UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of	)	
	)	
	)	Docket No. 05-16
LYLE E. CRAKER, PH.D.	)	
	)	

RESPONDENT'S PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW AND ARGUMENT

Respondent Dr. Lyle Craker respectfully submits these proposed Findings of Fact, Conclusions of Law, and Argument.

INTRODUCTION

The National Institute on Drug Abuse ("NIDA") has a monopoly on the supply of legal marijuana. By 2000, NIDA had declined to sell medical marijuana to two separate eminent researchers with FDA-approved protocols seeking to study the therapeutic qualities of marijuana. Because NIDA would not provide the marijuana, those studies could not take place. In response, the sponsor of those researchers, the Multidisciplinary Association for Psychedelic Studies ("MAPS"), decided to establish an alternative supply. This supply would be available for the FDA-approved research NIDA turned down and for a serious and substantial program of FDA-approved research leading to the conduct of large-scale Phase III studies evaluating whether marijuana is safe and efficacious in the treatment of specific patient populations.

MAPS consulted with Dr. Lyle Craker, an expert in medicinal plants from the University of Massachusetts, and in 2001, Dr. Craker applied to the DEA to be registered as the second supplier of marijuana in the nation. After three and a half years of silence,

and a federal district court order to show cause as to why it had not ruled on the application, DEA declined in December 2004 to grant that application. Now, in 2006, the issue before this Court is whether it is in the public interest to license Dr. Craker to cultivate medical marijuana for the use of properly licensed researchers who seek a better quality product than NIDA provides, and as a source for a sponsor seeking to generate data the FDA can use to evaluate the efficacy and safety of medical marijuana and of alternative delivery devices. Dr. Craker has established at the hearing that it is in the public interest for his application to be approved.

Procedural Statement

Dr. Craker submitted his application to be registered as a bulk manufacturer of marijuana on June 28, 2001.[1] On December 10, 2004, the DEA issued a show cause order, effectively denying his application unless he requested a hearing.[2] Dr. Craker did timely request a hearing. Testimony and evidence were presented at this hearing during August 22-26, 2005 and December 12-16, 2005.

FINDINGS OF FACT

A. The State of Research With Medical Marijuana Before Dr. Craker's Application.

The Controlled Substances Act specifically requires that Schedule I substances must be available for legitimate research. 21 U.S.C. § 823. And, given the lengthy

[1] Dr. Craker first submitted his application on June 28, 2001. Although it was DEA date-stamped and later returned to Dr. Craker (in a plain brown envelope), the DEA claimed in August 2002 that he had never filed it. At DEA's request, Dr. Craker re-filed his original request on August 22, 2002. Gov't Ex. 2; Tr. 28-31.

[2] After waiting over two years for the DEA to rule on his application, Dr. Craker was forced to sue for a writ of mandamus to force the DEA to respond. Tr. 47-49.

history of claims of medical benefits of marijuana throughout history, some researchers have been quite interested in studying those claims. However, other groups had strong concerns about the potential for abuse. In these circumstances, it is not surprising that research into those medical benefits has been a source of conflict. Indeed, as a former Acting Associate Deputy Director for the White House Office of National Drug Control Policy ("ONDCP"), Dr. Barbara Roberts, testified, the ONDCP was in the middle of the conflict because it took a position against allowing medical doctors to recommend the use of medical marijuana to their patients. Thus, at her suggestion, ONDCP decided to ask the Institute of Medicine, a division of the National Academy of Sciences, to examine the scientific evidence to help resolve the conflict with science. Tr. at 285-87, 337-338.

The IOM accepted that mandate and in 1999, it issued its report, "Marijuana and Medicine, Assessing the Science Base." Resp. Ex. 1. In that report, the IOM concluded

> The accumulated data indicate a potential therapeutic value for cannabinoid drugs, particularly for symptoms such as pain relief, control of nausea and vomiting, and appetite stimulation. The therapeutic effects of cannabinoids are best established for THC, which is generally one of the two most abundant of the cannabinoids in marijuana. (Cannabidiol is generally the other most abundant cannabinoid.)

Id. at 22.

Although it noted that the "effects of cannabinoids on the symptoms are generally modest," the Report also noted that "people vary in their response to medications, and there will likely always be a subpopulation of patients who do not respond well to other medications. The combination of cannabinoid drug effects (anxiety reduction, appetite stimulation, nausea reduction, and pain relief) suggests that cannabinoids would be moderately well suited for particular conditions, such as

chemotherapy-induced nausea and vomiting and AIDS wasting." *Id.* at 22. The IOM also warned that "Cannabinoid-based drugs will only become available if public investment in cannabinoid drug research is sustained and if there is enough incentive for private enterprise to develop and market such drugs." *Id.* at 22. Accordingly, the very first recommendation of the IOM was: "Research should continue into the physiological effects of synthetic and plant-derived cannabinoids and the natural function of cannabinoids found in the body." *Id.* at 21. And the IOM specifically recognized the need for alternative delivery devices to smoking, to avoid the deleterious effects of smoking. *Id.* at 25-26.

After the IOM issued its report, there was little or no response to it from NIDA or ONDCP, nor any change in policy. Tr. at 339. Indeed, as Dr. Roberts testified, ONDCP's (and NIDA's) policy remained opposed to using the plant marijuana as medicine while it supported the use of Marinol. Tr. at 343-47.

B. NIDA's Conditions For Providing Marijuana to Researchers Are Unique Among Controlled Substances.

NIDA has provided researchers access to certain controlled substances through its Drug Supply Program. Tr. at 1625. Although the Drug Supply Program includes other Schedule I substances, marijuana is one of the few drugs for which NIDA is the sole supplier. Tr. at 1644.

NIDA makes its marijuana available to researchers in one of two ways. If NIDA or NIH agrees to fund research, it provides the marijuana free of charge to the researcher. Tr. at 1633. If the researcher does not seek NIH funding, but seeks simply to purchase marijuana from the Drug Supply Program, the researcher must submit its FDA-approved protocol to a Public Health Service Committee for "peer" review of the protocol. Tr. at

1625-28. The PHS Committee reviews the protocol under NIDA guidelines, and decides whether to grant the application or deny it. Gov't Ex. 24, Tr. at 1632-33.

Three critical differences distinguish research requests to purchase marijuana from requests to purchase all other Schedule I substances. First, unlike other Schedule I substances of interest to researchers, NIDA has an absolute monopoly on medical marijuana in the United States. There are a variety of other sources for most other Schedule I substances. To take just one example from the many chemical supply companies operating in the U.S., Sigma/Aldrich Chemicals lists thirty Schedule I substances available commercially for researchers. Resp. Ex. 59. But a researcher can currently obtain marijuana for medical research *only* from NIDA.

Second, as NIDA's Dr. Steven Gust made clear, the research protocol review process required for marijuana research is unique among all controlled substances. For requests to purchase substances other than marijuana, NIH uses an "ad hoc" peer review that relies largely on outside (non-government) experts in the area of the proposed research. Tr. 1627 - 1628,1632-33. But for requests to purchase marijuana for medical research, the PHS Committee consists of *government employees*, including a NIDA representative. Tr. 1633.

Third, the 1999 Guidance on which NIDA and the PHS Committee rely to determine which requests will be granted, plainly does not aim to provide marijuana for all legitimate medical and scientific purposes, as the CSA specifies must be available. To the contrary, the 1999 Guidance specifically envisions that some legitimate research projects that request marijuana will not be provided with it. For example, the Guidance states, "HHS intends to make available a sufficient amount of research-grade marijuana

to support those studies that are *the most likely* to yield usable, essential data." Thus, if a study is not "the most likely" to yield the data NIDA considers "essential," it will not be provided with marijuana under the plain language of the Guidance. Gov't Ex. 24 at 3. And, the Guidance plainly states which data it considers "essential": the goal of the NIDA marijuana distribution program "must be to determine whether cannabinoid *components* of marijuana administered through an alternative delivery system can meet the standards enumerated under the [FDA requirements] for medical products." Gov't Ex. 24 at 2 (emphasis added). Moreover, although NIDA requires FDA approval before a request will be reviewed for clinical protocols, NIDA simply ignores the fact that the FDA has *already decided* that the protocol has scientific merit and is likely to result in data capable of meeting FDA requirements for approval. 21 C.F.R. § 312.22. As Dr. Gust, NIDA's representative at the hearing candidly agreed, "a privately funded researcher might well obtain the appropriate DEA Schedule I registration, have their protocol reviewed and approved by the FDA and still be denied access to NIDA marijuana by a PHS Committee under the conditions and priorities that are set forth" in the 1999 Guidance. Tr. at 1694.

Thus, the evidence established that the NIDA-required PHS Committee review for scientific merit is redundant. The FDA engages in its own careful and comprehensive review of research protocols. Although Dr. Gust tried to suggest that FDA reviews such protocols only for safety, and not for scientific merit, he was forced to eventually concede that in fact, the FDA does review Phase 2 and 3 submissions for "scientific quality." Tr. at 1726-27.

C. Unlike Other Schedule I Substances Being Researched, The Government Has A Complete Monopoly On the Supply of Medical Marijuana.

Although no statute requires it, and indeed, 21 U.S.C. § 823 appears to forbid it, since that statute requires a sufficient number of bulk manufacturers to ensure adequate competition, the National Institute on Drug Abuse has an absolute monopoly on medical marijuana in the United States.

First, the DEA has licensed only one entity in the country as a bulk manufacturer of marijuana. That entity is The National Center for the Development of Natural Products, a project at the University of Mississippi headed up by Dr. Mahmoud ElSohly. Gov't Ex. 74, 75.

Second, the marijuana Dr. ElSohly grows for use in medical research is strictly controlled under a contract with NIDA. Indeed, his testimony was that although he can grow other marijuana for his own research purposes, or to make THC extracts his University can then sell to a commercial pharmaceutical company, he is not permitted to distribute any medical marijuana except as NIDA directs. TR. at 1393-94.[3] Thus, by contract and by license, only NIDA can determine research can be done with the only marijuana grown and available for medical research in the nation. *Id.*

[3] Interestingly, Dr. El Sohly appears not to have known, at least for some time period, that his license was so limited. He indicated to Dr. Doblin in the late 1990's that he would consider contracting directly with MAPS to provide Dr. Abrams with medical marijuana for his research, though he later declined to do so. Tr. at 504, 515-518. And even when he was drafting his objections to Dr. Craker's application for a bulk license in 2003, he clearly believed that he could certainly provide medical marijuana "to researchers that are properly registered with the DEA and that for some reason do not want or do not choose to go through the NIDA program or somehow do not qualify to receive materials under the NIDA program." Resp. Ex. 5. Though he later characterized that position as a "big boo-boo", (Tr. at 1397-99) it is a straightforward assertion in the letter. It is not credible that he knew that information to be wrong when he wrote it. Rather, it is more likely that NIDA, who critiqued and edited the letter, informed him of their view and he took NIDA's view as his own.

