Exhilarating, astonishing, hard-earned, and transformative. All of those words are necessary to describe the remarkable developments of the past several months. MAPS is now poised tantalizingly close to initiating realistic drug development research programs with MDMA (see page 7) and marijuana (see page 9), with the goal of transforming them into FDA-approved prescription medicines. One reflection of MAPS' progress and growing maturation as an organization is my selection by the Drug Policy Alliance (www.drugpolicy.org) as the 2003 recipient of the Norman E. Zinberg Award for Achievement in the Field of Medicine. This award belongs to MAPS and all its members and staff since MAPS was founded in 1986, for our efforts struggling together to obtain permission to conduct medical research with Schedule I drugs.

Foremost among the recent developments is that on September 23, 2003, MAPS was finally able to obtain Institutional Review Board (IRB) approval for Dr. Michael Mithoefer's MAPS-sponsored MDMA/PTSD protocol. MAPS previously had enormously frustrating interactions with seven other IRBs, all but two of which refused to even accept the protocol for review. Of the two that did review the protocol, one approved the study and then revoked approval several months later for political reasons. The other tabled its review after months of exhaustive negotiations saying that while a majority of its members agreed with MAPS that several fundamental changes in design proposed by the IRB were not appropriate, unanimous agreement was now going to be required. MAPS almost started its own IRB, as we feared we would be unable to find an IRB that would prioritize science over politics. Yet once again persistence paid off, as the latest IRB did an excellent job of evaluating the protocol, in the process suggesting several important changes that significantly improved the design.

"This award belongs to MAPS and all its members...for our efforts struggling together to obtain permission to conduct medical research with Schedule I drugs."

As the IRB's evaluation of the protocol was in its final stages, a fortuitously-timed event took place exactly one year after the September 6, 2002, decision of the Western IRB to revoke its initial approval of the study for political reasons. On September 6, 2003, to the scientific world's astonishment, Drs. George Ricaurte and Una McCann formally retracted their National Institute on Drug Abuse (NIDA)-funded study, published in September 2002 in *Science*. The study claimed that even a "common recreational dose regimen" of MDMA could cause "severe dopaminergic neurotoxicity" resulting in MDMA users developing Parkinson's disease. In their retraction, they explained that instead of injecting MDMA into the primates used in the *Science* paper, they mistakenly had injected mislabeled methamphetamine, and when they finally injected accurately labeled MDMA into new primates, there was no dopaminergic neurotoxicity!

MAPS had advance notice of the impending retraction and was able to contribute to the content of its substantial media coverage, resulting in a tremendous opportunity for public education about the

exaggerated nature of the risks of MDMA and a temporary tripling of Internet traffic to MAPS' website. MAPS offers on its website numerous documents, both by MAPS and others, relating to Ricaurte el al.'s original study, MAPS' June 6, 2003, critical letter published in *Science* and Ricaurte et al.'s response: the retraction, MAPS' Freedom of Information Act (FOIA) request to NIDA, and its letters to NIDA Director Nora Volkow and NIDA's National Advisory Coucil on Drug Abuse seeking additional data about Ricaurte et al.'s research. Also included are challenges to Dr. Ricaurte and McCann's previous reports of substantial reductions in serotonin in human Ecstasy users, which have also not been replicated and are now generally considered methodologically flawed (http://www.maps.org/mdma/studyresponse.html). To its credit, NIDA is revising what it says about MDMA on its website and has withdrawn an educational campaign based on Ricaurte/McCann's serotonin PET scan data.

Even DEA is acting responsibly! On October 28, 2003, DEA agents finally inspected Dr. Mithoefer's facility as part of DEA's long-delayed review of his June 2002 application for a Schedule I license to handle the 3.5 grams of MDMA to be used in the study. Dr. Mithoefer's DEA Schedule I license is the last regulatory requirement we need before the study can begin. The DEA agents seemed to approve of the safe, alarm system and forms and procedures for tracking and administering the MDMA, and spoke to Dr. Mithoefer about *when* – not *if* – his license would arrive, not if. Still, we shouldn't start celebrating the successful fulfillment of MAPS' 17+ year effort to start FDA-approved MDMA psychotherapy research until Dr. Mithoefer actually receives his Schedule I license.

Once Dr. Mithoefer's Schedule I license is in hand, MAPS' Israeli MDMA/PTSD pilot study will begin its final design and approval process, we may be able to reopen MAPS' Spain MDMA/PTSD project (halted for political reasons), and MAPS and Dr. John Halpern will begin in earnest to start research at Harvard Medical School into the use of MDMA in the treatment of depression, anxiety and pain in end-stage cancer patients (more information about all these projects can be found at: http://www.maps.org/research/mdma/).

