

Columbia Bioethics/ Columbia Law
CLE Program
Outline/ Timed Agenda
April 18, 2024
6:15-8:15pm

Title: Psilocybin vs. The DEA: Law, Ethics, Society & DRUGS

Program description:

Notwithstanding that the U.S. Food and Drug Administration (FDA) has twice designated psilocybin a Breakthrough Therapy—first for treatment-resistant depression and then for major depressive disorder, the U.S. Drug Enforcement Administration (DEA) has steadfastly refused to even initiate the process for rescheduling the drug. In early 2021, Dr. Sunil Aggarwal and Advanced Integrative Medical Science Institute, PLLC asked the DEA how he might obtain psilocybin for therapeutic use under Right to Try laws. In response, DEA said it had no authority to permit such uses because psilocybin is a schedule I drug permitted for research use only.

DEA's refusal to accommodate access to psilocybin under RTT, let alone open a scientific review related to a rescheduling petition, not only undermines congressional goals, but also exceeds its authority. The food, drug and cosmetics act (FDCA), controlled substances act (CSA) and right to try (RTT) laws were created to protect the life and health of the public from dangerous and ineffective medications. But as was learned during the early days of the HIV/AIDS when those legal protections only produce suffering and death, they serve no legitimate legal and public health purpose. Sometimes government can do best for its citizens by simply stepping out of the way.

This program will explore the potential therapeutic role of Psilocybin, and the paths available to meaningful scientific review of its use.

Speakers:

David Hoffman
Assistant Professor
Columbia University, Bioethics Master's Program
Clinical Ethics Consultant, VNS HEALTH Hospice Program

Linda Brooks Uchal
Critical Care Pharmacist
University of Texas
Southwestern Medical Center

Steven P. Field

Clinical Assistant Professor, Department of Medicine at NYU Grossman School of Medicine;
Medical Ethics Consultant, NYU Langone Medical Center
Clinical Ethics Consultant, VNS HEALTH Hospice Program

Dan Arshack

Partner, Arshack Hajek and Lehrman
Criminal Defense Attorney
Co-Founder, Bronx Defenders

Timed Agenda

- 1) Do the purposes of the FDCA and CSA apply to Psilocybin, and how? Is it worse than alcohol? The case for rescheduling.

David N. Hoffman

6:15-6:45pm

- 2) What is Psilocybin, how does it work, and what can it do for patients that other drugs can't?

Linda Brooks Uchal

6:45– 7:05pm

- 3) Why Psilocybin, and how do we know it's safe? The value of the lived experience of indigenous communities, and the moral imperative to evaluate rescheduling.

Steven P Field.

7:05– 7:25pm

- 4) The value and peril of criminalizing cultural practices and stigmatizing efficacious medicines.

Daniel N. Arshack

7:25-7:45pm

- 5) Did classifying Psilocybin as a schedule 1 drug ever make sense, and does it now. A multidisciplinary review of the law and ethics of the rescheduling regulations.

Panel Discussion

7:45-8:15pm

Reading Materials (provided by hyperlink):

[Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer](#)

[Charles S Grob¹, Alicia L Danforth, Gurpreet S Chopra, Marycie Hagerty, Charles R McKay, Adam L Halberstadt, George R Greer](#)

[DEA Drug Scheduling Statement](#)

[DEA list of controlled substances](#)

In the United States Court of Appeals for the Ninth Circuit

DR. SUNIL AGGARWAL, MD, PHD; ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC, *Petitioners*, v. U.S. DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION; AND MERRICK GARLAND IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL, *Respondents*. **BRIEF OF AMICUS CURIAE KATHY CERMINARA, DAVID N. HOFFMAN, AND JILL SIMONIAN IN SUPPORT OF THE PETITIONERS AND GRANTING THE PETITION**

Aggarwal v DEA, Memorandum Decision
Case: 22-1718, 10/27/2023, Dkt Entry: 82.1

[From prohibited to prescribed: The rescheduling of MDMA and psilocybin in Australia](#)

[Psilocybin for End-of-Life Anxiety Symptoms: A Systematic Review and Meta-Analysis](#)

[A regulatory framework review of Schedule I psychedelics in the United States](#)

Speakers BIOS:

David Hoffman, J.D.

