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# The Heffter Research Institute: Past and Hopeful Future

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# The Heffter Research Institute: Past and Hopeful Future

David E. Nichols, Ph.D.[a]



**Abstract** — This essay describes the founding of the Heffter Research Institute in 1993 and its development up to the present. The Institute is the only scientific research organization dedicated to scientific research into the medical value of psychedelics, and it has particularly focused on the use of psilocybin. The first clinical treatment study was of the value of psilocybin in obsessive-compulsive disorder. Next was a UCLA study of psilocybin to treat end-of-life distress in end-stage cancer patients. While that study was ongoing, a trial was started at Johns Hopkins University (JHU) to study the efficacy of psilocybin in treating anxiety and depression resulting from a cancer diagnosis. Following the successful completion of the UCLA project, a larger study was started at New York University, which is near completion. A pilot study of the value of psilocybin in treating alcoholism at the University of New Mexico also is nearing completion, with a larger two-site study being planned. Other studies underway involve the use of psilocybin in a smoking cessation program and a study of the effects of psilocybin in long-term meditators, both at JHU. The institute is now planning for a Phase 3 clinical trial of psilocybin to treat distress in end-stage cancer patients.

**Keywords** — alcoholism, cancer, Heffter Research Institute, meditation, OCD, psilocybin, psychedelics, research, smoking

The year 2013 marks the twentieth anniversary of the founding of the Heffter Research Institute (http://www.heffter.org). This essay is an attempt to give an overview of the Institute, how and why it came into being, what we have done, and what we are doing now.

First, however, I should set the stage by giving a very brief background on what led to the founding of the Institute. The author entered graduate school in the fall of 1969, with a Ph.D. thesis project to study the structure-activity relationships of what were then called "psychotomimetics," also known as hallucinogens or psychedelics. By the time my Ph.D. was completed in early 1973, however, the Controlled Substances Act of 1970 had been passed, and research on these fascinating substances had virtually ceased. A planned career studying psychedelics therefore seemed very remote at that point in time.

Fortunately, I obtained an academic appointment as an Assistant Professor at Purdue University, which allowed me the freedom to continue to work on psychedelics. After a few years, I was able to secure funding for my project from the National Institute on Drug Abuse (NIDA). Although at that time I was doing mostly synthetic organic chemistry, it concerned me that no one had continued any clinical research on psychedelics. I knew that only clinical research had the capacity really to understand the effects of psychedelics on human consciousness.

As I attended regular scientific meetings and conferences, I met numerous colleagues who had been interested in the study of psychedelics, but who realized that research in this field was controversial, at best, with only a remote chance of research funding, so they directed their efforts

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toward more mainstream (and fundable) research topics. When discussing the absence of clinical research, my colleagues would argue that it simply was no longer possible to do studies in humans. I would disagree, and reply that I believed it was possible, but the challenge would be to secure funding. That is, I believed if you had the credentials and an institutional affiliation you could get the approvals, but you would not get federal funds to support your research. Without funding, scientific research is impossible, and no academic clinician would survive without a funded research program. Rather, I proposed, one needed private money, and in the beginning I suggested that perhaps an endowment of around $1 million might suffice to start some kind of research institute. As years went by, and I told and retold this same story many times, the figure I thought might be needed eventually reached the $10 million mark.

In the fall of 1984, I was invited to a meeting at the Esalen Institute in Big Sur, California. The attendees at the meeting were people who had either been involved with research on psychedelics in earlier years, had done recent work on psychedelics, or else had some compelling interest in the field. The theme of the meeting largely revolved around the potential value and benefits of MDMA, a drug that was still "legal," and had been quietly used as an adjunct to psychotherapy, but was then becoming extremely popular as a recreational drug. It was apparent that MDMA was likely to provoke a negative response from the Drug Enforcement Administration, and there was general discussion as to how MDMA might remain legal for medical use.

As a scientist from a Midwestern university, I had not had many encounters with others in the field, particularly those on the West Coast, and it was a good chance to meet with people such as Stan Grof, George Greer, Oscar Janiger, Dennis McKenna, Ralph Metzner, Claudio Naranjo, Sasha Shulgin, Leo Zeff, and many others. Although I knew some of them by reputation, I had not had personal contact with most of the attendees at the meeting, many of whom were psychiatrists with some past experience administering psychedelics. The thing that most impressed me was the sincerely held belief by virtually everyone that psychedelics, as well as MDMA, held great promise as medicines for healing. Stories of patients who had been helped, told by many of the psychiatrists there, were impressive and compelling, even if by scientific standards they were only "anecdotal" or case reports.

