

# MAPS Medical Marijuana Production Facility: A Progress Report

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Inspectors from the Massachusetts Department of Public Health visited University of Massachusetts/Amherst (UMass Amherst) in early August to look at the facility where UMass Amherst Professor Lyle Craker, with a grant from MAPS, is proposing to create a DEA-licensed medical marijuana production facility to grow marijuana for use in FDA-approved clinical research projects. The inspectors asked a series of reasonable questions and seemed generally sympathetic. Prof. Craker and MAPS have submitted a written response to the questions and await a response from the Massachusetts Department of Public Health.

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The questions asked were the following:

1. From where will we obtain seeds?
2. Who will fund the research?
3. Who will dry the material? Other processing steps? Where?
4. How will the material be transported?
5. Overall purpose of production? The big picture? The part UMass plays?

Our answers are as follows:

1. From where will we obtain seeds?

Once we have legal permission for the growing operation, we will explore importing them from a licensed supplier in either the Netherlands, England or Canada, all of which have legal medical marijuana growing operations. We will also try to see if we could obtain them from the University of Mississippi, where NIDA’s supply is grown. However, they probably have seeds of too low a quality (though perhaps their low quality product is due to production methods rather than poor quality seeds). I don’t see any point in trying to resolve this issue further until we have permission but can do so if necessary.

2. Who will fund the research?

MAPS, in the form of a grant to UMass Amherst.

3. Who will dry the material? Other processing steps? Where?

The material will be dried at UMass Amherst. We will try not to have to produce the

material into standardized joints of uniform weight, but will simply try to provide it to patients as buds in weighed containers to use in vaporizers or for self-rolling. The material produced at the U. of Mississippi is shipped to Research Triangle Institute for rolling into joints, which we could also do if necessary. This is an issue for the specific researchers to negotiate with FDA. One of the advantages of the use of marijuana as medicine is that patients can self-titrate, and one of the advantages of the use of vaporizers is the reduction in particulate matter.

It therefore may be possible to negotiate with FDA to provide marijuana for use in vaporizers. This is an issue that does not need to be resolved at this time but must be resolved by negotiation between researchers and FDA. We will do whatever is required. Perhaps FDA may even negotiate different arrangements with different researchers. If more information is required at this point, we can get more specific.

#### 4. How will the material be transported?

In accordance with standard DEA procedures for shipping Schedule 1 drugs intended for FDA-approved research. This usually means FedEx with DEA Form 222.

#### 5. Overall purpose of production? The big picture? The part UMass Amherst plays?

The major purpose of production is to develop high-quality material for FDA-approved research. MAPS has received Orphan Drug designation from FDA for the use of marijuana for AIDS wasting disease. The long-term goal is to develop marijuana in plant form as an FDA-approved medicine, not just for AIDS wasting patients, but also for other indications. No material will be supplied to patients outside of FDA- and DEA-approved protocols. This means that no Massachusetts patients will be supplied marijuana unless they are part of FDA-approved research protocols. This is NOT an attempt to produce material for Massachusetts patients in the event that a Massachusetts State medical marijuana initiative passes, unless the Massachusetts Department of Public Health works something out with FDA.

Another purpose of production is to facilitate re-

search at UMass Amherst into the production of marijuana for medical purposes. This can include research into different growing techniques, genetic research, or anything else that Professor Craker is interested in studying.

NIDA-produced marijuana is low-quality and is not easily obtainable, thus even privately funded research is

restricted only to protocols approved by FDA and also by a special Public Health Service (PHS) review process.

Privately-funded researchers interested in studying any other Schedule 1 drug, such as MDMA, LSD, DMT and psilocybin, do not need to go through this PHS review since NIDA does not retain a monopoly on the supply of these

drugs. NIDA only has a monopoly on the supply of marijuana for FDA-approved research. NIDA has refused to supply its marijuana to some FDA-approved researchers, even though the researchers were going to pay NIDA for the costs of the marijuana and the studies were going to be privately funded. Some researchers have been discouraged from even applying to FDA for permission to conduct research with marijuana in plant form.

If initial pilot studies are promising and large-scale trials are approved, and especially if FDA ever approves the use of marijuana for prescription use, the amount that is needed to be produced will increase over the initial estimate of 25 pounds per year. If that occurs, MAPS and UMass Amherst will negotiate a contract to produce whatever amounts are required. Perhaps UMass Amherst would prefer to continue to grow smaller quantities for research purposes only and have any larger quantities produced by a private company, perhaps with some link to UMass Amherst. We will explore all these options together at the appropriate time, though these discussions would probably not be needed for at least several years after production begins to take place.

Now we wait for the next round of questions from the Massachusetts Department of Public Health. If we do manage to obtain approval from the Massachusetts Department of Public Health, negotiations will begin in earnest with DEA. The Washington, DC law firm, Covington & Burling, will likely assist MAPS and UMass Amherst on a pro bono basis in those negotiations.

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