David N. Hoffman is a health care attorney and clinical ethicist and is the Chief Compliance Officer at Carthage Area Hospital, where he supports the clinical and administrative staff in the areas of ethical practice and legal compliance. He has written on a variety of healthcare subjects including use of medical imaging technology in litigation, equal protection rights of physicians, and regulatory responses to the emerging physician shortage, and has served on and advised hospital ethics committees and institutional review boards. He was a member of the faculty of the Montefiore Medical Center/NYU Pilot Certificate Program on Human Research Subject Protection. Hoffman is a volunteer member of the Surrogate Decision-Making Committee of the New York State Department of Health, Commission on Quality of Care/Justice Center. He served as the Chair of the Committee on Bioethical Issues of the Association of the Bar of the City of New York (ABCNY) and as a member of the Committee on Professional Ethics of the New York State Bar Association. He was the principal author of the committee's advisory opinion on internet-based attorney referral services. He previously served as the Legislative Liaison for the Special Committee on Medical Malpractice at ABCNY, where he authored the Association's policy statement on the National Practitioner Databank. He also chaired the ABCNY Subcommittee on human transplant organ procurement. Mr. Hoffman completed the pilot post-graduate program in Bioethics and the Medical Humanities at Columbia University Medical Center.

Steven P. Field

Steven P. Field is a Clinical Assistant Professor in the Department of Medicine at NYU Grossman School of Medicine. He is board certified in internal medicine and gastroenterology. Steven current serves as Medical Ethics Consultant at the NYU Langone Medical Center, and as Clinical Ethics Consultant for the VNS HEALTH Hospice Program.

Linda Brooks Uchal

Linda received her B.S. in Pharmacy degree from Duquesne University and a Doctor of Pharmacy from a joint program at The University of Texas at Austin and The University of Texas Health Science Center in San Antonio. She did a pharmacy specialty residency in Adult Internal Medicine at the University of Texas at Austin and Baylor Scott & White Hospital in Temple, Texas. Currently she is a MS in Bioethics student at Columbia while working as a critical care pharmacist at UT Southwestern Medical Center in Dallas, where she serves on the Ethics Committee, the Moral Distress Team, and is a facilitator for the clinical Ethics in Medicine course at the UT Southwestern Medical School. She is a member of the Ethics Task Force for the American Society of Clinical Pharmacy and is the section leader for the Pharmacy and Ethics Affinity Group at the American Society of Bioethics and Humanities.

Daniel Arshack

Daniel N. Arshack focuses on the criminal defense and civil rights of individuals and businesses in state and federal courts in the United States and in various jurisdictions throughout the world. He graduated from Brandeis University and the University of Stockholm in 1978 and started his career as a systems analyst at Abt Associates, a social science think-tank in Cambridge, Massachusetts. He obtained his law degree from the Antioch School of Law in 1983 and thereafter practiced criminal and civil rights law in Washington, D.C. before moving to New York and becoming a public defender in Manhattan. He has a professional certificate in Medical Bio-Ethics from Columbia College of Physicians and Surgeons and Einstein Medical School. Mr. Arshack has successfully defended a wide range of cases, from securities fraud and international arms-dealing to homicide and professional malpractice. Mr. Arshack has represented thousands of clients in forty years of practice both as a Public Defender and in private practice. He has successfully fought for his clients in every level of court throughout New York, in other states, in the Supreme Court and in courts throughout the world. Mr. Arshack was US counsel in a case at the International Criminal Tribunal for the Former Yugoslavia at the Hague and appeared on behalf of a client, as Learned Counsel, in Kenya. He is regularly called upon to represent a variety of foreign diplomats and foreign missions in courts in the United States.

In 1991, Mr. Arshack was instrumental in starting the Manhattan School for Children, an award-winning public school in New York which both of his children attended. In 1996, Mr. Arshack, under contract to the City of New York, co-founded a new public defender's office in The Bronx known as The Bronx Defenders and thereafter supervised 25 lawyers and the necessary support staff to handle 13,000 cases/year. Mr. Arshack teaches trial advocacy skills regularly and throughout the world. Since 2015, Mr. Arshack has been consulting counsel to the National Advocates for Pregnant Women and in that capacity has provided direct defense services to women across the United States charged with crimes associated with being pregnant. For many years he has taught trial advocacy at Benjamin Cardozo School of Law.

Mr. Arshack served as President of the New York State Association of Criminal Defense Lawyers. He has served on the Board of Directors of the National Association of Criminal Defense Lawyers (NACDL) and was Co-Chairman of its International Committee. He was the elected representative to the Council of the International Criminal Bar and was a member of the Board of Directors of the International Criminal Defense Attorneys Association – USA. He was a founding member, served on the board and remains general counsel to the board of New York Sun Works which provides solar power powered greenhouses and teacher training to schools throughout the New York metropolitan area. Mr. Arshack also helped found and is Vice-President of the Center for Restorative Justice, an organization which provides restorative justice training and interventions.

He was also a founding member of the board of the Wheelhouse School in Catskill and is a board member of the Catskill Community Center. Since 2016, Mr. Arshack has been President of the Center for Community Alternatives which is New York's only statewide organization focusing on alternatives to incarceration for legal system involved adults and children, reintegrative

services and award-winning housing for formerly incarcerated people and state and national grassroots organizing and advocacy on criminal justice issues such as Clean Slate legislation, bail reform, ban the box and mandatory minimums.