D. NIDA's Marijuana Does Not Meet A Rational Drug Development Sponsor's Requirements For Product Development.

It is undisputed that MAPS seeks to develop botanical marijuana as an FDA-approved prescription drug. Tr. at 551, 580, 647. Evidence presented at the hearing conclusively established that that goal cannot be accomplished, or even attempted, under NIDA's current monopoly control. Dr. Irwin Martin was qualified as an expert in new drug development. Based on his lengthy experience in that field, he testified that one of the first questions any drug developer must ask before even starting to try to develop a particular product is whether the developer has a consistent and reliable source that the developer can control, from which the developer can obtain a consistent product. Tr. at 117-120. Dr. Martin noted that control of the formulation of the product was essential for FDA approval, because the developers must repeatedly demonstrate that the product is consistent and has the same potency from the beginning of the research to distribution of the product as an approved drug. Dr. Martin stated: "One of the biggest problems in drug development is the unfortunate need sometimes to repeat studies. If you have a new formulation or your drug source has changed, you may need to repeat years worth of data because you can no longer assure that the data you developed with this earlier version of this drug will actually be the same as the drugs you now have." Tr. at 118; *see also* Tr. at 109. For these reasons, Dr. Martin concluded, "If you know from the beginning of the development that you're not going to have a reliable consistent source, *the impact is no development*. No company, no reasonably business-oriented company would ever develop a product." Tr. at 120 (emphasis added).

The government's expert witness, Dr. David Auslander, confirmed Dr. Martin's expert testimony. After discussing the problems that could be caused if a sponsor of a

botanical product has to switch sources for that product in the middle of the FDA approval process (Tr. at 2026), he concluded that a consistent source within the sponsor's control was a very important factor in choosing to move forward. In particular, Dr. Auslander testified as follows:

> Q: Based on what you just testified to, if you were advising a pharmaceutical development company that was seeking to take a botanical to market, would you advise them to obtain control of a reliable and consistent source to avoid these concerns that we've discussed?
>
> A: Well, I think it would be important, clearly. Companies should have a consistent source, pipeline. It makes good business judgment and good business sense and good scientific sense, foremost, that the sponsor company should have a source which is pretty well established to avoid the complexities going down the road.

Tr. at 2033. *See also* Tr. at 437.

Thus, the evidence is uncontested that to develop a pharmaceutical product, a developer must have assured access to a reliable, dependable source of the particular formulation of the product the developer needs, both for research, and for distribution if the product is approved. Without such a source, as Dr. Martin said, there is no development.

Numerous witnesses also testified that an important part of the FDA approval process is the Drug Master File. According to the undisputed testimony, even before the Phase I and Phase II studies on a product, the developer must generally submit a Drug Master File containing the processes, procedures, qualifications, validations, analytical data, and manufacturing process for the product being proposed for testing and approval.

Tr. at 448, 1208-1210.[4] It is uncontested that a particular Drug Master File is proprietary; the owner may license its use or give permission, but there is no procedure to force that owner to make a Drug Master File, or the information in it, available to a drug developer. Tr. at 447-449.

Dr. ElSohly testified that NIDA owns the Drug Master File for the NIDA marijuana Dr. ElSohly grows. Tr. at 1209. It is also undisputed that NIDA has submitted that Drug Master File to the FDA and has allowed the researchers whom it chooses to supply with marijuana to rely on that file. The FDA's approval of the limited Phase I and Phase II studies that have been permitted with NIDA's marijuana is based, in part, on the information contained in that file. Tr. 1210.

The evidence is also overwhelming that NIDA, whose mission is to study and understand the harmful effects of drug abuse, would not be likely to choose to serve as the supplier to a medical marijuana pharmaceutical product developer even if it were authorized to do so. As to NIDA's unwillingness to supply 10 grams of marijuana for research, NIDA Director Dr. Nora Volkow declared: "It is not NIDA's role to set policy in this area or to contribute to the DEA licensing procedures. Moreover, it is also not NIDA's mission to study the medicinal use of marijuana or to advocate for the establishment of facilities to support this research." Resp. Ex. 13. In addition, the 1999 Guidelines NIDA uses to determine whether or not to supply marijuana to an independently-funded researcher with an FDA-approved protocol specifically state: "The goal of this [NIDA marijuana distribution] program must be to determine whether cannabinoid components of marijuana . . . can meet the standards enumerated under the

[4] Although Dr. Auslander questioned whether the FDA requires a Drug Master File in all cases, he certainly agreed that, either through the Drug Master File or some other compilation, the FDA would require detailed information about the chemistry and manufacturing control data for the product. Tr. at 2023-2025.

[FDCA] for commercial marketing of a medical product." Gov't Ex. 24 at 2. And it expressly states that "the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug." *Id.*[5]

Further, it is not at all clear that NIDA *could* serve as a source for a pharmaceutical product. Dr. ElSohly explained that he had to grow marijuana separately for THC extract the University was developing commercially because neither he nor others could use "government material to prepare things that you would eventually have [in] a commercial product." Tr. 1463. Indeed, Dr. ElSohly went further and agreed that "if somebody wants to develop a commercial product with marijuana, they could not use the NIDA marijuana." *Id.* Nor did the government introduce any evidence that NIDA could or would do so to support its claim that NIDA's supply is adequate to meet all legitimate medical and scientific purposes.

Dr. ElSohly and others have also indicated that NIDA is not in the business of offering new products. Dr. ElSohly testified that while NIDA is sometimes willing to allow him to make up special materials other than what is available in the inventory, "[T]hey [the researchers] have to have a good justification as to why we need to make a new batch." Tr. at 1598. And researchers agree. Reflecting on whether NIDA could or would provide a higher potency product, Dr. Igor Grant, the Director of the Center for Medicinal Cannabis Research ("CMCR") noted that CMCR researchers "had concerns that NIDA would say they are not into product development. They (NIDA) usually leave these issues to the manufacturing sector." Gov't Ex. 16 at 18. Here, of course, if NIDA

[5] Although Dr. Gust tried to suggest that NIDA could fund and provide marijuana for research even if the goals of that research, are inconsistent with stated NIDA policy, that testimony is simply inconsistent with the explicit statements to the contrary in departmentally-published guidelines. Gov't Ex. 24.

maintains its monopoly, there is not, and can be no "manufacturing sector" to develop those products desired by researchers, and eventually, by consumers.

E. NIDA Does Not Provide Medical Marijuana To All Legitimate Researchers.

The undisputed evidence is that NIDA has refused to provide marijuana to at least three legitimate researchers.

1. *Dr. Donald Abrams was unable to obtain marijuana for legitimate medical research.* One of the leading AIDS researchers in the country, Dr. Donald Abrams, sought to investigate whether marijuana could assist patients suffering with AIDS wasting syndrome. Tr. 493-495. With a small grant from MAPS, he designed a study in 1995 that was:

> (i) approved by the Committee on Human Research at the University of California at San Francisco, the institution where the research would be conducted;
>
> (ii) approved by the Scientific Advisory Committee and Community Advisory Forum (the San Francisco Bay Area review panel for research involving AIDS);
>
> (iii) approved by the California Research Advisory Panel (the state of California's reviewing body for research involving Schedule I and II drugs); and
>
> (iv) approved by the FDA after the FDA had been involved in developing the study and strongly influencing its design.

Id. at 495-496; Resp. Ex. 15.

Once all these approvals were obtained, Dr. Abrams applied to NIDA solely to obtain medical marijuana to use in his research. Dr. Abrams did not seek NIDA funding, or indeed, any federal funding of any kind. He asked only that NIDA, the only source in the United States from which he could legally obtain the supply to conduct the approved medical research, provide the marijuana for the medical research. Tr. at 496-97.

But NIDA refused. After refusing to respond to Dr. Abram's request at all for nine months, NIDA finally notified Dr. Abrams that his study, approved by four different review entities with expertise in reviewing and designing medical research studies, *including the FDA*, did not meet NIDA's qualifications. Tr. at 494-502; Resp. Ex. 15. Thus, NIDA refused to provide the marijuana necessary to conduct the research on AIDS wasting that Dr. Abrams wanted to explore. Although MAPS and Dr. Abrams tried to locate other sources, including importing medical marijuana from Netherlands, and contacting Dr. ElSohly to see whether they could purchase marijuana directly from him, those avenues were closed off as well. Dr. Abrams had to abandon his AIDS wasting research protocol.[6] Tr. at 503-522.

2. *Dr. Ethan Russo was unable to obtain medical marijuana for legitimate FDA-approved medical research.* Dr. Russo is a neurologist specializing in migraines. Tr. at 527. Based on indications that marijuana might be efficacious to treat migraines, Dr. Russo originally attempted to obtain government funding from the National Institutes of Health in 1996-1999 to conduct research on that issue. After those requests for funding were denied, MAPS and Dr. Russo decided to fund the research privately. Tr. at 527. Again, the Institutional Review Board in the facility where the research would be done *and the FDA* both approved Dr. Russo's protocol. *Id.* NIDA, however, refused to provide the marijuana necessary to conduct the research. Tr. at 527. Responding to a letter from NIDA, Dr. Russo stated, "The only reason I have not completed my FDA-

[6] After California Proposition 215 became law, making use of medical marijuana legal under state law in 1996, Dr. Abrams sought funding and marijuana from NIDA to conduct research about the *risks* of using marijuana in AIDS patients. NIDA precluded him from conducting this research with the AIDs wasting patients he had originally tried to do research with. Thus, the 4-time-approved AIDS-wasting research he wanted to do was never permitted to be started or completed because there was no supply of medical marijuana. Tr. at 522-525.

approved clinical study of cannabis in migraine is that NIDA refused to supply the material." Gov't Ex. 30B. He continued by noting the poor quality of NIDA cannabis, especially as compared with clinical cannabis available elsewhere, and he concluded, "Considering that millions of dollars may be required to complete Phase III clinical trials, no sponsor of cannabis research is likely to accept a situation in which they have no say or control over the product that they hope to be marketing in the future." *Id.*

3. *Chemic Labs was unable to obtain ten grams of marijuana for legitimate scientific research.* Because the IOM and others have called for development of non-smoked delivery devices to deliver the therapeutic benefits of marijuana without (or with fewer) harmful effects, MAPS first sponsored testing with water pipes. When the results of those tests showed the device did not work well, MAPS determined to investigate the potential of a vaporizer.[7] Tr. at 530, 31. Thus, MAPS requested Chemic Labs to conduct a laboratory study testing a vaporizer with different kinds of marijuana to determine what constituents of marijuana would exist in the vapor and at what levels. Tr. at 530-532. Chemic is a DEA-licensed contract research lab that works with many companies in the pharmaceutical industry. Tr. 549. Chemic applied to receive, *and pay for*, 10 grams of NIDA marijuana on June 24, 2003. It also applied for a permit to import ten grams from the Netherlands, where the government makes available what NIDA does not -- a strain of medical marijuana with higher levels of THC and of cannabidiol ("CBD," another cannabinoid believed to have useful therapeutic properties). Tr. at 531-32. The aim of the research was to vaporize both kinds of marijuana, evaluate what was in the vapor, evaluate whether THC was carried in the vapor (and how much), and

[7] The vaporizer heats the medical marijuana to just below the point of combustion, so that when the cannabinoids are released, they are not accompanied with the harmful substances created by combustion.

evaluate whether CBD from the Dutch marijuana was also present in the vapor (and how much). MAPS planned to use this Good Laboratory Practices laboratory research to submit information to the FDA about how the vaporizer device works and how substances used in it can be measured, as preliminary information necessary to conduct further testing with the vaporizer. Tr. at 532-533.

