Psychedelic Research and the American Psychiatric Association (APA): A Panel Discussion at APA's 1993 Annual Meeting

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(Note: Richard Karel adapted this story for MAPS from an article he wrote for the the APA's June 18,1993 Psychiatric News)

IN THE FIRST SESSION ON HALLUCINOGENIC DRUGS at an American Psychiatric Association meeting in many years, psychiatrists Rick Strassman, M.D. and Charles Grob, M.D. addressed a standing room only audience in San Francisco this May about their efforts to systematically establish the safety and efficacy of hallucinogens including DMT, MDMA, and psilocybin in humans.

Although several audience members raised questions regarding spirituality and the possible limitations of traditional scientific methodology in evaluating the multifaceted potential of these drugs, both researchers steered the session back to the subject of building up a rigorous data base so that hallucinogenic drugs might some day find a niche in the legitimate pharmacopoeia.

Researchers are on shaky ground when they suggest that spirituality may be subjected to rigorous scientific evaluation, said Strassman. But he noted that individuals will continue to use these drugs on their own regardless of what researchers or governmental authorities may think of it.

Strassman, an associate professor of psychiatry at the University of New Mexico in Albuquerque, has been conducting Phase I human trials with dimethyltryptamine (DMT) since 1990. This March he received a $500,000 grant from the National Institute on Drug Abuse (NIDA) to continue Phase I trials with DMT and psilocybin, a mushroom derivative, for another three years. He has administered DMT to about 30 subjects to date, and anticipates administering the drug to another 20 subjects over the next three years.

Phase I studies are set up to evaluate safety and basic physiological response to investigational drugs. In general, the Food and Drug Administration (FDA) requires successful Phase I trials before trials involving clinical applications may be undertaken.

Researchers interested in hallucinogens received an additional boost last year when the FDA approved a Phase I study by Grob with

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methylenedioxymethamphetamine (MDMA). Grob is director of the Division of Child and Adolescent Psychiatry at the University of California's Harbor Medical Center in Torrance. His study will involve six subjects.

"These are a fascinating class of drugs which have been understudied, or not studied at all in humans over the last 25 years," Grob commented. "The big question is, after 25 years of research quiescence, are we at a point now where we can responsibly investigate the very interesting and perhaps unique properties of these classes of drugs?"

Research on the hallucinogens lysergic acid diethylamide (LSD) and (DPT) in the late 1960s and early 1970s suggested these drugs had great potential for "alleviating depression and demoralization in cancer patients as well as, surprisingly, seeming to have a positive effect on raising threshold for pain perception," said Grob. "We felt this would be a very good group to work with, because in many respects this is a group encumbered with great suffering both psychological and physical, and as health practitioners we are often quite limited in what we can do to help alleviate the plight of these people."

Grob favors MDMA as a potential therapeutic agent because, unlike some hallucinogens, MDMA does not cause dissolution of ego boundaries, is relatively short-acting, and does not cause perceptual disturbances, he said.

Discussing the history of MDMA, Grob noted that although synthesized in 1912, it was not until the mid-1970s, following a paper suggesting its therapeutic potential, that MDMA attracted substantial interest. It was employed by a large number of therapists in the 1980s, particularly on the West Coast, with reports indicating that it might have utility as an adjunct to psychotherapy, Grob said. The therapeutic use, while not illegal, was never officially sanctioned.

But by the mid-1980s, said Grob, "it had also become identified as a drug of abuse. Kids, particularly college-age kids, had discovered the drug, and a great deal of media attention was given to its use." In 1985, the U.S. Drug Enforcement Administration (DEA) placed MDMA into Schedule I, the most restrictive legal category for drugs seen as having no safe medical use and high abuse potential.

When Grob approached the FDA last July with a protocol for experimental clinical use of MDMA in end-stage cancer patients, they rejected his protocol as premature, but told him they would look favorably on a redesigned, Phase I study.

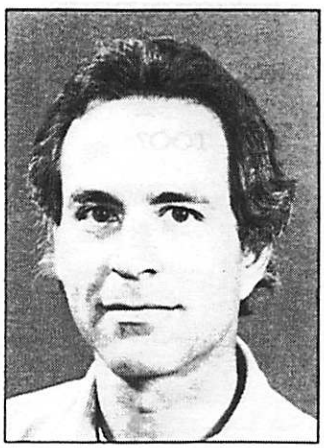
The FDA concluded that MDMA was no more dangerous than "many other drugs that were utilized in clinical research, or were even dispensed clinically in practice and the marketplace" and that MDMA "should not be treated any differently than any other drug," said Grob.

In addition to possible application in alleviating pain and depression in end-stage cancer patients, Grob is interested in the therapeutic potential of MDMA in various refractory patient populations, including those suffering from "severe refractory alcohol and substance abuse and severe post traumatic stress disorder (PTSD) that's been refractory to conventional treatment."

Descriptive case material from the 1950s and 1960s, although methodologically lacking, suggested that hallucinogens might be valuable in such refractory populations, according to Grob.

While no officially sanctioned clinical use of hallucinogens has occurred in the U.S. in decades, such use has occurred in Switzerland. Beginning in 1988, a group of about 30 Swiss psychiatrists interested in clinical applications of hallucinogens began legally sanctioned use of LSD, MDMA, DMT and other hallucinogens for various psychiatric conditions, according to Rick Doblin, President of the North Carolina-based Multidisciplinary Association for Psychedelic Studies (MAPS). Doblin, a Harvard doctoral candidate, has been implemental in facilitating approval of the Grob research protocols.

