a Shaman" and asks for a direct recommendation from her psychiatrist about doing so.

# Unintegrated care

- A 44 year old female attorney with relapsed AML s/p allogeneic SCT with multiple complications, most notable disseminated fungemia with refractory CNS lesions and subsequent IRIS (immune reconstitution inflammatory syndrome)
- She had mild pre-morbid depression but developed a refractory demoralization syndrome and depression with her complicated course
- She expressed interest in psilocybin, and then sought ketamine infusions in the community as an alternative, not disclosing her medical history to the community physician
- Her psychiatrist was asked to sign a release, prompting her to call the community ketamine physician who was shocked to hear of patient's complex medical history



# ETHICAL CONSIDERATIONS WITH PSYCHEDELICS

Carrie C. Wu, MD

# Question

In what circumstances can we **discuss** the use of potential therapeutics that are considered nontraditional in Western medicine, unproven therapies and/or illegal substances?

...And if so, how?

# Ethical Considerations

- **Yes, we should discuss it...**
- To promote informed decision-making
- To reduce harm
- To promote healing
- To be culturally responsive

# Informed Decision Making

- The experience of using psychedelics has been described as *transformative*<sup>1</sup>
- In research settings, enhanced consent already occurs, but is also relevant in clinical practice<sup>2</sup>



1. Jacobs E. Transformative experience and informed consent to psychedelic-assisted psychotherapy. *Front Psychol.* 2023 May 26;14:1108333. doi: 10.3389/fpsyg.2023.1108333. PMID: 37303902; PMCID: PMC10254809.
2. Barber GS, Dike CC. Ethical and Practical Considerations for the Use of Psychedelics in Psychiatry. *Psychiatr Serv.* 2023 Aug 1;74(8):838-846. doi: 10.1176/appi.ps.20220525. Epub 2023 Mar 29. PMID: 36987705.

# Harm Reduction

- Risks of psychedelics in non-research settings<sup>1</sup>
  - Lack of protocol
  - Naturalistic setting of use
  - Illegal procurement of substances
- Drug-drug interactions
  - SSRI may attenuate effects of LSD
  - Report of fatal effects from combining psychotropics with MDMA

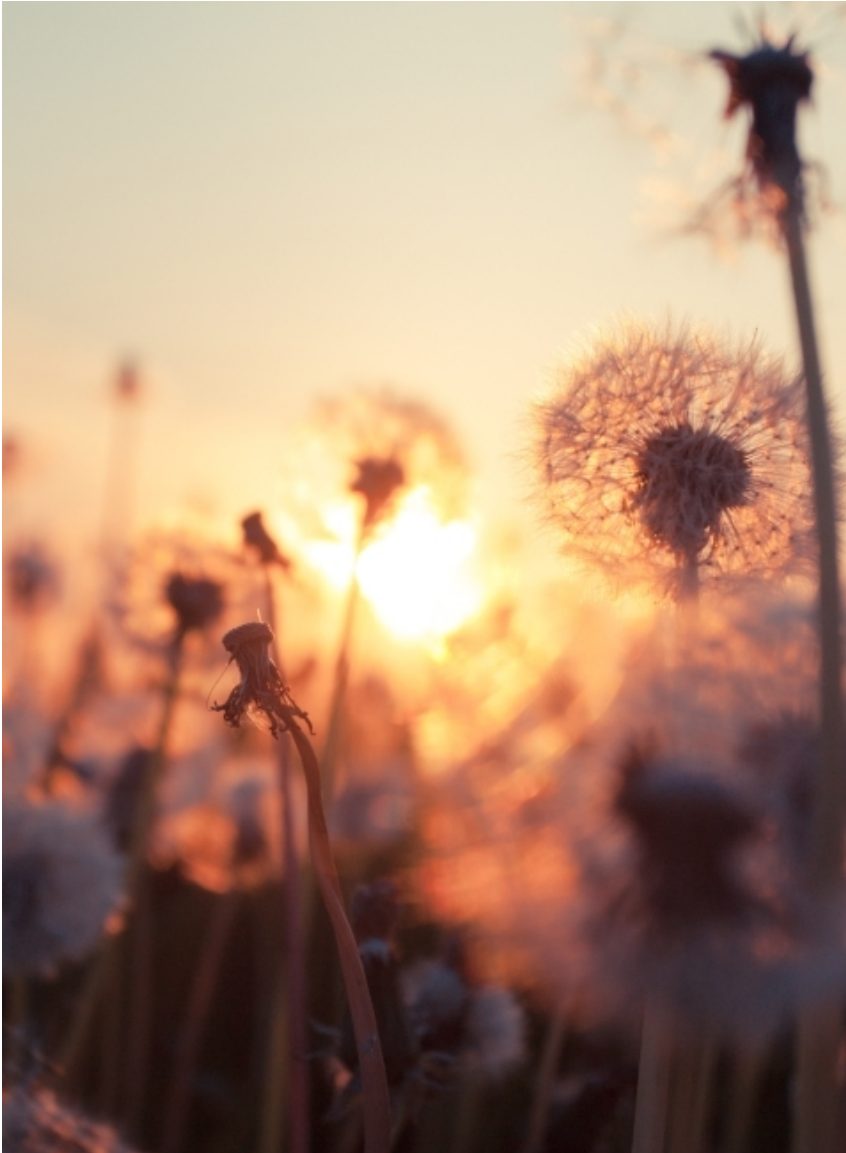
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# The argument for compassionate use