Everyone at the conference, however, seemed very pessimistic as to the possibility of doing clinical studies with psychedelics. As an example, Oscar Janiger gave a presentation one evening where he showed his famous and dramatic slides of Hopi Kachina doll paintings by artists before and after taking LSD. In an open Q&A session after his talk, I asked him, "You were qualified to continue clinical studies. Why did you stop?" His reply was, paraphrasing, "Young man, you just don't understand how badly we were burned." I didn't understand, and perhaps I was simply naïve, but it frustrated me that the very people who seemed qualified to do clinical studies appeared to have just abandoned ship.

I attended a second conference at Esalen in late spring of 1985 that had a similar theme and many of the same attendees. One person I met at this conference was Dr. Rick Strassman. I knew of Rick from a 1984 paper he had written showing that, under controlled conditions, the incidence of adverse reactions caused by psychedelics was very low (Strassman 1984). I had not met him before, but we struck up a conversation that continued throughout the meeting and long afterwards. We both bemoaned the absence of clinical studies, and I suggested to Rick that he could probably do one if he wished. He was an M.D. with good credentials in an academic psychiatry department, and I suspect he had already been toying with the idea himself. We kept up our dialogue after the conference was over, which included strategy meetings with Dr. Daniel X. Freedman, one of the early pioneers of human LSD research, who was then the Acting Head of Psychiatry at UCLA. I will have more to say on that later.

At this point, I need to go off on a brief tangent, the reason for which will become apparent shortly. One person at the first Esalen meeting I had not heard of was Rick Doblin. He was still an undergraduate at New College of Florida and was intensely focused on how MDMA could be made into a prescription drug. He had reactivated a not-for-profit organization named Earth Metabolic Design Laboratories. As a chemist with interest in the field who had published a 1982 scientific paper on the first in-vitro pharmacology of MDMA (Nichols et al. 1982), Rick and I had discussions about his goal, and kept in touch after the meeting. As his plans developed, he reached a point where he needed very pure MDMA for preclinical toxicology studies in order to support an investigational new drug (IND) application to the FDA, a requirement for any future clinical research. After obtaining quotes for this material from commercial synthesis laboratories, he realized that the cost was simply prohibitive for him. He asked whether I could make it in my laboratory. I had never worked with the FDA before, but after discussions with an FDA chemist, the task didn't seem all that difficult. We essentially just had to prove that our material was extremely pure, free of any significant contaminants, and the preparation had to be done in a clean laboratory where they had confidence that it was done right. The result was that we made about two kilograms of high-purity MDMA hydrochloride at the very low cost of $4,000! As it turned out, the toxicology tests would require less than 250 grams, so we had made much more than was needed. That proved to be fortunate because, over the next two decades, I donated samples of that same MDMA to most of the U.S. clinical investigators who carried out human studies with

MDMA, including the first FDA-approved clinical study of MDMA sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS), a non-profit founded by Rick Doblin. In addition, as a fortuitous consequence, we established that crystalline MDMA hydrochloride, when stored at ambient temperature in the dark, was stable with absolutely no decomposition over a period of more than 25 years!

The story now returns to my dialogues with Rick Strassman. After considerable effort, which Rick has documented (Strassman 1991), he was able to obtain all the approvals necessary to administer intravenous DMT to human subjects. At an earlier point during our discussions, Rick had asked me, "Dave, what if I get all the approvals but then I can't find any clinically acceptable DMT?" Having already made pure MDMA for Rick Doblin, I was confident that I also could prepare DMT. Not surprisingly, it turned out that no commercial firm was willing to make DMT that could be administered to humans, so after determining that my DEA license would allow it, my laboratory prepared it. Rick was thus the first psychiatrist in a generation to carry out clinical research with a psychedelic in the U.S., proving the thesis that clinical studies were still possible (Strassman and Qualls 1994; Strassman et al. 1994).

It should be noted that Rick's study also was possible because of some personnel changes at the FDA. Curtis Wright, an M.D, had recently arrived at the FDA in the division that had to approve Rick's study. Curtis had been able to convince others at FDA that there was no reason that a study with psychedelics couldn't be approved if it was done properly, with all the necessary committee reviews and approvals. Rick's tenacity, of course, was the other piece of the picture necessary for success, with his personal dedication to getting the study done.

