



Heffter Research Institute

Research
At the Frontiers
Of the Mind

November 2006



Hello Good Friends!

Here is the first of the Heffter updates that I promised to send out. I hope the year has been treating you well, and that you are all healthy and doing well in your lives. Our receptions don't come quickly enough and I look forward to seeing all of you again in the spring. We are now in the early stages of planning our reception in San Francisco next year.

I start with some sad news. Pam Sakuda, the woman who came to our receptions to talk about how psilocybin had helped her grapple with her dying (she was patient #3 in Charlie's study), died unexpectedly on Friday, November 10. We had just seen her at a small Heffter reception in LA a week earlier and she seemed in good spirits, but she took a turn for the worse the following Wednesday, and passed away from us that Friday. The cancer had metastasized throughout her body and she knew her time was short, but it was faster than anyone expected. Those of you who saw her video interview, or heard her speak in person, were privileged to hear her story and to see her courage. She became an ally in our struggle, and we'll miss her.

New Opportunities!

We have two new funding opportunities to tell you about. First of all, Dr. Stephen Ross, at New York University, is developing a protocol to parallel Charlie Grob's UCLA study, which would involve treating 20 cancer patients with psilocybin. He has been very excited by Charlie's initial impressions (see Progress Reports), and wants to extend Charlie's study with higher doses, using Charlie's FDA approval. Dr. Ross appears to have the infrastructure in place, as well as ties to oncologists, and we have every reason to believe that this study will be an important companion to the UCLA study. The cost of this project is estimated to be \$80,000 per year for two years, or about \$160,000 total costs.

A second opportunity that has us very excited is a proposed study of cancer patients at Johns Hopkins University. As many of you know, Dr. Roland Griffiths, an internationally-known researcher at Johns Hopkins University, recently published a study showing that when psilocybin is given to normal subjects under appropriate circumstances, a high percentage of

them experience mystical states, with accompanying positive changes in their lives. Dr. Griffiths has now submitted a proposal to us to study 44 cancer patients. Importantly, this study would include early stage patients, whereas the UCLA and potential NYU studies involve only late stage cancer patients. This important difference means that psilocybin could potentially be applied to the treatment of anxiety and depression in non-terminal cancer patients, and eventually could be expanded to patient populations battling other types of non-terminal illnesses in which effective management of depression and anxiety can contribute to ultimate recovery. *This study is a tremendous opportunity for the Heffter Institute and our friends.* The cost of this study will be \$125,000 per year for two years, or about \$250,000 total costs. If we can fund this project, as well as the one by Dr. Ross, assuming we obtain positive results like the ones that Charlie is seeing in the UCLA study, and that Dr. Griffiths has observed in normal subjects, we believe that the statistical sample will be large enough to provide proof of efficacy of psilocybin in cancer patients. It is too soon to know what size patient population we will need before the FDA actually approves psilocybin, and it will undoubtedly be much larger, but this size should be sufficient to allow us to initiate the dialogue with FDA that will ultimately result in psilocybin being moved into legitimate medical practice. It should also be of sufficient power to apply for grants from the NIH to fund expanded efficacy studies of this treatment.

This is a great moment, and we are poised on the threshold of history. If ever you wanted to make a difference, and be part of the process that moves a psychedelic medicine into a real treatment, these two studies, which will cost a total of \$410,000 over two years, are the vehicle to do it. I realize that this goal is more than a bit ambitious, but I am absolutely convinced that the donors we now have could make it happen if they wanted to. We CAN do it!

I wondered if we'd get this far in my own lifetime, and this opportunity is staring us in the face right now! Please join us in this history-making process. *As an added note, with the recent changes in congress there may be some greater probability of increased capital gains tax rates next year, so now may be a good time to take those capital gains, before the end of the current tax year.* Remember, you also can make a donation on our web site (www.heffter.org) using PayPal!

Progress Reports

Arizona OCD study. The results of this study have now appeared in print in the *Journal of Clinical Psychiatry*, Vol 67, pp 1735-1740, 2006, "Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder," by Francisco A. Moreno and co-workers. Francisco tells us that the results were sufficiently positive that he intends to send a grant proposal to the National Institutes of Health, seeking additional funding for an expanded study. Other than the Russian ketamine research, also supported by Heffter, this project was the first psychedelic treatment study in the world in more than 30 years.

UCLA Cancer Study. Seven subjects have now participated in the UCLA cancer study. Each received one psilocybin session and one placebo session. Charlie says they "haven't crunched the data yet, but our impression has been from staying in touch with our subjects that they all seem to have benefited from the experience, particularly regarding mood regulation, anxiety control and quality of life." They are actively seeking five additional subjects, and inclusion/exclusion criteria and contact information can be obtained at www.canceranxiestudy.org.

The Heffter Zürich Center. Our research team has spent a long time developing a tracer molecule to image brain serotonin receptors using PET scans. Since July, our team has been using this imaging molecule while administering different doses of psilocybin, and major effects are being observed. The plan is to determine the regional psilocybin receptor occupancy in

about 10 to 12 subjects, and then to study the modulation of the receptor 12 or 24 hours afterwards in more subjects. This study will provide information on the potential receptor changes induced by psilocybin. The effects of psilocybin on cognitive tasks are also correlated to the PET data. We hope this work will be the first published study on visual illusions/hallucinations and neuroreceptor mechanisms.

This foundation work leads to the next step: to make similar measurements using psilocybin for patients with eating disorders and possibly obsessive-compulsive disorder. We wish to determine whether and how psilocybin can help them recover from their symptoms. Imaging studies in normal controls will establish baseline receptor maps. Imaging of the brains of patients with eating disorders, or obsessive-compulsive disorders will show whether these receptor maps are perturbed in the illness. Then, following psilocybin treatment, we can observe how the treatment may have restored or altered the receptor maps.

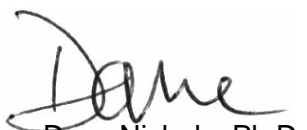
A study into the experiential and neurophysiological effects of meditation is also underway at the Heffter Zürich Center. Sophisticated 3-D EEG recordings have been made with both novice and experienced meditators under various conditions designed to tease out how Buddhist meditation practices affect the brain, including the experience of self, cognition, and visual perception. Very interesting data are emerging, which are now being analyzed and the final results will be reported in a future update. Eventually, the data can be compared to similar measurements on the effects of psilocybin, so that a comparison can be made between the effects on the brain of the experience of meditation, and psilocybin.

Heffter Photos

Finally, Kathrin Schneider, M.D., one of Arthur Heffter's descendents, is an anesthesiologist in Germany. She has been helping me to obtain more information about our remarkable namesake, Dr. Heffter. A few weeks ago, she sent me several scanned old photos of Arthur Heffter from the family archives. I have attached one of them below, showing him when he was the Dean at the University of Berlin, in 1923. As soon as we get the time, we will post the rest of them on our web site.



In closing, On behalf of the board, I thank you profoundly for your support of the Institute, and invite you to continue supporting our work as we progress toward a new era of scientific and public awareness of the benefits of these medicines.


Dave Nichols, Ph.D.
President