After a delay of over *two and a half years*, NIDA (through the PHS Committee) finally informed Chemic that it would not provide the ten grams in part because the proposed study did not present "clinical potential," and because "some of this [GMP internal protocol] work has previously been conducted." Resp. Ex. 52B. Chemic promptly responded to these comments by noting that (1) the protocol stated clearly that it was not seeking marijuana for clinical testing and (2) the previous vaporizer studies were "proof of concept studies supporting the development of the protocolled cGMP study" that would be necessary to support future clinical studies with the vaporizer. Resp. Ex. 55. But, in reliance on its 1999 Guidance, which gives priority to clinical research and to the development of isolated cannabinoids rather than botanical marijuana, (Gov. Ex. 24), NIDA has refused to provide ten grams of marijuana necessary for Chemic to develop what even NIDA conceded would be information required by the FDA for anyone seeking to develop an alternative delivery system using botanical marijuana. Resp. Ex. 52B.

4. *The Center for Medicinal Cannabis Research Obtained NIDA Marijuana When It Conducted Research Not Aimed at Product Development.* As a result of state initiatives allowing some patients to use medical marijuana under state law, and of growing interest in the medicinal value of cannabis, California funded fifteen research

projects to evaluate the efficacy of marijuana for various medical conditions. Tr. at 395-99. After PHS Committee review, NIDA provided medical marijuana to those researchers. Tr. at 400-402. The evidence established, however, that CMCR had no intention of seeking FDA approval of a marijuana as a prescription product. Tr. at 403. It is also clear that no further funding is available from California. *Id.*

The CMCR research is not typical. Although NIDA's representative did not apparently investigate before he came to testify the actual numbers of how many requests to purchase marijuana for medical research it has granted, he admitted that he thought there might be five or so instances over the previous ten years, outside the CMCR research, in which researchers with FDA-approved clinical protocols were allowed to purchase NIDA marijuana in non-government-funded research. Tr. at 1753. And the evidence has shown that at least two additional such researchers---Dr. Russo and Dr. Abrams—were denied NIDA marijuana. So out of what NIDA says were seven FDA-approved clinical requests to purchase marijuana over ten years, NIDA rejected two of those requests, resulting in a denial rate of almost 30%.

F. The Quality of the NIDA Marijuana Raises Concerns for Researchers and Patients.

Despite the insistence of the government that neither NIDA nor Dr. ElSohly ever heard any "formal" complaints about the quality of the medical marijuana NIDA was distributing, the evidence is clear that researchers and patients have quality concerns. To look into the quality claims that Dr. Craker raised in his application, DEA interviewed eight researchers who used NIDA marijuana. Gov't Ex. 16, 17, 18, 19, 20, 21, 22, 28. Six of those researchers were associated with California's Center for Medical Cannabis Studies. Tr. at 801. Two others were NIDA-funded researchers with DEA licenses who

were located close to Washington. Tr. at 1078. Out of eight researchers interviewed, *six* of them identified concerns with the NIDA product. Those concerns ranged from consistency of potency to freshness of the marijuana, to seeds and stems being included in the product, to the need for higher potencies to use for research.

Patients using NIDA's marijuana product echoed these concerns. NIDA provides marijuana for use by the FDA's Compassionate Investigational New Drug patients, a small group of patients for whom the United States government regularly provides medical marijuana. Resp. Ex. 19 at p. 47. Dr. Ethan Russo studied the long term effect of marijuana on these patients, gathered information about the quality of the marijuana product NIDA provided, and published those findings. Resp. Ex. 19; *see also* Resp. Ex. 57.

1. NIDA's Marijuana Is of Inconsistent Potency.

Judging from the responses to the DEA interviews, consistency of potency is a serious issue. The chart below shows DEA questions and researchers' answers on this issue.

Researcher	DEA question	Researcher Response
CMCR Representative (Dr. Igor Grant) Gov't Ex. 16	Have you ever had any difficulty obtaining marijuana from NIDA for all strengths of cigarettes to meet research requirements?	Yes. Having consistency of 6% -8% have been difficult. They (NIDA) have been accommodating by trying to produce the high % production in a timely manner.
	Do you feel that any problems you've experienced could be remedied by the addition of a second supplier?	The one area we might like to see more reliability on is the strength of the medical marijuana cigarettes. We know this is difficult with plant

		materials, but we were told that GW has a very sophisticated procedure of better genetic engineering. They appear to be able to predict the concentrations. They [researchers] don't know if U Miss does that, but GW can guarantee with more certainty. If that were possible it would lessen the degree of uncertainty.
CMCR Representative (Dr. Igor Grant) Gov't Ex. 16	Is the potency of the current product consistent?	No -- there is variation along the target that NIDA ensures to be within.
Dr. Ronald Ellis Gov't Ex. 17	Is the potency of the product consistent?	No. At least 2 shipments, some variability in the stated THC and the actual measured. They have been very responsive.
Dr. Donald Abrams Gov't Ex. 21	Is the potency of the product consistent?	No. Originally approved for 3.9% THC content, midway through the "Short-term effects . . ." protocol, NIDA informed [us] that the potency had been downgraded to 3.5%. Everything since is said to be at 3.5%.

These concerns about consistency are not surprising in light of Dr. ElSohly's concession that the NIDA marijauna could easily be 20% more or less potent than it was labeled. Dr. ElSohly testified that to make different potency levels, NIDA marijuana is made by mixing up different potencies. He testified that to provide materials at six percent, they would have to manufacture them at approximately seven or seven and a half percent to account for losing potency through the manufacturing process. Tr. at 1198-99.

He continued: "Now if we don't have material exactly at seven, seven and a half percent, we will have some material from five percent, some from ten percent, some from eleven percent, some from nine percent to make a big batch and then combine this, and then when it goes through the manufacturing process, there is mixing process that will modualize the plant material so that all is the same that goes into the cigarette-making machine." Tr. at 1199-1200. He then testified he was "allowed" to distribute marijuana that ranged in THC potency by as much as plus or minus 20%, so that cigarettes that were labelled as 8% THC could be anywhere "between 6 and 9.6 percent." Tr. at 1294. In response to concerns from researchers about the difference, Dr. ElSohly's response was, "You have to live with what you get." Tr. at 1277.

As Dr. Grant's comments, especially, highlight, there are organizations that produce a far more consistent product, such as GW Pharmaceuticals in England. Gov't Ex. 16 at 9. Moreover, the evidence clearly established that plants grown from cuttings, or vegetative propagation, would be genetically identical, and, if grown indoors, subject to the same conditions, would be environmentally identical. Thus, if the same parts of the plants were harvested (the buds of female plants, for example) the percentage of THC and other cannabinoids in the resulting product would likely be far more consistent than mixing leaves, buds, stems, and seeds, and determining the THC content of that varying mix.

2. NIDA's Marijuana is Harsh.

Both researchers and patients also noted the harshness of NIDA marijuana.

Researcher	DEA question	Researcher Response
CMCR Representative (Dr. Igor Grant) Gov't Ex. 16	Have any patients ever complained about the "freshness" of the marijuana	Yes. "Harsh" Occasionally produces cough.
Dr. Ronald Ellis Gov't Ex. 17	Have any patients ever complained about the "freshness" of the marijuana?	Yes. Some patients have reported that the smoke was "harsh" and it was hard to finish the cigarette. Cannabis-naïve patients are allowed, but most if not all are experienced cannabis users. One patient removed because of cough only.
Dr. Jody Corey-Bloom Gov't Ex. 18	Have any patients ever complained about the "freshness" of the marijuana?	Recently 1 of 10 patients complained of the product being "harsh." Didn't explore what the means, don't know if it was placebo or active.
Dr. Donald Abrams Gov't Ex. 21	Have any of the issues discussed regarding quality of research-grade marijuana adversely impacted your research?	Yes. A few patients have terminated early due to the harshness (quality). 4 out of 50 have dropped out because of quality.
Dr. Donald Abrams Gov't Ex. 21	Additional comments	[A] few [patients] dropped out due to harshness of cig.
Dr. John Polich Gov't Ex. 22	Have any patients ever complained about the "freshness" of the marijuana?	Yes. Out of 100 plus subjects, no more than 3 may have commented that the product was "harsh."

In addition to the concerns expressed by researchers, patients who have used NIDA marijuana have noted

> "'that the marijuana is inferior in sensory qualities (taste, harshness) than the marijuana they smoke outside the laboratory. Some have stated it was the worst marijuana they had ever sampled, or that it tasted 'chemically treated.'"

> All the study patients criticize the paper employed to roll the cannabis cigarettes as harsh. and tasting poorly.

Resp. Ex. 19 at 48.

And other patients concur. The evidence showed that a patient named Phil Alden, who had previously smoked non-NIDA marijuana for his medical condition without respiratory problems, had to drop out of a CMCR medical marijuana study because the NIDA marijuana he was required to use in that study caused him to develop bronchitis.[8] Tr. at 722. When he stopped using the NIDA marijuana, his bronchitis cleared up and did not recur when he began to use non-NIDA medical marijuana again for his medical condition. Tr. at 725-26.

3. The Medical Marijuana NIDA Distributes Is Frequently Several Years Old And Not Fresh.

As noted above, several researchers also raised concerns about the freshness of the NIDA medical marijuana product by referring to its harshness. In addition, patients who use NIDA medical marijuana have raised similar issues. As Dr. Russo's article indicated, "NIDA cannabis is shipped to patients in labeled metal canisters containing 300 cigarettes (Figure 4), and material is frequently two or more years old upon receipt. Even under optimal storage conditions, a certain degree of oxidation of cannabinoids can be expected. Most consumers prefer a supply of cured cannabis that is as fresh as

[8] Although Mr. Alden had originally agreed to testify at the hearing on the issue of the quality of NIDA marijuana, as was set forth in Respondents' Supplemental Prehearing Statement, he was later advised by his attorney that he should not do so without a grant of use immunity because his medical use of marijuana, while completely legal under California law, is illegal under Federal law. The DEA refused to grant that immunity, and Mr. Alden therefore declined to testify directly. Tr. at 722. He did communicate directly with Dr. Doblin about his experience, and asked Dr. Doblin to report to the Court what he had said. Tr. at 726-28. Given his legitimate concerns as to questions the DEA would likely have asked him on the stand, (based on the questions DEA counsel asked Dr. Doblin about Mr. Alden's medical marijuana use (Tr. at 728)), the court should not discredit the testimony relating to Mr. Alden's experience simply because he did not take the stand himself. Indeed, the testimony about his experience with NIDA marijuana, but not with other marijuana, is corroborated by a San Mateo County newspaper article. Gov't Ex. 30A.

possible." Resp. Ex. 19 at 48 (internal citation omitted). This consumer preference was confirmed by Dr. ElSohly, who testified, "[T]he fresher the material is, the better the material is." Tr. at 1573.

But the NIDA contract requires the opposite. It specifies, "All stock items shall be maintained on a first-in, first-out (FIFO) inventory system, unless otherwise designated by the Project Officer." Gov't Ex. 13 at 7. Thus, without special permission to use the fresher product, Dr. ElSohly and RTI are required to use up the older medical marijuana before providing the fresher product to researchers. Moreover, Dr. ElSohly testified at the hearing in December 2005 that the last crop he'd planted had been in "the 2001-2002" timeframe. Tr. at 1253. So even if he were sending the freshest material he had available (instead of the oldest, as the contract requires), a patient receiving NIDA's medical marijuana today would be receiving marijuana that is 4-5 years old. And Dr. ElSohly's inventory shows that some of the NIDA medical marijauna available for research use was grown in 1997 and 1999. Resp. Ex. 53 (the two-digit number after the letters in the Description category is the year the material was grown, Tr. 1577).

