

Cannabis in Migraine Treatment Project Close to FDA Approval

The future of medical marijuana research is uncertain, though looks promising. In late July 1999, the FDA informed Dr. Ethan Russo, University of Montana, that his MAPS-supported protocol to study marijuana in the treatment of migraines was fully approved. However, the protocol was placed on hold until NIDA decides if it will supply the marijuana. NIDA's new policy is to submit FDA-approved projects to a special Public Health Service (PHS) review before agreeing to sell marijuana for a yet-to-be-determined price to non-government funded projects. Whether this PHS review will be conducted in a fair and timely manner remains to be seen.

Dear Friends,

I received word today from FDA that my revised protocol for the *Cannabis in Acute Migraine Treatment Project* has been accepted by that agency, but remains on "clinical hold" pending receipt of a letter from NIDA authorizing access to the Drug Master File on cannabis. I have previously been in contact with personnel at NIDA in regard to obtaining that letter. Thus it appears that my protocol is ready for the PHS review that has been mandated by NIDA, although seemingly without any legislative basis.

Although I would repeat my opinion that this process is redundant in view of FDA acceptance, I have willingly submitted the protocol to NIDA. Inasmuch as FDA assesses its IND applications in 30 days from receipt, I would expect similar treatment for this protocol from NIDA. I understand that NIDA has said that a price for the cannabis will not be available until December 1999, but that should not delay this process, since I am willing to pay any price that is required for the 200 grams of cannabis, and 200 grams of acetone-treated cannabis placebo. Thus, I would hope to hear from NIDA expeditiously as to plans and disposition of the project.

This application process began in early 1997 when FDA refused to review a first protocol due to lack of an approved supply of cannabis from NIDA. A subsequent

application to NIH for funding was denied. The process repeated itself in 1998 with an FDA refusal, and subsequent NIH denial of an amended protocol.

In 1999, the protocol was submitted a third time, but received the mandated 30 day review with request for certain clarifications and supplementation. These were recently returned, and apparently were sufficient to allow FDA approval pending NIDA cooperation. I am hoping that a "thaw" has occurred in NIDA philosophy on provision of cannabis for clinical studies. If so, an additional hurdle will remain in the fund-raising for performance of the study. What was originally envisioned as a simple clinical trial has grown into a budget of some \$250,000 to study effects of cannabis, Marinol (synthetic THC), and their placebo equivalents vs. injected sumatriptan (the current "gold standard") in 40 patients over five months.

We will provide additional news of developments as they become available. •

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