Charles Grob, M.D.



Rick Strassman, M.D.

During a two-year period, the Swiss psychiatrists treated several hundred patients with conditions including PTSD, anorexia, depression, phobias, obsessive compulsive disorder (OCD), and psychological problems of terminal illness with no adverse incidents and generally favorable outcomes, according to Doblin. Research was temporarily stopped by the Swiss government after a patient given another hallucinogenic drug, ibogaine, died during a therapeutic session headed by a Swiss psychiatrist in France. Whether the drug was causally linked to the patient's death was never established.

Research was resumed in June 1991, when four Swiss psychiatrists received permission to work with 100 patients using various hallucinogens. At present, Switzerland is the only country where hallucinogens may be routinely employed for clinical treatment, according to Doblin.

Although supportive of the Swiss, both Grob and Strassman noted that the clinicians have failed to apply strict methodologies in evaluating the efficacy of their hallucinogenic drug therapy. This is reminiscent of what occurred several decades ago in the U.S., they noted.

The problem with early work with hallucinogens in the U.S. was "a lot of extravagant claims," said Grob. "You had a lot of what were, by and large, unsubstantiated claims. I think if we're going to go back and work with this very, very unique and intriguing class of pharmacological agents we really have to proceed cautiously and not make any claims or pronouncements that haven't been very clearly documented with careful methodological studies."

As a child and adolescent psychiatrist, Grob is concerned that young people not use hallucinogens recklessly.

Grob contrasted how contemporary Euro-American youth tend to abuse drugs while youth in aboriginal cultures traditionally employ psychoactive plants in a healthy and socially cohesive manner, often as a rite of initiation. In those societies, the process is

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socially sanctioned, geared towards social cohesion, and facilitated by the elders, according to Grob.

"I think in our culture, what we have is often a system of rampant chaos where the kids are just blundering in the dark, and as a result often getting themselves into a great deal of trouble," Grob commented.

During an audience discussion period following their presentation Strassman and Grob were asked about their views on whether hallucinogens should be viewed as something widely beneficial, as was the view of former Harvard psychologist Timothy Leary in the '60s, or whether they should be reserved for an elite illuminati or cognoscente, as was the view of the late author Aldous Huxley.

"I think people will do whatever they want to, really," Strassman commented. "That's sort of a *fait accompli*, I think. The question is, are (hallucinogens) just going to stay completely underground or... going to be studied within the context of current methodologies in psychiatry too?" Because the work will continue going on in the field, as it were. So I guess that's not that important of a question for the kind of work that I'm doing. (My work) is above board and sanctioned. And I do screen people carefully as opposed to taking all comers, so I suppose if I would fall in one camp or the other it would be for a group of small, carefully screened group of volunteers."

Responding to the same question, Grob excoriated Leary for having made rash and irresponsible statements regarding hallucinogens. "I think that looking back to the early '60s when Leary was making his pronouncements I think a lot of damage was done by very rash statements that really colored the whole area of psychedelic research in a very negative way. And I think what we saw in our society was that although we would hear reports of people who had profoundly positive experiences, life changing experiences, we heard even more reports of people who got into a great deal of trouble. I'm particularly concerned when it comes to the whole issue of kids taking these drugs in an uncontrolled way. You know I'm a child and adolescent psychiatrist, that's one of the things I do, and I work with a lot of adolescents who take drugs. And I have a lot of concerns about the uncontrolled conditions with which they are doing their own experimentation. They're often very, very poorly prepared."

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In response to questions about the potential of hallucinogenic drugs to precipitate psychosis, both Grob and Strassman said that unless an individual is highly vulnerable, it is extremely unlikely, and that the risk could be eliminated through careful screening.

By taking hallucinogens into the laboratory, Grob and Strassman are imposing a highly artificial set and setting, which might invalidate the responses they see, one psychiatrist commented. But Strassman said that despite the clinical setting, his experimental subjects have "typical psychedelic experiences" ranging from beatitude and bliss to terror. "People seem to have the full gamut of effects, and most of them are positive," said Strassman. If the experimenter does not approach the situation as if he or she anticipates psychotic reactions, but is, instead, supportive, the laboratory setting will not generate adverse or atypical responses, he contended.

Strassman said he encourages people to relax and "go with whatever they are experiencing." The setting provides a sense of safety and security, Strassman said.

He has developed a 100-question hallucinogen rating scale to aid future researchers in evaluating hallucinogenic drug response. The scale breaks the experience into six specific categories—perceptual, cognitive, somatic, affective, volitional, and global intensity.

Strassman has two papers in press (The Archives of General Psychiatry) dealing with the biological and subjective effects of DMT, with the latter based on the hallucinogen rating scale. They are expected out later this year.

Alluding to the controversial history of hallucinogens in the United States, Strassman stressed the importance of avoiding unsubstantiated clinical claims without prior, carefully collected clinical data.

"Clinical Phase II treatment studies must stay within the bounds of observable data derived from systematic Phase I inquiries," said Strassman. "In the past, research in this field sometimes put the cart before the horse."

Strassman said that he hopes that his research will stimulate other researchers to study hallucinogens. Since his initial research has gone well, said Strassman, future approval and funding of human research with hallucinogens should be less problematic.

He anticipates completing his current Phase I studies by early 1996. •••