4. NIDA's Available Product is Low-Potency.

Several researchers commented on the need for a higher potency product.

Researcher	DEA question	Researcher Response
CMCR Representative (Dr. Igor Grant) Gov't Ex. 16	Do you feel it would be important to evaluate the efficacy of a higher potency cigarette for your patient population?	Yes. Benefits: Cancer population (terminal) not uncommon to have high consumption of drugs for pain. Less tars/smoke. Efficacious dose may be achievable with higher strengths/lower number of inhalations.

		Risks: No perceived risk because toxicity is not an issue. There is dependence/tolerability that may be of concern.
CMCR Representative (Dr. Igor Grant) Gov't Ex. 16	Does any information favor or suggest that a higher potency produce would have a beneficial outcome as compared to current product provided by NIDA?	Yes.
CMCR Representative (Dr. Igor Grant) Gov't Ex. 16	Has the CMCR made any contact with NIDA to ascertain the feasibility of producing a higher potency product?	Yes. Have not addressed specifically. They could see the utility. It was Dr. Grant's impression that 8% was the highest limit, perhaps future. They do have concerns that NIDA would say they are not into product development. They (NIDA) usually leave these issues to the manufacturing sector.
Dr. Ronald Ellis Gov't Ex. 17	What is the potency of the marijuana cigarettes currently approved for use in your research?	8% received, but tested potency was approx. 7%.
Dr. Donald Abrams Gov't Ex. 21	Do you feel that it would be clinically important to evaluate the efficiency of a higher potency cigarette for your patient population?	Yes. Benefit: consume less to achieve a pharmacologic dose. Would more closely resemble what they consume on the street. Risks: They may have more dysphoric effect. Notes benefits would outweigh the risks.
Aron Lichtman Gov't Ex. 28	Is the current product adequate for your research purposes with regard to potency?	No. They would prefer something at a higher potency, but at the time, 3-4% was the highest potency available. This is

		based on what they've read about regarding availability in the UK.

In addition to these concerns, Dr. Russo's study indicated that medical cannabis patients preferred a higher potency product, but that they could not get it from NIDA. Resp. Ex. 19 at 47. After noting that the strongest potency product NIDA had was 5%, Dr. Russo continued, "[i]t was further stated that the strongest material was not provided to patients in their cigarette shipments because it was too sticky and would interfere with the rolling machines' functioning." Resp. Ex. 19 at 48 (citing Personal Communication to EBR [Dr. Russo], Steve Gust, December 1999).

As Dr. Doblin testified, "NIDA's marijuana has been low potency, low THC marijuana, and when you do the risk-benefit analysis of a drug . . . the higher potency marijuana means that people would inhale smaller percentage of particulate matter per therapeutic cannabinoids. So I felt that we needed to experiment with higher potency strains that had other cannabinoids in it as well as THC." Tr. at 552.

The evidence established that NIDA's inventory offers medical marijuana cigarettes with a THC potency up to 7%. Tr. at 1265. Dr. ElSohly also testified that he had, one time, hand rolled an 8% THC medical marijuana product, and that they have in their inventory, bulk marijuana with a higher THC percentage, up to 13 or 14 %. Tr. at 1203. However, Dr ElSohly also testified that NIDA did not make cigarettes at potencies higher than 4% until sometime "past 2001." Tr. at 1454. (Interestingly, Dr. Craker filed his application raising potency issues with NIDA's medical marijuana in 2001.) He also testified that although he could grow the NIDA medical marijuana indoors under environmental controls, he has never done so. Tr. at 1459.

Finally, the uncontested evidence also established that in Canada, the government distributes medical marijuana with 12.5% THC, and the Dutch government distributes medical marijuana with 13 to 18% THC. Moreover, Dr. ElSohly testified that to his knowledge, neither he nor NIDA had ever contacted any researchers to ask what they might want or need in a medical marijuana product. Indeed, when he was asked whether he had ever spoken to doctors or researchers to determine what level of THC potency they would want to use for their research, he responded: "I think it's—it's kind of—takes the point away from the scientific end of it when you say what they want to do with it." Tr. at 1388. When pressed again as to whether he had talked with any researchers about their desired potency levels, he responded, "They haven't talked to me." Tr. at 1389.

5. NIDA's Marijuana Has Included Stems and Seeds.

Several researchers indicated the NIDA medical marijuana product they saw included stems and seeds.

Researcher	DEA question	Researcher Response
Dr. Donald Abrams Gov't Ex. 21	Have you observed physical deformities in the appearance of the cigarettes?	No, nicely rolled, but there is a loss of material in the can from dropping out of the cigarette as a result of the freeze/thawed process. Rolling the ends would prevent loss.
Dr. Donald Abrams Gov't Ex. 21	What plant parts have you observed in the cigarettes you obtain for research?	seeds, leaf, some stems.
Dr. Donald Abrams Gov't Ex. 21	In your professional opinion, do any of the plant parts make the cigarettes unacceptable for your research?	Yes. If the goal is to mimic that which is being consumed in the SF area, then it would seem inappropriate to have stems and seeds in them. Also, trying to minimize those components

		resulting from smoke that are harmful while at the same time raising the medicinal value of THC.
Aron Lichtman Gov't Ex. 28	What plant parts have you observed in the bulk material you obtain for research?	Leaves, seeds, buds, twigs.

The compassionate use patients were similarly concerned with the material in the cigarettes. Part of Dr. Russo's study involved examining the NIDA cigarettes:

> A close inspection of the contents of NIDA-supplied cannabis cigarettes reveals them to be a crude mixture of leaf with abundant stem and seed components. The odor is green and herbal in character. The resultant smoke is thick, acrid, and pervasive.
>
> In contrast, a typical sinsemilla "bud" is seedless, covered with visible gladular trichomes, . . . and emits a strong lemony or piney terpenoid scent. The smoke is also less disturbing from a sensory standpoint to most observers.

Resp. Ex. 19, 49-51.

Those patients also unrolled three of the NIDA marijuana cigarettes for photographic documentation. *Id.* at 49-50. The picture plainly shows the presence of significant seeds and sticks. *Id.* Indeed, the photograph so plainly demonstrates the poor quality of the cigarettes that Dr. ElSohly testified "it's hard for me to believe that those are materials from—actually coming from a cigarette." Tr. 1600. And, he was so unwilling to admit that the pictures were of his product, that he resorted to suggesting that perhaps the caption of the pictures contained a typographical error. Tr. at 1602-03 ("That could be a typo . . ."). However, as the article made clear, and as witness Al Byrne, who was present when the photograph was taken, confirmed, the photograph was of three unrolled NIDA cigarettes, and it "accurately depicts the marijuana leaves, seeds, and stems, and the sizes of the leaves, stems and seeds relative to each other, as they existed

at the time the marijuana cigarette was unrolled and the photographs taken in my presence." Resp. Ex. 57 at 1. Indeed, Mr. Byrne went on to note that because of the constant presence of seeds and stems, "[m]ost of the patients felt it necessary to open each cigarette in order to cull out the seeds and stems. When smoked, stems were harsh and the seeds often exploded as well as having some negative therapeutic value. " *Id.*

In sum, the evidence demonstrated serious concerns about the quality of NIDA's medical marijuana for researching the beneficial effects of marijuana. The NIDA product may be suitable for its more common use—NIDA-funded research into the harmful effects of marijuana, where there is little concern about whether the test subjects' views about quality since the research does not intend the subjects ever to use it again. But testing in sick people for medical benefits involves a very different purpose and requires a product that patients can use without distaste. The NIDA marijuana does not meet that need very well.

G. MAPS Seeks to Sponsor Developing Marijuana as an FDA-Approved Medical Product As It Has Sponsored Developing Other Medical Products.

The evidence established that MAPS serves here as the sponsor of Dr. Craker's application for a bulk manufacturer's license. It is undisputed that MAPS seeks to develop marijuana into an FDA-approved prescription product. *E.g.* Tr. at 551, 580, 647. Moreover, Dr. Doblin testified that based on his knowledge of the current state of evidence about the safety of marijuana, and his experience in sponsoring other drug development, MAPS believes it can carry out the necessary trials at a cost of between $5 million and $10 million. Tr. at 700-701, 736-740. He also testified that once a source for the medical marijuana is available, he believes MAPS can raise adequate funds to accomplish that goal. *Id.*

The uncontested evidence also establishes that MAPS and Dr. Doblin have experience in sponsoring the development of other Schedule I and Schedule II substances as potential medical products. For example, MAPS holds a Drug Master File on MDMA, a Schedule I substance since 1986. It has sponsored and is currently sponsoring FDA-approved research in Charleston, SC, into the use of MDMA-assisted psychotherapy in subjects with treatment-resistant post traumatic stress disorder, and has designed, obtained approval for, and arranged funding for a study at Harvard Medical School using MDMA in subjects with anxiety associated with advanced stage cancer. Tr. at 483. Those MAPS studies are conducted by DEA-licensed researchers. In addition, MAPS is sponsoring MDMA studies in Israel and Switzerland relating to post-traumatic stress disorder, and has a study in the design and approval process in Spain. Tr. at 483. MAPS can and has obtained MDMA from several non-governmental commercial manufacturers in the United States for the researchers to use. Tr. 485-86.

MAPS has similarly sponsored FDA-approved and DEA-licensed research with psilocybin, another Schedule I substance. Tr. at 486. When NIDA refused to sell MAPS the half-gram it applied for to conduct the already FDA-approved study, MAPS purchased the psilocybin from a non-governmental commercial producer. Tr. at 487. Researchers at the University of Tucson, sponsored by MAPS, were then able to conduct promising research into whether psilocybin may be helpful in the treatment of obsessive/compulsive disorder. Tr. at 486-87. MAPS has also sponsored medical research with other controlled substances, including research to determine whether ketamine and ibogaine may be of some use in the treatment of alcoholism and heroin addiction. Tr. at 478, 489-90.

In addition to its interest in developing medical marijuana for other conditions, MAPS has an existing financial interest in that development. In May, 1999, the FDA granted MAPS an orphan drug designation for marijuana. Resp. Ex. 12. The approved orphan drug use is to treat AIDS-associated wasting syndrome. *Id.* If MAPS could sponsor research into AIDS wasting and could thereby obtain FDA approval of medical marijuana for that use, MAPS would then have the exclusive right to distribute that product for seven years. Tr. at 121-24, 576-78. But when MAPS worked with Dr. Abrams to research whether marijuana was helpful for AIDS wasting, NIDA denied access to the marijuana, and, in a later study, specifically prohibited Dr. Abrams from researching the AIDS wasting patient population. Tr. at 523-34. Thus, due to the NIDA monopoly, MAPS has been wholly unable to pursue developing the medication the FDA has specifically authorized MAPS (and no one else) to pursue.