Another helpful event occurred in 1992 when the National Institute on Drug Abuse (NIDA) organized a meeting of preclinical researchers that I attended to decide whether to recommend resumption of clinical research with psychedelics. The FDA organized an Advisory Committee meeting the next day to discuss the resumption of psychedelic research in general, but also to consider whether to permit an MDMA/cancer anxiety study that was to be sponsored by MAPS, with Dr. Charles Grob as the Principal Investigator. These meetings resulted in recommendations by both NIDA and the FDA Advisory Committee that clinical research could be resumed, subject to the same regulations that the FDA used to review research with all other drugs.

It was about this time that I was at a scientific meeting, telling the story again about how clinical research with psychedelics could be done, but that one would need private funding to support it, probably with an endowment by then that I estimated would have to be at least $10 million. I distinctly remember going home afterwards and thinking to myself, "You will be telling this same story when you are old and retired, sitting in a rocking chair, and there will still be no one doing it." I decided then that I needed to do something.

It had been impossible for me to do clinical research because I did not have an M.D. degree. But I had met many physicians who, I believed, might be interested in joining some kind of enterprise to carry on legitimate research with psychedelics. Some of the people I had met at the Esalen meetings immediately came to mind. I contacted Drs. Rick Strassman, Charlie Grob, and Phil Wolfson, all psychiatrists, as well as professional colleagues Drs. Dennis McKenna and Mark Geyer. In addition, I got in touch with Jerry Patchen, a Houston attorney I knew who had done pro-bono work for the Native American church. They were all enthusiastic about participating in some kind of research institute to study psychedelics.

We decided to incorporate as an IRS 501(c)3 not-for-profit organization in New Mexico because the regulations there were less onerous than in Indiana, where I lived. Just as we were getting started, however, Rick Strassman decided that the goals of the Institute did not mesh with his, and withdrew his participation. I had met George Greer at the 1984 Esalen meeting, and he also seemed an ideal person to be involved. In addition, he was a psychiatrist who lived in New Mexico and could serve as the point person for the legal details of our incorporation. Fortunately, George also was very enthusiastic about the idea of the Institute. Thus, we were incorporated in New Mexico in August 1993, and had a first board meeting near Los Angeles, at a Zen retreat on Mount Baldy. We had officially begun.

As for selection of the name of the Institute, I had long been aware that the naturally-occurring psychedelic first to be isolated and chemically identified was mescaline, a feat that had been accomplished in the late 1890s by a German scientist, Dr. Arthur Heffter. He had ingested different purified alkaloids that he had isolated from peyote until he discovered the single psychoactive molecule, which he named mescaline. I won't list his biographical details here, as those are detailed on our web site and are well worth reading. I should say, however, that Dr. Heffter is very much underappreciated today. He had Ph.D. degrees in both chemistry and pharmacology, as well as an M.D. degree, and his outstanding scientific work and many accomplishments seemed to serve as a good example for the Institute.

As a group of scientists and clinicians with no experience in business, we began to try to envision how we might move forward. Our paradigm was to encourage and support scientific research of the highest quality, done at top institutions, and to have a peer-review process for vetting studies that we wished to support. We reasoned that early work in this field had not been taken seriously and had not produced definitive results because much of that research had been done in a relatively haphazard manner by investigators

who were often not qualified, or who did not understand how a controlled clinical study had to be done. A notable exception to that generalization was the work done at the Spring Grove State Hospital in Maryland (e.g., Grof et al. 1973; Pahnke et al. 1970), to which I will refer later on. Further, with psychedelics, the immediate effects on subjects often were so profound that the investigators typically sensed little need to do the kind of systematic study that would be accepted by the mainstream. Published "studies" quite often were nothing more than case reports, or collections of anecdotal accounts. Of course, the state of the art in clinical research methods also had advanced significantly since the 1950s and 1960s.

The first serious obstacle we encountered was a very basic one: where would we get the funds to support the Institute? I am not aware of any other research institutes, virtual or otherwise, that started out with absolutely no financial foundation. More typically, a very wealthy donor will decide that s/he wants to start an institute to study some specific illness such as cancer or heart disease. The donor will then contact a high-profile scientist or administrator at a good university or medical institution to set up the details, and then make a donation to get the institute started. Such endowments typically run from tens to hundreds of millions of dollars. An endowment of that size essentially jump-starts the institute, gives it instant credibility, and allows the hiring of top researchers and usually supports building a facility to house the Institute.

