

THE STRUGGLE TO RESUME KETAMINE PSYCHOTHERAPY STUDIES IN ST. PETERSBURG



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In April 2002, the studies of ketamine-assisted psychotherapy we had been conducting since 1985 were halted, for two reasons. The first reason was that the room where we kept the ketamine did not meet new regulations for the storage of scheduled drugs (These include two iron doors with two locks each, brick or concrete walls, concrete floor, a special alarm system, etc.). More seriously, several months earlier, ketamine was moved from Schedule III into Schedule II. This was part of Russia's own "War on Drugs," and was probably related to the increased prevalence of ketamine abuse among youth. The rescheduling is an important distinction, since under the recently accepted Russian federal "Law on Narcotics," it is forbidden to use Schedule II drugs to treat addictions. That law was mainly aimed against substitution therapy for heroin addiction (I should probably mention here that both methadone and buprenorphine maintenance have always been prohibited in Russia). However, with the reclassification of ketamine into Schedule II (where it joins methadone, buprenorphine, and some other drugs of addiction), this law turned out to target ketamine psychotherapy as well.

Since our ketamine studies have been on hold, we have taken active steps to obtain permission to continue our work. First of all, our hospital built a new room for ketamine storage, meeting all requirements of the new regulations (the cost of the renovation was approximately \$2,000). The hospital then received an official license for keeping ketamine in that room from the local authorities of the Ministry of the Interior.

We also initiated paperwork to obtain a permit from the Ministry of Health Care. First of all, we submitted a set of documents to the Control Committee on Narcotics at the Ministry of Health Care, which usually gives permission for any work with controlled substances. In several months, we received a reply saying that for this sort of permit, we should apply to the Ministry of Health Care's Pharmacological Committee (Russian analogue of US FDA), which issues permission for clinical trials. We submitted a package of the documents to the Pharmacological Committee, and in another several months received an answer. They cannot issue a permit, because under the new narcotics law, ketamine cannot be officially registered for treatment of addictions, and they are give permission only for the clinical trials of medicines that will be registered in Russia (pre-registration trials). When we asked where we should seek permission to do scientific studies without the intent of registering ketamine for a new indication (e.g. for heroin addiction), they recommended that we apply to the Scientific Department of the Ministry of Health.

We then submitted a package of documents to the Scientific Department, and received an answer stating that it is not possible to include this study in the Federal Research Program without having it first approved by the Control Committee on Narcotics at

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the Ministry of Health Care.

Thus, the circle was completed. In one year, we turned out at the same place where we started.

We later re-submitted our documents to the Control Committee on Narcotics at the Ministry of Health Care. As expected, we were denied a permit under the new federal narcotics law. This means that our multiple vs. single ketamine psychotherapy (KPT) session study in heroin addicts is now completed. I am completing statistical analysis for 59 randomized patients, and will draft a paper within a few months.

I do think we might have two possibilities for the future: (1) We could apply for permission to do ketamine studies in alcoholics, or (2) We could ask for permission to treat PTSD or personality disorders in heroin addicts with dual diagnosis. In that case, we would treat secondary psychiatric diagnosis in heroin addicts, which is not forbidden – the law prohibits using Schedule II drugs to treat *addictions*, but not *addicts*. For now, we wait for the response from the Control Committee on Narcotics at the Ministry of Health Care, and if it is negative, we will initiate a new round of paperwork to get permission for alcoholics or dual diagnosis patients. This will take months, or maybe even years, since there is a strong prejudice against ketamine psychotherapy among conservative Moscow authorities. However, we still hope that at the end of this long road, we will start doing ketamine studies again! ■

UPDATE FROM LISA: A SEXUAL ASSAULT SURVIVOR WHO BENEFITED FROM MDMA

Last summer, I published a testimonial in the MAPS Bulletin about how MDMA helped me heal on a deeper level from lingering trauma many years after a sexual assault. Several months later, I was diagnosed with Post Traumatic Stress Disorder (PTSD) after I'd already begun to recover from it. Ironically, I was making an appeal in my testimonial in support of clinical testing for a disorder that I didn't even know I had.

Without a doubt, MDMA was the catalyst that began and accelerated my healing. It made me more aware on a conscious level of the fundamental problems I was facing. It helped facilitate effective communication with my therapist. And, most significantly for me, it gave me a goal. I wanted to feel connected to others and accepting of myself as much and as often as I possibly could.

It's remarkable how calm and happy I am now. The recurring nightmares have not come back. I sleep and eat better. I'm not constantly focused on negative thoughts or replaying events from the past in my mind. And, for the record, I have not had a desire to take the drug again. Although, it would be reassuring to know that I could safely and legally if I ever wanted that kind of healing again.

MDMA is certainly not a panacea, but it is inhumane to deny its therapeutic benefits to people who could have their lives restored if they had safe, clinical access to it.

Many blessings to those of you who are working to modify the current fear-based policy.

Lisa

To read Lisa's original account in the Summer 2002 MAPS bulletin, go to <http://maps.org/news-letters/v12n2/12207rc.html>