The evidence establishes that MAPS' goal in working with Dr. Craker to obtain a DEA bulk-manufacturer's license is to sponsor research, and possibly eventual development of marijuana into an FDA-approved medicine. Dr. Doblin testified:

> [F]rom my understanding, NIDA is authorized to provide marijuana for research, but they are not in the business, as Dr. Volkow says, of trying to support medical marijuana research nor are they authorized by Congress to go into the business of selling marijuana for prescription use. And so what I wanted was a product that we could do the initial clinical studies with that we would have a guarantee would be available for prescription use should FDA decide that that would be acceptable.
>
> ***
>
> NIDA has a—NIDA's marijuana has been low potency, low THC marijuana, and when you do the risk-benefit analysis at FDA, when they are faced with the risk-benefit analysis of a drug, the higher potency marijuana means that people would inhale smaller percentages of particulate matter per therapeutic cannabinoids. So I felt that we

> needed to experiment with higher potency strains and then we also needed to experiment with strains that had other cannabinoids in it as well as THC.

Tr. at 551-552. [9]

Developing any substance into an FDA-approved product is difficult, and marijuana, is no exception. However, in June 2004, the FDA issued its Guidance for Industry, Botanical Drug Products, which "provides sponsors with guidance on submitting investigational new drug applications (INDs) for botanical drug products" such as marijuana. Gov't Ex. 92A at 1. As the government's expert, Dr. Auslander, testified, these guidelines indicate that "the [FDA] guidelines tend to be a little bit more lenient with botanical drugs than they are with pure synthetic materials," Tr. at 1997. He also pointed out that the Guidance specifically recognizes the complexity of botanicals by requiring certain information only "if known." Speaking of that phrase, Dr. Auslander testified, "Certainly, in a drug substance origin where you have a synthetic origins as opposed to botanicals, you wouldn't have the 'if known' aspects. But the FDA recognizes the complexity of a botanical program and gives a certain amount of allowance by saying 'if known' for a botanical material." Tr. at 2009.

H. Dr. Craker Is Qualified To Hold the DEA License.

1. Expertise In Plant Growth and Propagation

The evidence plainly establishes that Dr. Craker is an eminent plant and soil scientist with substantial experience growing, propagating, and breeding medicinal

[9] DEA witness Dr. Eric Voth, admitted as an expert in marijuana as it pertains to its effects, abuse, and constitutents on humans, agreed that cannabis with different ratios of cannibinoids was an area deserving more research and pointed out that G.W. Pharmaceuticals has found that marijuana with a higher ratio of cannabidiol to THC "is more effective for the things that they're using it [for]." Tr. at 1907. He also noted that a potential medical benefit in smoking marijuana over oral THC "might be the rapidity in absorption." Tr. at 1909.

plants. He is a full professor in the Department of Plant, Soil, and Insect Sciences at the University of Massachusetts, Amherst. He has studied, gathered, and propagated medicinal plants, and has received grants from federal agencies, state governments, and foreign governments to carry out his research. Tr. at 17-22. As Dr. Craker's CV shows, he is the Chairman of the International Society for Horticultural Science ("ISHS") section on Medicinal and Aromatic Plants, founder of the International Council on Medicinal and Aromatic Plants, editor of The Journal of Herbs, Spices, and Medicinal Plants, and editor of The Herb, Spice, and Medicinal Plant Digest. Resp. Ex. 3. He is also a member of the ISHS Working Group on Culture of Medicinal and Aromatic Plants, as well as the author of over 100 scientific articles and numerous books/book chapters relating to plant and soil science. *Id.*

There is no doubt whatsoever that Dr. Craker, and the University of Amherst are qualified candidates for the license Dr. Craker seeks, and the government has not suggested otherwise. To the contrary, even the government's main witness, Dr. ElSohly, agreed that Dr. Craker is an expert in horticulture and medicinal plants:

> Q: And so you don't have any reason to question his [Dr. Craker's] expertise in plant and soil sciences--
>
> A: No, absolutely not, no.
>
> Q: So you would agree he would have an expertise in that area?
>
> A: Sure, yes.

Tr. at 1347.

Finally, the University of Massachusetts, a research institution, fully supports Dr. Craker's application for a license, even in the face of DEA agents trying to discourage the University's administration by noting that the University could get a "bad reputation" if it pursued getting the license to grow medical marijuana. Tr. at 43.

2. Dr. Craker's License Will Promote Scientific and Technical Advances

Dr. Craker also testified that granting him a license will lead to scientific advances and technical advances. He intends to grow a defined medical marijauna product that will meet the potency and constituent requirements of the FDA-approved research (and DEA-licensed pre-clinical non-human research) MAPS sponsors as it works with the FDA in conducting tests aimed at developing an FDA-approved medical marijuana product. Tr. at 33-34. Licensing Dr. Craker will promote scientific advances in four ways:

(1) Because his product would allow research to go forward that was not allowed to go forward by NIDA, it will lead to advances in understanding any possible clinical use of marijuana (Tr. at 75).

(2) Because his product will be grown indoors, under more controlled conditions than the NIDA crop, which is grown entirely outdoors (Tr. at 1509), it will allow Dr. Craker and others to "learn more about how the environment affects the constituents in the plant materials which would enable, if this does become at some stage down the road here, becomes a useful drug, and that the manufacture of it has to be controlled under security conditions, they would know the environment it needs to be grown under to produce a clinical marijuana, medical marijuana." Tr. at 76.

(3) Because one goal of his product is to provide marijuana for use in testing and developing a non-smoked delivery system for botanical medical marijuana, Dr. Craker's license will promote the development of a new and less harmful way of delivering the therapeutic benefits of marijuana, as called for by the Institute of Medicine's report. Tr. at 77-78.

(4) Because the scientific process benefits when more than one scientist tests principles, granting a license would help alleviate the problem created by "the current research . . . being controlled by the Government, because they can choose who they gave the material to to influence the research." Tr. at 366. Dr. Craker added, "in science, we don't go by one thing. We have replicated by different investigators whether things work or not, and that's certainly a principle I adhere to." Tr. at 366.

In addition, Respondent established that an alternative source to the U.Miss. NIDA marijuana will diminish the risk to the national supply system should Dr. ElSohly's or RTI's inventory or current crop be destroyed by flood, fire, Gulf Coast hurricane, or other natural disaster. Tr. at 1347-48.

3. *Dr. Craker's Distribution Will Be Limited to Government-Approved Researchers.*

The evidence shows that Dr. Craker would make any marijuana grown in his facility available *only* to "FDA approved clinical studies that have permission to use this material in clinical trials," and to DEA-licensed researchers doing legitimate non-clinical scientific research. Tr. at 73. As Dr. Craker testified, he would grow medical marijuana to suit the particular requirements of FDA approved researchers identified by MAPS. Tr. at 34.

4. The DEA Has Agreed the U. Mass. Facilities Will Meet Security Requirements.

The evidence was also undisputed that Dr. Craker is familiar with and understands the importance of security procedures. Dr. Craker noted that when he served in the Army, he worked on classified matters involving de-foliation of trees, with significant security restrictions in place. Tr. at 366-67. He further testified that he understood the importance of the security concerns as a bulk manufacturer under a

Schedule I license. Tr. at 367. Respondent has established that the DEA has inspected the building and the rooms in which Dr. Craker plans to grow the marijuana and dry it, and that the DEA agents agreed those facilities, which include a partially underground area, would meet their security requirements. Tr. at 44-45, 354-55. DEA has not notified U. Mass. of any other security requirements, but Respondent has made clear that he will comply with the appropriate conditions, similar to those in place at the University of Mississippi. Tr. at 79.

5. Dr. Craker Has No Criminal Convictions or Record.

Dr. Craker has had no criminal convictions other than one speeding ticket. Tr. at 78-79.

I. Dr. ElSohly And U. Miss. Have A Financial Interest In Remaining the Sole Manufacturer of Marijuana.

Dr. ElSohly holds a non-NIDA manufacturing license in addition to the one he holds to manufacture marijuana for the NIDA Drug Supply Program. Tr. at 1337-38. He is able to conduct his own research with marijuana he grows without having to request it through the NIDA Drug Supply Program and the PHS Committee. Tr. at 1497. Through his research, he has developed an alternative delivery device—a suppository—for ingesting THC. Tr. at 1333. In addition, Dr. ElSohly has had the opportunity to extract THC from the marijuana he grows under his non-NIDA license. He and the University of Mississippi now have an agreement to sell that extract to a commercial pharmaceutical company, Mallinckrodt, who seeks to develop that extract into a generic equivalent of the oral THC capsule Marinol. Tr. at 1465-1466. And to facilitate that agreement, DEA agreed in June 2005 to seek a 500% increase in the national quota (which is the same as

Dr. ElSohly's quota) for growing marijuana. Gov't Ex. 79 at 1. Thus, DEA has agreed that it will allow Dr. ElSohly to increase his crop from 913 kg to 4500 kg, and that it will seek approval of that increase from the United Nations. (Dr. ElSohly and U.Miss. also stand to collect royalties on Mallinckrodt's future sales of its product. Tr. at 1530-34. And because Dr. ElSohly is the only entity authorized to grow marijuana in the country, Mallinckrodt could not look to any other domestic producer for a competitive price or product. Thus, as Dr. ElSohly candidly agreed, "The University of Mississippi has a financial interest in being the only grower of marijuana from which an extract can be produced." Tr. at 1542.

CONCLUSIONS OF LAW

The registration requirements in the Controlled Substances Act direct that the "Attorney General *shall* register an applicant to manufacture controlled substances in Schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." 21 U.S.C. § 823 (emphasis added). By regulation, an applicant for registration as a bulk manufacturer has the burden of proof to demonstrate by a preponderance of the evidence that the requirements of registration are met. 21 CFR 1301.55. The government and any objector bears the burden of proving the facts and law upon which it relies. *Id.*

I. Registering Dr. Craker as a bulk manufacturer of marijuana is consistent with the public interest.

Registering Dr. Craker as a bulk manufacturer of marijuana to create an alternative to the NIDA-controlled monopoly would promote the advancement of science and research by adding competition to the current monopoly on distribution of marijuana

to researchers without posing additional diversion risks, and is therefore consistent with the public interest. 21 U.S.C. §823 sets forth six factors the Attorney General is required to consider in determining whether registering an applicant is consistent with the public interest. Under these factors, if the application poses no actual increased diversion risk, and the applicant meets the other requirements, the DEA *must* grant the application without regard to whether there is already an adequate supply. The evidence establishes that Dr. Craker's application poses no additional diversion risks and advances the public interest as defined by the factors listed in 21 U.S.C. §823.

A. Dr. Craker's application would maintain effective diversion controls while producing an adequate uninterrupted supply under adequately competitive circumstances.

