

Medical Marijuana News

Following up on Orphan Drug designation

THERE IS VERY GOOD NEWS to report regarding MAPS's efforts to obtain permission from the DEA to establish a medical marijuana production facility.

During the week of January 21, 2000, Rick Doblin had a series of meetings with Lyle Craker, PhD, Professor of Plant and Soil Science at the University of Massachusetts at Amherst and a specialist in medicinal plants; Peter Hutt, JD, among the most respected FDA regulatory lawyers in the country (Hutt is also a professor of FDA law at Harvard Law School during the January interterm and is a partner in a major DC law firm, Covington and Burling); and Dr. Lester Grinspoon, Harvard Medical School, foremost academic on the medical uses of marijuana.

The outcome of the meetings was that Peter Hutt has agreed to have his firm represent MAPS pro-bono in its efforts to request permission from the DEA for MAPS to contract with U-Mass Amherst to establish a medical marijuana production facility under the direction of Professor Craker. This effort could easily take years and not be successful, but at least we are going forward with a team that has about the best possible chance of obtaining approval from the DEA. It has taken many months to build a team to act upon MAPS' Orphan Drug designation for marijuana for AIDS wasting syndrome but it has been well worth the wait. The next several months will be spent obtaining information from NIDA and the DEA about issues and obstacles that need to be addressed in obtaining permission for the facility.

If the facility is eventually permitted, MAPS will need to raise additional funds for the contract with U-Mass Amherst. Current efforts are being conducted under a grant to MAPS from Peter Lewis' PLACE Fund. For more about the Orphan Drug Designation success, see *MAPS Bulletin* 9(3) or www.maps.org/mmj.

New grant for vaporizer study

MAPS and California-NORML have each agreed to contribute \$12,500 for additional research into the ability of a vaporizer to filter marijuana smoke. This research will build upon a previous study of the effectiveness of water pipes and vaporizers in filtering marijuana smoke, also sponsored by MAPS and California-NORML. See *MAPS Bulletin* 6(3) or www.maps.org/mmj for the previous study.

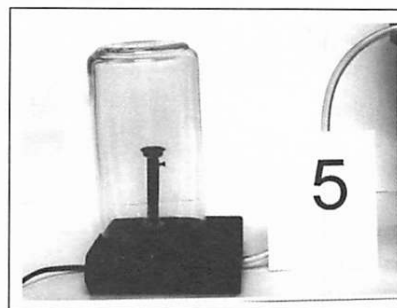
NIDA rejects medical marijuana research

FRUSTRATING NEWS. On December 6, 1999, Dr. Ethan Russo, University of Montana, learned that NIDA's special review committee rejected his MAPS-supported, IRB- and FDA-approved protocol, and that he will not be permitted to purchase marijuana from NIDA for his study. Dr. Russo was told nothing about why the protocol was rejected and was also told he should expect to wait a month or longer before receiving any formal notification from NIDA. The FDA gave its final approval for the study in September 1999.

On February 2, 2000, Dr. Russo received the formal explanation detailing why NIDA rejected his request to purchase marijuana for his research. The over 40 pages of correspondence with NIDA and NIH regarding Dr. Russo's study are online at www.maps.org/mmj/mjrusso.html.

Health and Human Services guidelines for medical marijuana research permit NIDA to create its own special review committee to review protocols that have already been approved by the FDA and Institutional Review Boards. All that Dr. Russo and MAPS have been seeking is the ability to purchase low quality marijuana from NIDA at a price that has not yet been made public. Unfortunately, NIDA is still successfully blocking medical marijuana research. We are currently reassessing how to proceed with efforts to conduct privately funded medical marijuana research. NIDA's monopoly control over the supply of marijuana that can be used in FDA-approved research projects highlights the importance of MAPS' long-term effort to obtain permission from the DEA to establish an independent facility to produce marijuana for FDA-approved research.

MAPS has given a grant of \$1000 to Dr. Russo to continue his efforts to seek approval for a study of marijuana in the treatment of migraine. To date, MAPS has contributed a total of \$8000 to Russo's research efforts to initiate the second study in the last several decades into the medical use of marijuana in a patient population. The first study is underway at the University of San Francisco under the supervision of Dr. Donald Abrams (see www.maps.org/mmj).



A commercial vaporizer that was tested in the 1996 MAPS/CA-NORML study