Unfortunately, we were not in that situation. Also, we all had regular jobs, so no one could devote full-time work to the Institute. Our earliest funds came from the board members themselves, as well as a very few small donors. Initially, we had envisioned that some of the Silicon Valley entrepreneurs would be enthusiastic to support us, as there seemed to be a general consensus that many in the tech industry had benefitted from experience with psychedelics such as LSD. Unfortunately, that did not prove to be the case. We gained no traction at all using that approach, with one notable exception: Bob Wallace. Bob had been the ninth employee of Microsoft Corporation and had a good chunk of Microsoft stock that had appreciated significantly. Even more important, however, was Bob's passion for brain science. He always carried a pack of note cards in his shirt pocket, and picked the brains of all of the board members at our meetings. He was perhaps less interested in finding treatments for illnesses than he was in just supporting good research of any kind relating to neuroscience, especially if it involved psychedelics. Bob joined as the first board member after the founding members. He was our principal supporter for many years until his death in 2002, and we remember him fondly.

At about the same time as Heffter was getting underway, Rick Doblin also was in his early efforts to develop MAPS as a viable organization. He had a donor who supported his early newsletters, but he wanted to find ways to raise money to allow MAPS to move toward his mission of making MDMA into a prescription drug. He and I had many useful exchanges as to the best way to support our respective organizations, and initially Rick believed that, as a membership organization, MAPS would be able to raise the necessary funds from subscriptions. I disagreed, with my belief being that you could only raise enough money for drug research and development from high-net-worth individuals. It wasn't long before Rick realized that he could never make MAPS the kind of organization that he had envisioned only through subscriptions, and he too adopted the approach of seeking wealthy donors to support his efforts.

Bob Wallace's largesse did allow us to do a few important things in our early years, mostly in attempts to gain some name recognition with the public, but especially in the scientific community. We were able to attract numerous highly respected scientists to serve on our Scientific Advisory Board. We gave several awards to academic scientists who had done outstanding work in the field of psychedelic research, and supported several graduate students with stipends who were working in the field. We have continued to give fellowships and awards from time to time as, for example, our recent "Lifetime Achievement Award" to Dr. Stan Grof in 2011. Even with Bob Wallace's dedicated support, however, we did not have sufficient funds actually to carry out a significant clinical study.

One of the early decisions we made was to provide support for Dr. Franz Vollenweider at the Psychiatric University Hospital in Zürich, Switzerland. Franz was a very promising young psychiatrist who had set the goal of understanding the effects of psychedelics on the brain. He was introduced to us by board member Dr. Mark Geyer, who had been very impressed with Franz and his accomplishments. Franz was using state-of-the-art techniques and ran a very productive laboratory where he was training top neuroscientists. We had discovered, however, that donors were not particularly inclined to fund basic clinical research, so Bob Wallace's interest in brain research proved invaluable to our support of Franz's laboratory. As time went on, and his laboratory developed further, he was able to leverage Heffter support to create a Heffter Research Center in his hospital—actual physical facilities with some staff support. The HRI Center Zürich has grown over the years and is the central place where we continue to support basic brain research focused on the actions of psychedelics and other psychoactive drugs. Franz became the second board member added after Bob Wallace and the founding members. It would take an entire essay to detail all of the breakthrough studies that have come out of Franz's laboratory, so I recommend you consult the Heffter web site and see the publications of his that are listed there (http://heffter.org/research-all.htm). Suffice it to say, however,

that today Franz is probably the world's top researcher in the area of basic clinical neuroscience studies of psychedelics.

Bob Wallace's unexpected death in 2002 dealt us a severe blow. With his support gone, we faced an uncertain future less than a decade after our start. Fortunately, shortly afterwards, new donors unexpectedly appeared who largely replaced the support that Bob had provided, and who also were enthusiastic about helping to grow Heffter. With their support, and a growing list of smaller donors, we were able to fund for the first time a number of clinical studies using psychedelics. Our first U.S. clinical study, funded largely by Heffter with an assist from MAPS, who paid for the psilocybin, was Dr. Francisco Moreno's investigation of the value of psilocybin in treating patients with obsessive-compulsive disorder (OCD) at the University of Arizona (Moreno & Delgado 1997). The results were promising, but not definitive, & a follow-up application by Dr. Moreno to the NIH for a larger study was not funded.

