

Regulation of the Medical Use of Psychedelics and Marijuana

A thesis presented

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## DEDICATION

To the late Dr. John Harter  
whose vision resulted in the creation of the  
Food and Drug Administration's Pilot Drug Evaluation Staff,  
a short-lived but remarkable laboratory for bureaucratic innovation.  
Its legacy includes the renewal of FDA-approved psychedelic research  
and an enduring institutional framework emphasizing science over ideology.

# The Regulation of the Medical Use of Psychedelics and Marijuana

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## ABSTRACT

Part 1 of this dissertation analyzes the historical development and current status of the regulation of medical research with psychedelic drugs and marijuana. The analysis is based on interviews with current and former government officials, review of published and unpublished documents, and on-going discussions with all known researchers who have filed applications within the previous fifteen years seeking permission to conduct any human studies with psychedelics, or studies with marijuana in patient populations. A special analysis is made of the creation in 1989 and dissolution in 1995 of FDA's Pilot Drug Evaluation Staff, an extraordinary bureaucratic experiment that, among its many other accomplishments, established FDA's current policy of evaluating psychedelic and marijuana protocols with the same standards FDA uses for the review of all other studies.

Part 2 analyzes regulatory, ethical and methodological issues involved in the design of the Phase III studies that FDA requires to evaluate the safety and efficacy of the medical uses of psychedelics and marijuana. The standard of proof that FDA uses to evaluate data about other drugs, comparison to placebo, is determined to be optimal for the review of data about psychedelics and marijuana. A two-arm protocol design comparing psychedelic psychotherapy against psychotherapy alone is concluded to be "adequate and well-controlled." Taking into account political considerations, a four-arm study is proposed comparing three groups receiving high, medium or sub-threshold (placebo) doses of psychedelic psychotherapy with an unblinded group receiving the best alternative treatment. The economic implications of this enhanced design are determined not to impose an excessive burden on research sponsors.

Part 3 is an exercise in policy design for the regulation of the hypothetical prescription use of psychedelic psychotherapy. The legal basis for FDA's authority to impose special restrictions is reviewed, as is the regulation of thalidomide, methadone, GHB, and electroconvulsive therapy. The proposed system restricts prescribing authority to specially-licensed and trained psychiatrists working within clinical settings meeting minimum standards. Distribution is directly to psychiatrists through the mail from one centralized production and distribution facility. A national registry of patients is proposed to track all treatment sessions.

## ACKNOWLEDGMENTS

Born Jewish in 1953, I grew up in the shadow of the Holocaust. In 1968, I worked inside the Chicago Democratic Convention as one of Mayor Richard Daley's many young messengers for the delegates, wearing a red, white and blue uniform while the riots took place downtown. In 1971, when I turned eighteen, I refused to register for the draft for the Vietnam War, an act of non-violent resistance for which I expected to be prosecuted.

In 1972, I conscientiously objected to President Nixon's War on Drugs and decided to embark upon a career as an underground psychedelic psychotherapist. I hoped that psychedelic psychotherapy would empower me, and by extension others, to address deep-seated fears, mitigate projection and scapegoating, and provide access to profound feelings of connection and unity. I believed that psychedelics used wisely would enable us as individuals and collectively as a society to develop a sense of core identity that transcended divisive distinctions based on national origin, religion, race, gender, class and political orientation. For inspiring me to forge these dreams, and to consider them within the bounds of possibility, I thank Dr. Stanislav Grof. His psychedelic research and theoretical work provided the superstructure around which I have built my professional life. As a teenager imagining my future, I considered it likely that I would one day be wearing prison blues; the possibility that I could eventually be wearing Harvard crimson and receiving a Ph.D. from the Kennedy School hadn't entered my mind. I owe a profound debt of gratitude to President Jimmy Carter, who pardoned all draft resisters on his first day in office and allowed me to consider the possibility of a socially-sanctioned career.

My thesis committee at New College, Charlene Callahan, David Smillie, Ed Barker and Gene Lewis, guided me skillfully into the world of academic research. They enabled me to study psychedelic psychotherapy, transpersonal psychology, and the regulation of drugs, and taught me that personal passions were strengthened by analytical rigor.

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Much gratitude is due to Ed Hughes. He helped free me from the tyranny of the empty page. He empowered me to find the courage to follow my ignorance to its roots, thereby finding the euphoria in asking ever deeper questions rather than settling for the smug satisfaction of arriving at an answer.

In moments of doubt, I drew much strength from knowing that I had a responsibility to live up to the bold statement of an unknown copy writer, whose advertisement for the National Organization for the Reform of Marijuana Laws, which I had framed and hung near my computer, states, “What they say is true, many people who smoke marijuana move on to harder things. Graduate School, for example.”

To all my partners in the psychedelic quest, those whom I’ve had the honor to work with in this lifetime and those who have walked this way before me, this dissertation is part of my effort to repay a small portion of what I have already gained. I hope to some extent to make the path a bit smoother for those who will inevitably follow.

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