Lyle Craker's DEA Lawsuit for a MAPS-Sponsored **Medical Marijuana** Production Facility: An Update

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THE COURTROOM DRAMA IS OVER. The political wrangling is in temporary respite. And, the possibility of MAPS-sponsored FDA-approved clinical trials with marijuana is now hinging on a recommendation to DEA Administrator Karen Tandy from DEA Administrative Law Judge Mary Ellen Bittner, expected by summer or fall of 2006.

Following two rounds of hearings and an aborted hearing in January, lawyers for the DEA and lawyers from the ACLU and the two Washington, DC, law firms working largely pro bono for Prof. Lyle Craker, Ph.D., are now preparing final legal briefings. The legal briefings, due April 27, will build legal arguments based on the evidence presented in court during oral arguments, but cannot introduce new evidence.

If Judge Bittner recommends that the DEA issue a Schedule I manufacturing license to Prof. Craker, it will be just that-a recommendation. The DEA could still reject the Judge's ruling, leaving us with the unenviable option of suing the DEA in the Washington, DC, Circuit Court of Appeals on the grounds that their rationale for rejecting a favorable recommendation was flawed, a process that could delay the case for several more years. Therefore, if Judge Bittner makes a favorable recommendation, we will need to place political pressure on the DEA to follow it, even though we already have letters to the DEA urging it to issue the license from 38 members of the House of Representatives (36 Democrats and 2 Republicans), both US Senators from Massachusetts (Kennedy and Kerry), Republican strategist Grover Norquist, and organizations such as the California Medical Association, the Lymphoma Foundation of America, the United Methodist Church (UMC), and several state nurses' associations.

The Background

Although Federal law requires adequate competition in the production of Schedule I drugs [21 U.S.C. § 823(a)(1); 21 C.F.R. § 1301.33(b)], at present, the federal government's National Institute on Drug Abuse (NIDA) has a monopoly on the supply of marijuana, but no other Schedule I drug, that can be legally used in federally-approved research. This monopoly has been used to obstruct privately-funded research aimed at developing marijuana into an FDA-approved prescription medicine.

For example, NIDA has refused to

supply marijuana to two FDA-approved protocols sponsored by MAPS, preventing these studies from taking place. In addition, for the last two and a half years, NIDA has refused to sell 10 grams of marijuana to a MAPS-sponsored laboratory study evaluating the effectiveness of a marijuana vaporizer, a non-smoking drug delivery device that eliminates the products of combustion that patients would inhale after burning marijuana. As NIDA well knows, sponsors will not invest millions of dollars into research studies until there is reliable access to a supply of high quality research material that can be used both in research and–if the research should prove successful– as an FDA-approved prescription medicine.

In June 2001, with support from MAPS, Prof. Craker, Director of the Medicinal Plant Program at the UMass-Amherst Department of Plant, Soil and Insect Sciences, applied to the DEA for a license to manufacture marijuana exclusively for use in federally-approved research. Prof. Craker's facility would have been funded by a grant from MAPS. Yet the DEA has refused to issue a Schedule I manufacturing license to Prof. Craker for over four and a half years. DEA licensing is the final regulatory hurdle in MAPS' quest to create a privately-funded federally-approved medical marijuana production facility, which would pave the way for a serious drug development effort aimed at developing marijuana into an FDA-approved prescription medicine.

One of the DEA's key legal arguments is that Prof. Craker's facility is not "in the public interest". During the first weeklong trial that took place in August 2005, Prof. Craker's lawyers established through the testimony of long-time California State Senator John Vasconcellos and former ONDCP senior policy analyst Barbara Roberts that there is an unmet demand for research that investigates the safety and efficacy of marijuana's potential therapeutic uses (see Allen Hopper's update in the Fall 2005 Bulletin at http://www.maps.org/news-letters/v15n3-html/dea.html).

During the second weeklong proceeding in December 2005, DEA lawyers called their witnesses to the stand. Amazingly, their testimony seemed to support MAPS' case more than their own.

The December DEA Hearing

The DEA first called on Prof. Mahmoud El Sohly, Ph.D., NIDA's marijuana grower at the University of Mississippi. During cross examination, Prof. El Sohly was asked to explain his personal commercial interests in marijuana-based products. This includes both his THC suppository and his new DEA license permitting him to grow marijuana to extract THC for sale to the pharmaceutical company, Mallinckrodt, to manufacture generic Marinol. We established that Prof. El Sohly would have a major conflict of interest if he were the sole supplier of marijuana to MAPS for prescription use, since marijuana would compete with products in which he has a personal financial interest.