As our donor base grew slowly larger, we began to consider what kind of research we might support that would have a high probability of leading to positive results, and where the benefit-to-risk ratio was high. Considering all of the indications where psychedelics had been used in the past, the one that seemed to stand out, where efficacy was most well-documented with a sufficient number of patients, was the treatment of dying cancer patients with LSD at the Spring Grove State Hospital in Maryland (Grof et al. 1973; Pahnke et al. 1970). That work had been inspired by earlier observations by Dr. Eric Kast (Kast 1966; Kast & Collins 1964) that LSD, when given to dying patients, gave relief, and in some gave a new perspective toward their impending death. This treatment appeared very promising, as the approach to death can be extremely distressing and as a society we deal very poorly with dying. We reasoned that if we could improve quality at the end of life, the FDA might respond favorably to such an indication. Further, the extreme anxiety and depression that often accompanies dying were endpoint symptoms that could be quantified fairly easily in a clinical trial, and the benefit-to-risk assessment was obvious.

The next question we addressed was which psychedelic we should use. We debated this topic extensively at several board meetings. Although LSD had been used successfully in the earlier Spring Grove studies, we believed that the "social baggage" carried by LSD was still too great and we feared a media feeding frenzy if we announced a study with LSD. With the level of misinformation that had been propagated in earlier years, it seemed we might invite a public relations disaster that could derail all of our efforts. As in those earlier studies, there also might be patients who would decline to receive an LSD treatment based on the media scare tactics still resonating from the 1960s. As a final point, the duration of action of LSD was fairly long, and might require an overnight stay in the clinic, adding to the cost of a study.

Another psychedelic that was known to have effects similar to LSD was mescaline. It is recognized, however, that mescaline can cause nausea and even vomiting in some users. The nausea and potential sickness that might occur with mescaline ruled out its use in terminal patients. In addition, it also has a very long duration of action that would perhaps exhaust a fragile dying patient and would tax the clinical team.

Dr. Charles Grob would be the principal investigator on the study, and he had originally planned to use MDMA, an entactogen, to treat terminal patients in a study to be sponsored by MAPS. MDMA was a more benign substance, and had a shorter duration of action than LSD or mescaline, but it activates the sympathetic nervous system, producing cardiovascular effects in ways that are similar to methamphetamine. He raised the concern that terminal cancer patients were often weakened, had lowered physical stamina and generally compromised health, and might be too fragile to tolerate the stress of an MDMA treatment. We had a discussion of the pros and cons of the various substances, and Dr. Grob ultimately decided to use psilocybin for his study. It carried none of the social baggage of LSD, it was short-acting, did not cause nausea, and had no effect on the cardiovascular system. Further, if you asked the average person on the street what psilocybin was, most did not know. Many had heard of "magic mushrooms" or "shrooms," but were not aware that psilocybin was the active component in these mushrooms. Psilocybin mushrooms had been used for millennia, and had been widely used in current times, so safety issues seemed moot.

After we decided to use psilocybin, the next question was: will it be efficacious? Even though both psilocybin and LSD are classic hallucinogens thought to work by a similar pharmacological mechanism, psilocybin is not LSD. LSD has a more complex psychopharmacology and, in particular, there is evidence that later in the course of its action its pharmacology may differ from its initial effects and from the effects of other classic hallucinogens (Marona-Lewicka et al. 2005).

Nevertheless, the decision was to move forward with psilocybin in our first significant clinical trial. The Principal Investigator was Dr. Grob, and the research was conducted at the Harbor-UCLA Medical Center. Although the study involved only a small number of patients, the results were very promising and were published in the top psychiatry journal in the field (Grob et al. 2011).

In 2008, Dr. Roland Griffiths also had initiated a study of psilocybin in cancer patients at Johns Hopkins University. Those patients did not require a terminal diagnosis for inclusion in the study, only symptoms of anxiety and depression related to a cancer diagnosis. The encouraging results from the Grob study allowed us to move toward

a larger study at New York University (NYU) under the direction of Dr. Stephen Ross. The Hopkins team, which had by then developed significant expertise, was able to train the NYU team, which helped their study get off to a smooth start.