The first factor in §823(a) provides that the Attorney General shall consider "(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." 21 U.S.C. §823(a)(1). Thus, the DEA is required to balance the competing aims of diversion control and adequate supply and competition. But as the D.C. Circuit has noted, the statute "expressly directs the DEA to limit competition *only* as a means to achieve maintenance of such control." *Noramco of Delaware v. DEA*, 375 F.3d 1148, 1153 (D.C. Cir. 2004) (emphasis added). And the DEA itself has decided that if "there would be no increased difficulty in controlling diversion, the requirements [of Section

823(a)(1)] are satisfied, and an analysis of adequate competition is not required." 67 Fed. Reg. 39041, 39044 (June 6, 2003). Indeed, DEA's policy is that Section 823(a)(1) "permits the DEA to restrict entry to a number of registrants constituting adequate competition *only when actually necessary* to maintain effective controls against diversion." Bulk Manufacture of Schedule I and II Substances, 39 Fed. Reg. 12,138 (DEA 1974) (April 8, 1974).[10]

But even if the DEA finds granting that an application may increase the risk of diversion, the DEA must still grant the license if doing so will ensure the statutorily required adequate supply and adequate competition to meet the needs of those who have legitimate medical, scientific, research, and industrial purposes. 21 U.S.C. Section 823(a). In this case, the evidence plainly establishes *both* that the current supply is not adequate for legitimate research *and* that restricting the national medical marijuana supply to one cultivator is not "actually necessary" to maintain DEA's controls against diversion, especially where the DEA has recently agreed to expand Dr. ElSohly's and the national quota from 913 kg to 4500 kg, and where Dr. Craker seeks initially to grow only 11.34 kg (25 pounds) of medical marijuana.

1. The Current NIDA Monopoly System Has Failed To Provide an Adequate and Uninterrupted Supply for Legitimate Purposes.

The evidence presented at the hearing clearly demonstrated the problems with the current supply and distribution of marijuana for legitimate scientific and medical

[10] Thus, the "DEA is 'required to register an applicant who meets all the other statutory requirements, without regard to the adequacy of competition, if the Administration determines that registering another manufacturer will not increase the difficulty of maintaining effective controls against diversion.'" *Noramco*, 375 F.3d at 1153. *See also* 21 C.F.R. §1301.33(b) ("In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.").

research. Dr. Craker's application seeks to address the limitations and gaps of the current supply system.

a. NIDA's Distribution System and Criteria Exclude Some Legitimate Medical and Scientific Research.

When Congress required an adequate and uninterrupted supply of all controlled substances for "legitimate" medical, scientific, research, and industrial purposes, it is presumed to have used that word in its ordinary and commonly understood sense. The Websters' Third New International Dictionary (1993) defines the word legitimate as "genuine," which suggests that it refers to non-sham purposes. Thus, since it is certainly possible that someone could propose sham research that is simply a cover for illegitimate use, Congress required that the medical and scientific purposes be legitimate or genuine. At least with regard to *medical* research about the efficacy and safety of new drugs or new drug delivery systems—an area of the law delegated to the Food and Drug Administration, rather than to NIDA or DEA— it can hardly be disputed that, at a minimum, research protocols the FDA approves and allows to go forward must qualify as "legitimate" medical research.

Moreover, the context of the phrase is important. *American Pharmaceutical Assoc. v. Weinberger*, 377 F. Supp. 824, 828 (D.C. Cir. 1974) ("a general term should not be construed in isolation but should be interpreted according to the context of the statute within which it is found."). The CSA is a "statute combating recreational drug abuse." *Gonzales v. Oregon*, ___ U.S. ___, 126 S.Ct. 904, 924 (2006). But because some drugs subject to abuse are also helpful – even essential – to ease symptoms, cure diseases, provide industrial materials, or advance scientific knowledge, the Congressional scheme also recognizes that such non-recreational uses of those drugs must be protected. Thus, it

distinguishes between the *illegitimate* purposes of recreational or non-medical use, and the *legitimate* purposes of scientists and doctors researching the properties, characteristics, or effects of the substance. *See Gonzales*, 126 S.Ct. at 911 (noting "the main objectives" of the CSA are "combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances"). And to ensure that those substances are available, Congress has required DEA to use its licensing power to ensure an adequate and uninterrupted supply of controlled substances for legitimate (or genuine, non-sham) medical, scientific, research, and industrial purposes.

But NIDA does *not* make its medical marijuana available for all legitimate medical and scientific research. Instead, NIDA relies on internal criteria to allocate its marijuana to a *subset* of legitimate research. Specifically, it says it will "make available a sufficient amount of research-grade marijuana to support those studies that are *the most likely* to yield usable, *essential* data." Gov't Ex. 24 at 2 (emphasis added). Under these criteria, it naturally excludes studies that it considers *not* the most likely to yield essential data, but which are nonetheless studies with legitimate, genuine medical or scientific purposes.

In addition, NIDA's internal criteria for distributing its marijuana require that for any research it supplies, "the goal must be to determine whether cannabinoid components of marijuana administered through an alternative delivery system can meet the standards enumerated under the [FDA requirements for] medical products." Gov't Ex. 24 at 2. Thus, NIDA has determined it will *not* supply marijuana to research whose goal is, for example, FDA approval of a smoked marijuana prescription product. *Id.*[11]

[11] DEA appears to also have adopted this view since it advised Dr. Craker that smoked marijuana "ultimately cannot be the permitted delivery system for any potential marijuana medication due to the

NIDA's criteria make clear that it will not provide marijuana for some research, despite the fact that such research is plainly "legitimate" since it aims to provide the FDA with information necessary for the FDA to weigh the risks of different delivery systems against the benefits. Even NIDA's Steve Gust has candidly admitted that its guidelines can and do preclude medical research that has been approved by the FDA and by university and other institutional review boards. Tr. at 1694.

The effect of those guidelines, coupled with the NIDA monopoly, is that NIDA, instead of the FDA, ends up determining what medical marijuana research goes forward, and what does not. But this result is contrary to the system Congress set up. By statute, Congress has delegated to the FDA the responsibility of evaluating the efficacy and safety of all new drug products. 21 U.S.C. 393(b). To do that, the FDA reviews protocols submitted by researchers, and decides whether that research will go forward or not. 21 U.S.C. § 355; 21 C.F.R. 312.42. Especially in Phase 2 and 3 protocols the FDA conducts "an assessment of the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval." 21 C.F.R. 312.22(a). Thus, while DEA (though not NIDA) has a statutory role to play in the distribution system *after* the FDA has decided whether it will be marketed, "[a]t the production or pre-marketing stage, the FDA is given the primary responsibility in determining which new drugs should be permitted to enter the flow of commerce." *Am. Pharm. Ass'n,* 377 F. Supp. at 830.

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deleterious effects and the difficulty in monitoring the efficaciousness of smoked marijuana." ALJ Ex. 1 at 4. (Show Cause Order). Like NIDA, the DEA appears to have improperly decided that it--instead of the FDA---is the agency empowered to evaluate and weigh the safety and efficacy of both medical marijuana and any proffered delivery system.

Moreover, there is no process or right to appeal a denial by NIDA and no alternative supply.[12] NIDA's monopoly over the supply of marijuana gives it – the organization whose mission is to study the abuse of and deter the use of certain drugs – an absolute veto over research that could reveal possible beneficial uses. It is hardly surprising, then, that NIDA views some legitimate (or genuine) research as not meeting its standards, and declines to supply that legitimate research.

b. Legitimate Medical and Scientific Research Has Been Denied Access to Marijuana.

Undisputed evidence presented at the hearing showed that some medical and scientific researchers whose legitimate research protocols had been approved by a variety of institutional research review boards, state review boards, and the FDA, were unable to purchase medical marijuana necessary for that research from NIDA. Dr. Abrams, Dr. Russo, and Chemic Labs are three specific instances in which the proposed research by plainly legitimate researchers was clearly not sham, and was scientifically valid. Findings § E. Yet all three of those researchers were denied access to the only medical marijuana legally available in this country under federal law.[13]

The DEA may try to suggest that these three protocols were not "legitimate." But there is certainly no indication that any of this research - developed by eminent

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[12] Nor is there any time limit to NIDA's consideration process (unlike at the FDA). Thus, despite Dr. Gust's assurances that the PHS Committee "generally takes" 3-6 months (Tr. at 1653), NIDA took nine months to deny Dr. Abrams, and three and a half years to deny Chemic. Findings § D(1) and (3). In the context of research, particularly research aimed at seeking FDA approval, a sponsor's inability to plan when research will be conducted because of undue and unpredictable government delay is yet another significant impediment to that research.

[13] DEA may try to argue that because two of those denials were in 1995 to 1999, they are irrelevant to current conditions. But Dr. Craker filed his application in 2001, not long after those denials. It was DEA who refused to rule on the application for three and a half years. DEA cannot sit on an application and then argue that the passage of time has made it irrelevant. More importantly, there is no evidence that NIDA is applying different standards today than it applied when it denied those requests. And finally, Chemic's request for 10 grams to establish parameters for a marijuana vaporizer as an alternative to smoked marijuana, was denied in 2005. Findings, A(1)-A(3). Thus, any suggestion by the government that all problems with the NIDA distribution scheme were in the past, and have been "fixed," must be rejected.

researchers and a commercial laboratory - was a sham attempt to get marijuana for illegitimate, recreational use. Nor can DEA credibly argue that they were not legitimate because they were reviewed and denied by either NIDA or the marijuana-specific PHS Committee. Genuine research proposed by licensed researchers, doctors, and scientists, which is approved by a variety of peer-reviewing bodies, for what are indisputably scientific and medical purposes cannot be dismissed as "not legitimate" simply because NIDA finds it does not meet NIDA's criteria for allocating its resources. Moreover, Dr. Russo's and Dr. Abrams' clinical research was reviewed by the FDA for scientific validity, and was approved.[14] Although Dr. Gust tried to say that NIDA's PHS Committee review was necessary to ensure that the proposals had scientific merit, and thus, impliedly, whether they were eligible under the CSA, that testimony is not credible. First, the standard in the CSA is not "scientific merit," but "legitimate medical, scientific, industrial, or research purposes." But even if the CSA did require a demonstration of scientific merit, most proposals, and certainly all Phase 2 and 3 proposals are reviewed for scientific validity before they ever reach NIDA. Indeed, as NIDA's own guidelines point out. FDA assesses the "scientific validity" of the protocols it approves:

> FDA's primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug's effectiveness and safety. Therefore, although FDA's review of Phase 1 submissions will focus on assessing the safety of Phase 1 investigations, FDA's review of Phases 2 and 3 submissions will also

[14] Protocols not involving human subjects, such as the Chemic vaporizer research, need not receive prior approval from the FDA as they pose no danger to persons. However, the reliability of such a protocol, must be demonstrated to the FDA at some point to justify FDA approval for the next step of studies which would rely on these preliminary protocols, and it would be a waste of effort to conduct protocols the FDA is not likely to deem reliable.

> include an assessment of the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.

Gov. Ex. 24 at 3-4 (citing 21 CFR 312.22(a)). Thus, every Phase II proposal coming to NIDA has already been approved by the FDA -- the agency charged with insuring the process of drug development -- as having "scientific merit." In addition, since most institutions require institutional review for safety and scientific merit even before the proposal goes to the FDA, most Phase II proposals have been at least twice approved on the basis of scientific merit. The additional level of review by NIDA is not "necessary" in any sense to ensure that the research is "legitimate research."

Although the government presented evidence that NIDA did provide marijuana to the non-NIDA funded CMCR researchers, this fact does not change the analysis. Respondent does not dispute that NIDA has supplied marijuana to some legitimate researchers. Its point is that NIDA has refused, and continues to refuse, to supply its monopoly product to all legitimate researchers as the CSA requires. Nor can it satisfy the statutory requirements to provide marijuana by providing to a single group of researchers, particularly where the evidence shows that that group, CMCR, is out of funding, and never intended to pursue FDA approval of botanical marijuana as a prescription medicine. Tr. at 403-405, 433-437, 440-444.

c. The Current NIDA Monopoly Is Also Inadequate Because It Does Not Meet the Legitimate Needs of A Sponsor Seeking To Develop Marijuana Into An FDA-Approved Pharmaceutical Product.