Prof. El Sohly also claimed that he could provide marijuana of any potency and cannabinoid (CBD) content. When he later referred to a document that contained information on the marijuana in NIDA's inventory, Prof. Craker's lawyers asked to see it, and it was introduced into evidence. As it turned out, there was nothing in the inventory that matched the THC and CBD content that the Dutch government is offering for sale for medical use. When pressed about the poor quality of his marijuana, Prof. El Sohly made a mistake that undermined the DEA's case by defensively questioning the accuracy of a photo published in an article by Ethan Russo, M.D., depicting seeds and stems from marijuana Prof. El Sohly produced for NIDA. Prof. El Sohly even stated that the photo couldn't have been from NIDA's cigarettes, but could have been from the raw material, prior to the removal of seeds and stems. He then said that the seeds looked larger than they should have compared to the size of the stems, and came close to claiming the photo was fraudulently doctored.

After Prof. El Sohly 's testimony, we contacted Al Byrne, who was present when Russo's photograph was taken, to ask if he would testify to the unaltered nature of the photo. Byrne agreed to submit a signed affidavit, which we introduced into evidence on Friday, the last scheduled hearing. The affidavit was submitted to DEA lawyer Brian Bayly and Judge Bittner. The Judge then asked Bayly whether he had any objections to introducing the affidavit as rebuttal evidence.

This was one of the most telling moments in the entire hearing-the classic pregnant pause. Bayly was silent and stared at the letter for an extended period of time.

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Nobody in the courtroom said a word for more than a minute. It was clear that Bayly was struggling to figure out how to object to this affidavit. He remained still for so long that Judge Bittner was compelled to speak again, asking him once more if he had any objections. Bayly shook off his paralysis and pored over the letter, paragraph for paragraph, line for line, trying to exclude any background information that wasn't directly about the photograph itself. MAPS' attorney, Julie Carpenter, skillfully argued that the background information was helpful to provide context. The Judge then ruled to admit the letter in its entirety. We now had Prof. El Sohly on record claiming that NIDA marijuana can't possibly be as bad as it really is, and we had photos and witnesses to prove that it is indeed that bad.

Then, in what seemed like an attempt to intimidate Byrne into withdrawing his affidavit, Mr. Bayly said that he wanted to cross-examine him under oath. All of the other testimony had been completed at that point, but the Judge scheduled another hearing for January 17 just to place Byrne under oath on the witness stand. What the DEA didn't realize at that time was that Byrne was eager to have his day in court to tell the Judge about the low quality of NIDA's marijuana. Predictably, a few weeks later, after it became clear that Byrne would not withdraw his affidavit, the DEA cancelled Byrne's cross-examination.

Prof. El Sohly also claimed that if NIDA-produced marijuana is approved by the FDA as a prescription medicine, researchers would have no trouble switching to another marijuana product with similar THC levels. This erroneous claim later hurt the DEA's case once it was contradicted by the DEA's other witnesses.

During the third day, the DEA called on Steve Gust, Assistant Director of NIDA, and our lawyers obtained several very important admissions from him under oath. First, he said that after the FDA has approved a protocol, the PHS/NIDA review takes an additional three to six months. This point strengthened our case that the NIDA monopoly is obstructing the development of marijuana into a prescription medicine, since time delays in pharmaceutical drug development are expensive and substantially impede the process. In contrast, the FDA has just 30 days to respond to protocol submissions.

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Then, Gust said that there is no formal appeal process, but that if an appeal is made, it could take another three to six months. He couldn't explain why the PHS/NIDA review of Chemic's vaporizer protocol and request for 10 grams took more than two years. Furthermore, he admitted that, unlike normal peer-review processes, the PHS/NIDA peer review process is composed entirely of government employees, with no outside experts. These sorts of delays, on top of the arbitrary nature of the review process, are more than enough to persuade potential funders of marijuana research that it isn't worth investing millions of dollars in a serious drug development effort.

Gust said that the purpose of NIDA's review is to ensure that the protocols are scientifically meritorious, and that the FDA merely reviews them for safety. Unfortunately for him, the official Health and Human Services (HHS) statement of policy about the provision of marijuana to privately funded studies says that the FDA reviews Phase I studies primarily for safety, but reviews Phase II and Phase III protocols for scientific merit. We directed Steve Gust to that portion of the guidelines and forced him to reluctantly admit that the FDA doesn't just review for safety but also for scientific merit. This clearly demonstrated that the NIDA review is duplicative and unnecessary.