Fortuitously, in my earlier collaboration with Rick Strassman, my lab had worked on improving the synthesis of psilocybin. In his original synthesis of psilocybin, Dr. Albert Hofmann had used a dangerous reagent to install the phosphate group onto psilocybin (Hofmann et al. 1958). The reagent was chemically unstable and was only available as a diluted solution that had to be stored at a very low temperature. It seemed unwise to employ a synthesis with such a troublesome reagent. There was an alternate reagent (TBPP) that had been mentioned in a 1963 patent also describing the synthesis of psilocybin (Hofmann & Troxler 1963). It was a much safer, white crystalline material so we adapted the synthesis using that. Thus, psilocybin became more accessible, albeit somewhat expensive, and has been the medicine of choice in all of our subsequent clinical studies.

More recently, we have funded a study of the value of psilocybin in treating alcoholism, carried out under the direction of Dr. Michael Bogenschutz at the University of New Mexico, Albuquerque (UNM). Alcohol addiction is extremely destructive and can destroy lives and families, so an improved treatment for alcoholism would have tremendous societal impact. As the study was in preparation, a meta-analysis appeared in print (Krebs & Johansen 2012), indicating that LSD indeed did have significant efficacy in studies with LSD in alcoholism that were done in the 1950s and 1960s. We were delighted by that very timely report, and it gave us confidence that we might obtain positive results from the UNM study. Although it is a small pilot study involving only 10 patients, all of them have now received the psilocybin treatment. The study is still in the follow-up phase, but the results thus far indicate excellent outcomes with the psilocybin-based therapy. Consequently, the Heffter board has just recently approved a larger two-site study to follow up on these initial, very encouraging findings.

We are also supporting other research related to addiction. In a small pilot study, Dr. Matt Johnson at Johns Hopkins University has been examining the effect of psilocybin in helping long-time smokers quit smoking. His results so far have been quite dramatic, and have been characterized by a senior scientist at NIDA as truly amazing. As is well known, nicotine is the most addictive drug known, and finding an effective way to help smokers quit smoking will have a profound impact on human health.

Finally, we are supporting a study by Dr. Griffiths characterizing the acute and persisting effects of psilocybin in long-term meditators who are expert observers of the mind. The interrelationship between detailed phenomenological descriptions of the psilocybin state and neuroimaging (fMRI) measures will help us to understand more deeply the interface between subjective consciousness and brain function.

Although we are providing full support for these other studies, our main focus is to move psilocybin treatment forward toward FDA approval for end-of-life distress. We have a formal pharmacokinetics study planned for 2014 to support our FDA application, and believe that the studies of psilocybin in psychologically distressed cancer patients at NYU and Johns Hopkins also will be complete in 2014. When added to the patients treated in the UCLA study by Dr. Grob, we believe we may have a sufficient number of subjects to close out the Phase 2 studies. We then plan to meet with the FDA to discuss the design of a larger, multi-site Phase 3 clinical trial of psilocybin in psychologically distressed cancer patients. The FDA only allows you to apply for a single indication, so the studies of alcohol and nicotine addiction cannot be considered in that application. The Phase 3 study will cost millions of dollars and will involve treating hundreds of patients using the same protocol at each of the different clinical sites.

Peering into the future is always risky, but let me try. After we complete the Phase 3 study of psilocybin in cancer patients, if we show the kind of efficacy we have observed so far in our Phase 2 studies, then the FDA can approve psilocybin for end-of-life distress. Because psilocybin is a Schedule I controlled substance, it will have to be reclassified into Schedule II so it can be widely used in treatment programs. How is that accomplished? There are three legal "prongs" that must all be met for a substance to be placed into Schedule I. In essence, the substance must have a high potential for abuse, must not have a recognized medical use, and must not be safe for use under medical supervision. We are already well on the way to demonstrating that psilocybin is safe when used under medical supervision, but the real key is to demonstrate a medical use. If that can be shown, there is no basis for keeping psilocybin in Schedule I, and we anticipate that it will have to be rescheduled.

We do not expect that, after psilocybin is moved into Schedule II, psychiatrists will be able to prescribe it as they wish. Rather, its use will most likely be restricted to physicians who have the specialized training necessary to employ it properly. There will be a training program for psychiatrists and other psychotherapists, and Dr. Jeffrey Guss at NYU has already created a training course and trained a number of therapists. The important thing to know is that psilocybin will no longer be an experimental substance available only for research, but will be a psychedelic medicine finally recognized to have a legitimate medical value. We all look forward to that day.

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