MAPS' medical marijuana research efforts have also made dramatic progress toward achieving the two necessary prerequisites for a serious medical marijuana drug development effort: an independent source of marijuana for clinical use as an alternative to the monopoly on supply currently held by NIDA, and FDA approval of the use of a vaporizer in clinical research that heats but doesn't burn the marijuana plant (in order to eliminate combustion products and reduce particulate matter).

On October 20, 2003, Senators Kennedy and Kerry wrote a powerful letter to DEA Administrator Karen Tandy urging her to approve the application from Professor Lyle Craker, UMass Amherst, for a license to establish a facility to produce marijuana for federally-approved research (http://www.maps.org/mmj/mmjfacility.html). Prof. Craker's facility would be funded by grants from MAPS. The support of both Senators from Massachusetts substantially raises the stakes for DEA and the Office of National Drug Control Policy (ONDCP), which can now expect significant political pres-

"MAPS had advance notice of the impending retraction and was able to contribute to the content of its substantial media coverage, resulting in a tremendous opportunity for public education about the exaggerated nature of the risks of MDMA and a temporary tripling of traffic to the MAPS website."

sure, unfavorable publicity and a major lawsuit if DEA continues to call for more medical marijuana research on the one hand while blocking it on the other by refusing to license a privately-funded production facility. Encouragingly, I've had a series of candid and remarkably reasonable discussions about the UMass Amherst facility with David Murray, special assistant to ONDCP Director John Walters.

"If anywhere near 1.8 million new people are trying Ecstasy for the first time each year, surely MAPS can raise $1 million a year over 5 years for our Clinical Plan to develop MDMA into a prescription medicine."

In vaporizer research, preliminary news from FDA is favorable regarding Dr. Donald Abrams' proposed study of cannabinoid blood levels, carbon monoxide levels and subjective effects in subjects who will be tested after smoking marijuana cigarettes and also after inhaling marijuana vapors from a vaporizer (Volcano, www.vapermed.de). MAPS and CA NORML have funded a sustained research program into the constituents of the vapors produced by the Volcano vaporizer and have given the data to Dr. Abrams to submit to FDA as part of his IND (Investigational New Drug) application for permission to conduct his smoked vs. vaporized comparative study.

While it's true that MAPS is primarily focused on scientific research for specific patient populations that is of limited relevance to non-medical users of psychedelics and to the larger social debates about drug legalization (see MAPS member Fred Grab's letter on page 39), MAPS has been active recently in the field of harm reduction, providing psychedelic emergency services at the Burning Man festival (see page 28). Our MAPS team offered the option of working therapeutically with difficult psychedelic states to people whose initial intentions had not included a visit to the Sanctuary tent. Personally, my main MAPS work involves years and even decades-long efforts to obtain permission and funding for psychedelic psychotherapy research that will be conducted by others. In contrast, the opportunity to provide direct assistance to people in crisis was tremendously satisfying, both despite and because of the emotional pain with which people were struggling. We found that most people were willing to work therapeutically once they felt safe, supported in their emotional process and unthreatened by arrest.

Not surprisingly, all has not been roses. In late October 2003, the Comcast cable company announced that it had pledged $51 million of ad space over three years to the Partnership for a Drug-Free America for anti-Ecstasy ads. Comcast is responding, in part, to recently released survey data from the National Survey on Drug Use and Health showing that 1.8 million Americans tried Ecstasy for the first time in 2001, more than cocaine (1.2 million), and second only to marijuana (2.6 million). Aside from the gloomy prospect of watching loads of distorted Partnership anti-Ecstasy ads, there's some hopeful implications. If anti-Ecstasy ads can be funded to the tune of $17 million a year for three years, and if anywhere near 1.8 million new people are trying Ecstasy for the first time each year, surely MAPS can raise $1 million a year over five years for our Clinical Plan to develop MDMA into a prescription medicine.

Meanwhile, we wait expectantly on DEA's decisions regarding Dr. Mithoefer's Schedule I researcher's license and Dr. Craker's Schedule I manufacturer's license, and FDA's decision regarding Dr. Abrams' vaporizer protocol. Your continued support is crucial to MAPS' ability to sustain our efforts and to respond to new opportunities as they arise. Best wishes from all of us at MAPS as we approach the celestial solstice and perhaps also a similar cultural turning point, marking the beginning of the gradual return of light after even the darkest days!

— Rick Doblin, Ph.D. MAPS President