NIDA's monopoly of the medical marijuana supply, and its policy of choosing to provide medical marijuana for some legitimate purposes, but not for others, also means

that the current system cannot provide an adequate and uninterrupted supply for a sponsor that seeks to go through the process of obtaining FDA approval of medical marijuana as a prescription drug and then making it available to patients.

As the witnesses for both parties agreed, a critical prerequisite for pharmaceutical companies seeking to develop a product for FDA approval is ready access to a consistent and reliable source of the exact product the developer wants to develop, both for the FDA approval process, and for distribution if approval is obtained. Findings, § D. In addition, the drug development sponsor must have access to the Drug Master File (or its equivalent), to demonstrate to the FDA that the manufacturing practices and quality control practices meet its requirements. *Id.* Such access to both the product and the product manufacturing information is critical because the FDA requires the sponsor to demonstrate that any product distributed after approval is the same product that was tested during the rigorous approval process. Findings, § D. Thus, a sponsor cannot, as a practical matter, pursue new product development---particularly a botanical new product--without significant confidence that (1) it will have a source to supply the necessary drug trials and distribution should the product be approved, and (2) it can provide the necessary information on manufacturing and quality control processes to the FDA to meet regulatory requirements. Findings § D.

Here, the evidence established that NIDA provides marijuana for some, but not all, legitimate research, and that it does so project by project. It has declined to provide medical marijuana for three separate research projects in which MAPS was involved. Even if NIDA marijuana were of sufficient quality for MAPS to rely on to seek FDA approval, MAPS can have no confidence that NIDA will provide its marijuana for all the

necessary drug trials, or that NIDA would authorize MAPS to rely on the NIDA marijuana Drug Master File currently on file with the FDA. Nor could MAPS have any assurance that NIDA would (or even could[15]) agree to meet MAPS' requirements for distribution of medical marijuana to patients if it were approved by the FDA. To the contrary, NIDA has indicated that it is *not* part of its mission to study the medical uses of marijuana and its guidelines reject the goal of FDA approval of marijuana as medicine instead of its isolated cannabinoid components. Findings § D; Gov't Ex. 24.

In these circumstances, no rational drug sponsor seeking to develop botanical marijuana as an FDA-approved product could proceed without seeking a source of supply alternative to NIDA's. Here, Dr. Craker has already agreed to provide the defined marijuana product MAPS believes it requires as a sponsor and that researchers will find the most efficacious and safe (which NIDA does not currently offer[16]). Dr. Craker has also agreed to supply further needs of research sponsored by MAPS, consistently with the DEA license, and to authorize MAPS to rely on all the necessary quality and manufacturing records about the product to meet the FDA requirements. Dr. Craker and the University of Massachusetts have also indicated they expect to be able to provide a more uniform product since, through growing and propagating techniques, they can better control for environmental and genetic variables than the marijuana currently grown for NIDA. Findings, § H(2). Thus, granting Dr. Craker's application for a license will

[15] It is wholly unclear whether NIDA's product could be used for commercial development. *See* Findings § D; Tr. at 1463.

[16] Dr. Doblin testified that MAPS seeks to have researchers test the efficacy of medical marijuana with higher levels of THC than NIDA has so that more of the therapeutic benefits can be obtained with less of the smoking by-product. Tr. at 552. Based on other researchers' findings, MAPS would also like to explore the efficacy of marijuana with a higher ratio of other cannabinoids, such as CBD, than the NIDA product has.

ensure an adequate and uninterrupted supply by providing the reliable and consistent supply that is a practical prerequisite for FDA-approved product development.

Whether or not the research MAPS seeks to sponsor will lead to the development of botanical marijuana as medicine either smoked, if the benefits outweigh the risks, or delivered through an alternative device such as a vaporizer, is of course, up to the FDA, the agency charged by Congress with evaluating claims of safety and efficacy of new drugs. Since the FDA has had no opportunity yet to evaluate any research, no one, including the DEA or NIDA, knows what the FDA will decide when it sees the science. However, the FDA has told Congress that "FDA will continue to be receptive to sound, scientifically based research into the medicinal uses of botanical marijuana and other cannabinoids. FDA will continue to facilitate the work of manufacturers in bringing to the market safe and effective products." Resp. Ex. 54.

If, after appropriate research, the FDA determines medical marijuana does not meet the requirements to treat a specific clinical condition, then it will not become a prescription medicine, and MAPS will either not then need the supply it seeks to ensure now or it may continue to study the efficacy of marijuana for other clinical conditions. But that is an issue for the FDA—not NIDA or the DEA. "While the functions of FDA and DEA are not entirely exclusive of one another, a certain division of authority and responsibility was clearly intended by Congress and must be recognized by this Court in order to preserve the integrity of the legislative scheme." *Am. Pharm. Ass'n*, 377 F. Supp. 831. Thus, DEA cannot use its licensing scheme to limit supply so to preclude or discourage sponsors from seeking FDA approval, particularly where, as the government has stipulated, "research continues about how cannabis may be of therapeutic benefit to

patients." ALJ Ex. 5 at 1. There is no question that it is in the public interest for researchers to generate data about medical marijuana for the FDA to evaluate. Indeed, given DEA's position that "Those who insist marijuana has medical uses would serve society better by promoting or sponsoring more legitimate scientific research, rather than throwing their time, money and rhetoric into lobbying, public relations campaigns and perennial litigation," 57 Fed. Reg. 10499, 10503 (Mar. 26, 1992), DEA's licensing scheme should *encourage* such legitimate research, not *preclude* it.

Because the NIDA monopoly fails to provide marijuana for what are indisputably legitimate medical and scientific purposes, and because it is not likely, even if able, to serve as the source for any FDA-approved medical marijuana, the current system fails to provide an adequate and uninterrupted supply.

2. The NIDA Monopoly Fails to Fulfill the Statutory Requirement of Adequate Competition.

In addition to ensuring an adequate and uninterrupted supply for all legitimate purposes, the DEA must ensure that medical marijuana is supplied under "adequately competitive conditions." 21 U.S.C. 823(a)(1). But that requirement is not met by the current NIDA monopoly.

It is almost axiomatic that when, as here, there is only one supplier of a product for which there is no substitute, competition is lacking. As economist Friedrich A. Hayek has observed:

> Our freedom of choice in a competitive society rests on the fact that, if one person refuses to satisfy our wishes, we can turn to another. But if we face a monopolist we are at his mercy. And an authority directing the whole economic system would be the most powerful monopolist imaginable.

Hayek, The Road to Serfdom at 93 (University of Chicago, revised edition,1976).

The DEA has suggested that because the NIDA contract is open to competitive bid from time to time, the provision of medical marijuana to researchers is adequately competitive. But that suggestion fails. First, the NIDA contract is for far more than manufacturing marijuana. Indeed, the lion's share of the contractors obligation is to analyze marijuana samples the DEA sends in. Gov't Ex. 13 at 2. This requirement effectively screens out potential competitors like Dr. Craker, who have no expertise or interest in such large-scale chemical analysis. Second, the NIDA contract assures only that the government pays a competitive price for the contract services and products, assuming more than one entity submits a bid. It does not ensure that researchers pay a competitive price since NIDA sets the price and there is no evidence as to how that price is set. Tr. at 1213 ("The NIDA contracting officer actually sets the price.") More importantly, the bid process does not encourage or seek competition in product development or quality.

The government may also suggest as did its party representative, Matthew Strait, that when NIDA chooses to sell medical marijuana to some independently-funded researchers "at cost," there is no need for competitive conditions. Tr. at 943-948. Of course, if another manufacturer could produce suitable medical marijuana for a lower cost, competitive conditions would, as they usually do, benefit the researcher-consumer. But more importantly, cost is not the *only* benefit flowing from competition. In reviewing a DEA decision to grant a license to import coca leaves and raw opium, based on inadequate competition, the D.C. Circuit noted that even if increased competition did not reduce consumer prices, "expanding the playing field [from two importers to three]

may yield other benefits such as reduced prices for bulk . . . purchasers and improved products quality, reliability of supply, financial terms and conditions, and order lead times." *Noramco*, 375 F.3d at 1158. *See also U.S. v. Portsmouth Paving Corp.*, 694 F.2d 312 , 317 (4th Cir. 1982) (citing 1 R. Callmann, The Law of Unfair Competition, Trademarks and Monopolies § 4.35, at 221 (4th ed.1981)) (noting anticompetitive supply "eliminates not only price competition, but also competition in service and product quality"). And, for those researchers to whom NIDA refuses to sell, since there is no alternative supply, the competition as to cost is irrelevant since no matter what they might offer to pay, they cannot obtain the materials.

As the courts have recognized, competition leads to improvements in the product. In the context of medical marijuana, those improvements could include more desirable potency levels, options for differing ratios of constituents, more uniform product consistency, fewer stems and seeds, a significantly shorter lead time on orders, and different terms on which the product is available to researchers. And the evidence showed that while some researchers find NIDA's product suitable, other researchers who have conducted studies with NIDA marijuana have voiced concerns about the quality and availability of the product. Findings § F. As is fully discussed in the findings of fact, the DEA interviews of researchers reflected concerns about: (1) the inconsistency of THC potency in NIDA marijuana, (2) the harshness of NIDA marijuana, (3) the lack of freshness, (4) the unavailability of the desired potency, and (5) the presence of stems and seeds in the medical marijuana cigarettes. Findings § F. Researchers would also likely value a quicker response as to whether a marijuana supplier could meet a request than the over two years it took NIDA to respond to Chemic's request. Findings § E(3). And, they

might value a customer-oriented approach instead of the complacent attitude of a monopolistic provider: "[Researchers] have to take what you get." Findings § F(1).

Despite the government's disingenuous claim that there have been no "formal complaints" about NIDA marijuana and despite Dr. ElSohly trying to insist that the caption of a picture of a disassembled NIDA marijuana cigarette "must be a typo" because of the quantity and size of the seeds and stems in the photograph (Findings § F(5)), the evidence is overwhelming that researchers see significant room for improvements in quality, availability, composition, and potency, as well as price, that competition would encourage. Findings, § F. Dr. Craker's registration would create competition for the first time in all these areas.

3. Even If The Current Number of Manufacturers Was Adequate And Competitive, No Evidence Suggests Licensing Dr. Craker Increases the Difficulty of Maintaining Effective Controls.

As noted earlier, under Section 823(a), if restricting the number of marijuana manufacturers to one instead of two is not "actually necessary to maintain effective diversion controls," the DEA need not even consider whether there is inadequate competition in the current system. Here, of course, the single provider fails to ensure adequate and uninterrupted supply under adequately competitive conditions. But even if it did, DEA must nevertheless grant the registration because Dr. Craker's registration will not actually increase the difficulty of maintaining effective controls.

a. Dr. Craker's Security Measures Satisfied DEA Requirements.