- What is the alternative for a terminally ill patient who has exhausted multiple treatment options?<sup>1</sup>
- In deciding whether to participate in phase I oncology clinical trials, more than 90% of patients said they would still participate in the study even if the experimental drug caused serious adverse effects, including a 10% chance of dying<sup>2</sup>

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# Spirit medicines



- Indigenous Peoples have used Spirit medicines, including psychedelics, for centuries
- Spirit medicines are used for emotional, physical, and spiritual healing
- Concerns around cultural appropriation, omission of Indigenous Peoples' voices, glorification of psychedelics, infiltration of drug cartels into traditional territories

# Ethical principles of traditional Indigenous medicine to guide western psychedelic research and practice

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## Summary

The resurgence of Western psychedelic research and practice has led to increasing concerns from many Indigenous Nations regarding cultural appropriation, lack of recognition of the sacred cultural positioning of these medicines, exclusionary practices in research and praxis, and patenting of traditional medicines. Indigenous voices and leadership have been notably absent from the Western psychedelic field currently widely represented by Westerners. An Indigenous-led globally represented group of practitioners, activists, scholars, lawyers, and human rights defenders came together with the purpose of formulating a set of ethical guidelines concerning traditional Indigenous medicines current use in Western psychedelic research and practice. A global Indigenous consensus process of knowledge-gathering was engaged which identified eight interconnected ethical principles, including: Reverence, Respect, Responsibility, Relevance, Regulation, Reparation, Restoration, and Reconciliation. A summary of the work is presented here with suggested ethical actions for moving forward within Western psychedelic research and practice spaces.



# Indigenous consensus process

- Oct 28, 2021 to March 11, 2022
- Indigenous-led group of practitioners, scholars, lawyers, human rights defenders, and activists, with representatives globally, came together to formulate a set of ethical guidelines

## Overarching interconnected ethical guidelines

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Acknowledgement	1. Reverence
	2. Respect
Knowledge-Translation and Education	3. Responsibility
	4. Relevance
Intellectual Property	5. Regulation
	6. Reparation
Belonging	7. Restoration
	8. Reconciliation

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**Table 1:** The main categories and eight individual ethical principles concerning traditional Indigenous medicines use in Western psychedelic research and practice.

Indigenous principles	Concrete problems	Possible solutions
1. Reverence for Mother Nature	High carbon footprint therapies (e.g., long-distance travel, monocultures), spiritual consumerism, and psychedelic tourism fail to promote environmental care.	Therapies based on Indigenous wisdom reorient attitudes towards better relationships with human, other-than-human, and Mother Earth.
2. Respect Indigenous ways of knowing and being	Extraction and failure to adequately reference Indigenous traditions (e.g., in medicines, rituals, ceremonial use).	Proper acknowledgment of Indigenous traditions.
3. Responsibility for use, benefits, harms	Colonial practices of exploitation, dissemination, capitalization, and promotion of appropriation of Indigenous medicines. Promotion of well-being in non-Indigenous Peoples without considering access to health for Indigenous Peoples.	Accountability for perpetuation of harmful practices and a responsibility for inclusive and respectful practice.
4. Relevance of Indigenous knowledges in psychedelic medicine	Western education and therapies, continue to colonize Indigenous practices.	Formal efforts establish Indigenous-led intellectual foundations in Western psychedelic science, therapy, and curricula.
5. Regulation of tangible and intangible use of traditional Indigenous medicines	Indigenous traditions are appropriated in psychedelic products, therapies, retreats.	Indigenous Peoples rights are respected through FPIC on the use of their medicines and practices. Benefits for any use of Indigenous medicine and practices are shared with Indigenous source communities as they see fit.
6. Reparation and sharing of benefits	Indigenous knowledges, material and genetic resources are a growing billion-dollar industry benefitting primarily Western populations.	Institutions and organizations using psychedelics for research and/or therapies, seek to promote and safeguard self-determination, and enable restitution of appropriate cultural, intellectual, religious, and spiritual property with the FPIC of Indigenous Nations.
7. Restoration of Indigenous authority	Indigenous voices are not part of deliberations related to psychedelic science, therapies, training, product development, etc.	Restoration of Indigenous authority is prioritized.
8. Reconciliation of Indigenous-Western relations	Indigenous voices are not part of institutions, both formal and informal, that are dictating the shape of the psychedelic research therapy movement.	Indigenous scholars, knowledge holders, and practitioners are actively included as leaders in deliberations related to the development of Western psychedelic research and practice.

Table 2: The eight ethical principles applied within western psychedelic research.

If we *should* talk about it,  
*how* do we do that?



# By asking more questions

- What does the patient hope for?
- How do these potential therapies align with the patient's values?
- What are we treating here? What is the clinical indication?
- What do they understand about the potential benefits or risks?
- Where are they sourcing information from?
- What has been tried already?
- What alternative options are available?
- Where are they sourcing the drugs?

# Finally, for our discussion...

- Is it ethical to ***recommend*** the use of potential therapeutics that are considered nontraditional in Western medicine, unproven therapies and/or illegal substances?
- ***If so, in what circumstances?***

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