medical **marijuana** update

Rick Doblin

AFTER MUCH EFFORT, a small amount of progress has been made toward obtaining FDA permission for medical marijuana research. On Friday, May 14, 1999, after refusing to do so for two years, the FDA formally critiqued the MAPS-supported protocol submitted by Dr. Ethan Russo, U. of Montana, for a study of the use of smoked marijuana and oral THC capsules (Marinol) in patients with treatment-resistent migraines.

The FDA's comments on the protocol were reasonable, though extraordinarily cautious. Both Dr. Russo and I believe that the revised versions of the protocol and informed consent form will receive FDA approval. The FDA had refused to review two previous protocols submitted by Dr. Russo, arguing that there was no point in reviewing them unless the National Institite on Drug Abuse (NIDA) had already agreed to supply the marijuana. The FDA's policy denied us the opportunity to benefit from FDA suggestions for improving the protocol design and also insulated NIDA from criticism for not providing marijuana to an FDA-approved protocol.

When Dr. Donald Abrams, UC San Francisco, had submitted his MAPS-supported protocol, designed to evaluate marijuana in AIDS wasting patients, the FDA had been willing to review and approve the protocol prior to NIDA's agreement to supply marijuana. FDA approval was an important part of our successful six-year effort to initiate Dr. Abrams' research, the first medical marijuana study in a patient population in fifteen years (see www.maps.org/mmj). Unfortunately, the FDA changed its policy when confronted with Dr. Russo's protocol, as far as we know the only study of smoked marijuana in a patient population currently before the FDA. On October 27, 1998, NIDA informed Dr. Russo that its condition for providing marijuana to his study was approval and funding by the National Institutes of Health (NIH).

However, Dr. Russo's two grant proposals to NIH were both rejected (see maps.org/mmj). Instead of giving up, Dr. Russo and I decided to submit the protocol to FDA for the third time, this time demanding more forcefully that the FDA review it. We benefited from inside support from an FDA ombudsman, with whom I had scheduled an appointment on March 17, 1999. This coincidentally was also the day the Drug Czar-funded Institute of Medicine (IOM) report supporting medical marijuana research was released, which was front page news. We also benefited from outside pressure resulting from the passage in November 1998 of additional state medical marijuana initiatives.

On the evening that the FDA finally reviewed Dr. Russo's third protocol, after Dr. Russo and I had discussed every nuance of the review, I was riding in a Washington, DC taxicab. The universe seemed to be smiling when I learned that the taxi drivers' mother used marijuana for her migraines! The FDA is once again prioritizing the needs of patients over NIDA's anti-marijuana agenda. A recent federal policy shift now requires NIDA to sell marijuana to non-government-funded studies. In a potential complication, FDA-approved studies still need to be reviewed and approved by the Public Health Service (PHS). If the PHS review is not a trap, the main unresolved issue for Dr. Russo's study will be finding funding. Dr. Russo was recently informed by NIDA that his research protocol is the first to come before NIDA with a request to purchase supplies of marijuana. Dr. Russo's protocol requires 200 marijuana cigarettes and 200 placebo marijuana cigarettes. NIDA's cigarettes usually weigh about .9 gram, which means that Dr. Russo needs about six ounces of regular marijuana and six ounces of placebo marijuana, or about four fifths of a pound. We await with interest what price NIDA sets for its marijuana, which a MAPS and California NORML study (to appear in the next *Bulletin*) have shown is about one third the potency of medical marijuana sold to patients at marijuana buyers clubs around the country. •

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