During the forth and final day, the first DEA witness was Eric Voth, M.D., a prominent and long-time prohibitionist. Even though he was supposed to talk specifically about the risks of diversion, he couldn't help but talk about the risks of marijuana smoke compared to tobacco smoke. This gave us an opportunity to submit Dr. Donald Tashkin's new study showing no link between marijuana and lung cancer, in which he found that marijuana actually has a slight protective effect. We asked Voth about the comparison he made between marijuana and tobacco smoke, and he discussed Tashkin's results in a rather accurate manner, stating on the record that there is no scientific evidence linking marijuana to lung cancer. He also explained that cannabinoids have anti-tumor properties while nicotine does not.

Voth then made claims about the dangers of high-potency marijuana and stated that there is no evidence that people self-titrate high-potency marijuana in a way that enables them to inhale less smoke. He made several

other inaccurate claims about the addictive nature of marijuana and its link with mental illness. This enabled us to request that a chapter from Lester Grinspoon's *Marijuana: The Forbidden Medicine,* "Measuring the Risks," be entered into evidence as a rebuttal. Even though Judge Bittner had previously upheld a DEA request to block the text since the risks and benefits of marijuana weren't at issue in this case, in this instance she agreed to our request. Thus, Grinspoon's chapter was officially entered as evidence, contradicting Voth's testimony in numerous ways.

The primary thrust of Voth's testimony was that marijuana has so many ingredients that it can't possibly be made into a medicine. He said that it is difficult to standardize marijuana because various strains have significantly different chemical compositions, implying that blocking us from doing marijuana research doesn't matter since there is no way that the FDA would accept the marijuana plant as a prescription medicine. This argument was more persuasive until about 10 years ago, when the FDA developed guidelines for investigation of botanical medicines. This argument also fundamentally contradicted Prof. El Sohly 's testimony-that research could be conducted with a strain of marijuana provided by NIDA and then the sponsor of research could easily obtain FDA permission to market a different strain-since NIDA can't legally provide marijuana for prescription use.

Later in the day, over strenuous DEA objections, we entered into evidence FDA statements saying that the FDA welcomes research protocols evaluating whether the marijuana plant deserves to be available as a legal prescription drug. Once again, the FDA's willingness to place science over politics was a major assistance to our efforts.

The DEA's final witness was David E. Auslander, M.D., an expert in pharmaceutical drug development. His entire testimony substantially helped our case by reinforcing Dr. Voth's view that it is extremely difficult to standardize a plant because different strains have significantly different chemical "fingerprints".

Most importantly, at the end of Auslander's testimony, we asked him if the FDA would be concerned about the variation in chemical "fingerprints" of different marijuana strains. He said yes, definitely. We then asked him if it would be problematic for a pharmaceutical company if it did research with one strain of a plant, got FDA approval to market it, but then tried to market a different strain with a different fingerprint. He said this would matter quite a bit to the FDA and could require replication of some clinical studies, which are very expensive. This was the exact opposite of Prof. El Sohly 's testimony, in which he said we could conduct research with NIDA marijuana and then just switch to another plant. Prof. El Sohly was not presented to the Court as an expert in pharmaceutical drug development, so Auslander's testimony therefore had more authority on these points.

Auslander supported one of our key arguments, that conducting research with NIDA marijuana from Prof. El Sohly isn't reasonable since NIDA's mission doesn't permit it to provide marijuana for prescription sales, just research. Therefore, if we use NIDA marijuana in research and the FDA approves prescription use, we would have to apply to NIDA to obtain the same strain from Prof. El Sohly again. But, as we established earlier, Prof. El Sohly has fundamental conflicts of interest, since he has other marijuana-based products that would compete, plus he could charge anything he wanted because there would be no competition. The only other option would be to apply for FDA approval to market a different strain from a new manufacturer, which would present additional difficulties because of the differing chemical fingerprints of marijuana strains. In any case, there is currently no alternative supplier with a DEA license, and starting a new facility could take a year or more, a costly delay if millions of dollars had already been invested in research. In response to our final questions, Auslander helpfully testified that pharmaceutical companies must be assured of a reliable and consistent supply of any drug that could be used in research and made available for prescription sales.

While we can't predict how Judge Bittner will interpret the evidence presented over the two weeklong trial proceedings, we are satisfied that our key arguments were presented thoroughly and accurately in this landmark struggle for scientific freedom.

To read transcripts of the court proceedings, media coverage, or background information on the case, see MAPS' DEA lawsuit page on the internet at: http://www.maps.org/mmj/DEAlawsuit.html