There is certainly no evidence that granting Dr. Craker's application to grow 25 pounds of medical marijuana would result in marijuana from his facility being diverted into illicit channels. To the contrary, the evidence adduced at the hearing established that

Dr. Craker will be growing the entire supply of marijuana for research in a secure indoor facility under DEA-approved security conditions. DEA agents themselves indicated they were satisfied with the proposed facility, and with Dr. Craker's plans and willingness to put secure measures in place; they have raised no objections to Dr. Craker's ability to carry these measures out. Tr. 44-45, Findings H(4). Dr. Craker testified without dispute that the marijuana grown in his facility would only be made available for legitimate medical and scientific researchers, and only to those researchers with the appropriate DEA permits and FDA approval for clinical trials. Tr. at 364.

In contrast, the DEA offered *no* evidence that the medical marijuana from Dr. Craker's facility would be diverted. Certainly it is not enough for DEA to simply speculate that adding one more manufacturer will, by definition, result in increased likelihood of diversion. In *Chatten Chemicals*, 71 Fed. Reg. 9834-02 (Feb. 27, 2006), the government argued that the addition of another importer would increase the amount of product, which could result in "diversion downstream" at the retail level, and it presented evidence that such diversion was increasing at an "alarming rate." *Id.* But the ALJ and the Deputy Administrator rejected that argument, reasoning that because DEA established manufacturing and procurement quotas every year to avoid overproduction, and that the demand for retail products was the major factor resulting in an increase in bulk manufacturing, "It therefore appears unlikely that granting Chattem's application for a registration to import NRMs would be a significant cause of increased diversion at the retail level." *Id.* at 9837. This was especially so because despite the growing diversion problem, DEA had continued to register additional bulk manufacturers of the same materials.

Here, DEA has not shown that existing bulk manufacturing has led to downstream diversion from the single existing bulk manufacturer, nor has it shown any recent trends that would justify precluding additional bulk manufacturers. While it presented evidence that marijuana can have harmful (though never lethal) effects, Tr. at 1898-99, that testimony simply explains why marijuana is listed as a controlled substance.

Further, as DEA witnesses testified, DEA establishes a manufacturing quota every year for marijuana. Tr. at 1357. Significantly, DEA agreed in June 2005 to seek U.N. approval to dramatically *increase* Dr. ElSohly's (and the identical national) manufacturing quota from 913 kg to 4500 kg. Gov't Ex. 79. If bulk manufacturing generally were leading to downstream diversion, DEA would surely not have been willing to approve a 500% increase in the amount legitimately manufactured in the country. Nor DEA's evidence that plant marijuana is the most widely abused form of marijuana justify a different result, since, again, it has approved a 500% increase in *plant* marijuana grown by Dr. ElSohly. Finally, if DEA truly believes that adding 11.34 kg (25 pounds) to the newly inflated ElSohly quota will open the floodgates of diversion, DEA has the authority to reduce the 4500 kg that Dr. ElSohly may grow by 11.34 kg, and allocate that amount to another manufacturer, such as Dr. Craker. Or NIDA could reduce the amount it wishes to grow by 11.34 kg. After all, Dr. ElSohly has testified that he currently has in storage about 1000 kilos of marijuana for NIDA's use (Tr. at 1266), and that NIDA has not asked him to grow a crop since 2001-2002. Tr. at 1253.[17]

[17] Clearly, NIDA's refusal to provide marijuana to legitimate researchers was not based on a shortage of marijuana; thus, the increase in the quota will not make NIDA more likely to supply marijuana for legitimate purpose. Rather, the dramatic increase in the quota is to allow Dr. ElSohly to provide Mallinckrodt with sufficient quantities for its product launch. Tr. at 1519.

Thus, there is no evidence in the record before this court that even suggests, much less establishes, that marijuana manufactured at the University of Massachusetts Amherst facility as proposed by Dr. Craker would be diverted, or that granting Dr. Craker's application would actually increase the difficulty in controlling diversion. To the contrary, especially in light of DEA's decision to approve a 500% increase in the amount of marijuana grown in the U.S., and in light of DEA satisfaction with Dr. Craker's security arrangements, the evidence shows that granting this application will not increase the difficulty in controlling diversion.

b. Generalized Information About Marijuana's Dangers as a Drug of Abuse Does Not Establish That Adding Dr. Craker As The Second Manufacturer Increases the Risk of Diversion.

The DEA introduced testimony from Dr. Eric Voth noting that marijuana is a drug subject to widespread abuse. Presumably, DEA will argue that therefore, marijuana is susceptible to diversion. But that fact is a given -- indeed, that is why it is currently scheduled on Schedule I, and why DEA must apply the factors of section 823(a) to this application. The issue here is whether adding one manufacturer, Dr. Craker, to a field of one will *actually* increase the risk of diversion.[18] And for that issue, DEA cannot rely

[18] At the hearing, the Court allowed some testimony on the potential harm caused by illegitimate marijuana use, but excluded evidence relating to benefits from marijuana use. Tr. at 1876-89 (discussion among counsel and the court). Respondents continue to argue that testimony should be excluded. While the DEA must examine an application to determine whether that application will *actually* increase the difficulty of maintaining diversion controls, it cannot use that mandate to usurp another agency's role. Here, DEA appeared to argue that because the license might lead to development of an FDA-approved product, the Court should consider whether some of that approved pharmaceutical product might be diverted to illegitimate use, and that such theoretical illegitimate use was relevant to whether the application increased the difficulty of maintaining diversion controls. Tr. at 1886. As noted earlier, however, it is the FDA's role to determine whether the risks and benefits justify the marketing of a new product. *After* that decision is made, the DEA may then weigh in on the issue of how that product is to be distributed, taking into account the possible illegitimate uses of that product. *Am. Pharma. Ass'n*, 477 F. Supp. at 830. But it puts the cart before the horse, and improperly usurps FDA's role, if DEA can argue, *before* the FDA has evaluated the product, that because the product can cause harm if used illegitimately by those who may legitimately obtain it. DEA should be able to deny a license aimed at developing the product for FDA

simply on speculation. *See Johnson Matthey*, 67 Fed. Reg. 39041, 39045 (rejecting speculation that merely permitting another party to import a controlled substance increases the risk that those substances will be diverted). Moreover, the evidence established that DEA has agreed to allow Dr. ElSohly to increase his current crop by 500%, up to 4500 kilos. It is simply not credible that allowing an additional 11.34 kilos (25 pounds) to be grown under secure conditions for indisputably legitimate purposes will *actually* increase the difficulty of maintaining diversion controls in the United States, if adding 3787 kilos does not raise the same issue.

c. No Evidence Suggests MAPS' Role As A Sponsor Increases the Difficulty of Maintaining Effective Controls.

DEA may attempt to argue that the involvement of MAPS as a sponsor of drug development of marijuana somehow increases the difficulty of preventing diversion. This argument is spurious. Regardless of DEA's view of MAPS' philosophy relating to the medical benefits of psychedelic drugs, and regardless of its views of MAPS' founder, it must point to evidence, not speculation, that licensing Dr. Craker will increase the difficulty of maintaining diversion controls. Here, the *undisputed* evidence is that MAPS has sponsored numerous DEA-licensed researchers in a variety of FDA-approved Phase I and Phase II drug trials involving controlled substances including MDMA, psilocybin, ibogaine, and marijuana, with no hint or allegation of diversion. And despite being in the best position to know about any diversion from any of these DEA-licensed studies, DEA

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approval. Thus, Respondent argues that the issue of harm in that circumstances is far too speculative to support any finding in this Court. *See Humphreys v. DEA*, 96 F.3d 658, 665-555(3d Cir. 1996) (cautioning DEA Adminstrator in remand that its inferences of public harm from diversion were overly broad where inference was speculative).

has not offered one shred of evidence of any diversion. Findings, § G.[19] As the sponsor of such research, MAPS has purchased controlled substances for that research from commercial suppliers that compete with NIDA. *Id.* Indeed, MAPS owns and maintains a drug master file for MDMA which it has filed with the FDA. Tr. at 482.

Further, as Dr. Doblin testified at the hearing, MAPS is the sponsor of the drug development effort, not a researcher. He stated that, just as MAPS does with the manufacturers of its MDMA and psilocybin, MAPS would specify the potency and strain of the marijuana, Dr. Craker would grow it, and MAPS would allocate it to the projects MAPS was sponsoring. Tr. at 589. Dr. Craker also outlined the procedure wherein MAPS would identify the FDA-approved researcher, the researcher would send Dr. Craker the appropriate forms, and Dr. Craker would then ship the product directly to the licensed researcher. Tr. at 73, 386. Both Dr. Craker and Dr. Doblin were clear that neither Dr. Doblin, nor any other MAPS employee, nor any other unauthorized person would ever have access to Dr. Craker's medical marijuana. Indeed, these procedures are very like NIDA's, in which NIDA directs Dr. ElSohly where to send the medical marijuana, and Dr. ElSohly or RTI then ships it directly to the researcher. Tr. at 1094. In both cases, the sponsor who paid for the marijuana to be grown never comes into contact with it. In these circumstances, there is no evidence that MAPS' involvement as the drug

[19] DEA may try to argue that Dr. Doblin indirectly "diverted" marijuana by making it known to the Compassionate Use patients that it would be useful for researchers to have an independent lab analysis of NIDA's marijuana. Tr. at 672-73. (Having the federally-provided marijuana they smoke for medical purposes independently analyzed, of course, is not what most patients would consider "diversion" of their marijuana.) But as the evidence shows, Dr. Doblin never "diverted" any marijuana; the NIDA marijuana that was sent was sent anonymously to the one DEA laboratory in the country allowed to accept anonymous samples for testing. Despite the disapproving tone of DEA counsel's questions, DEA put on no evidence even suggesting that this second-opinion analysis was improper, much less unlawful; the DEA did not establish that the anonymous submission by Compassionate Use patients, or one DEA-licensed lab sending marijuana to another DEA-licensed lab, violated any regulation or even any internal guidance. Nor does it appear that the DEA during or after this "diversion" made any attempt to discourage the patients (or the laboratories) from accumulating this important data.

development sponsor raises any risk whatsoever of diversion. Finally, it is well within DEA's power to condition the license on specifically excluding Dr. Doblin and MAPS employees from the premises or from any contact with the medical marijuana, and if DEA determines that is warranted, that measure should fully satisfy any DEA concerns about MAPS involvement.

DEA may also try to argue that the evidence it elicited, over objection, relating to Dr. Doblin's personal use of marijuana is somehow relevant to whether granting Dr. Craker's application will increase the likelihood of diversion. First, that evidence is not relevant to any issue before this court, and should not be admitted.[20] Dr. Craker is the applicant for the license, and his history of marijuana use might therefore be relevant, but the government did not ask him. But even if the Court were to find it relevant, that admission cannot establish that the medical marijuana *Dr. Craker* seeks to grow will increase the risk of diversion since, as discussed above, Dr. Doblin will have no access to that material. Moreover, under DEA regulations, the researchers who obtain Dr. Craker's marijuana must be DEA-licensed, and will be under significant restrictions as to what they can do with it, how they must store it, and how they must account for it. Without any access to Dr. Craker's marijuana, Dr. Doblin's personal use of marijuana is simply irrelevant. Nor is there any indication that Dr. Doblin has engaged in this five-year expensive process for anything but the wholly legitimate purposes of obtaining for legitimate DEA-licensed researchers access to marijuana that can be used to develop an FDA-approved product. MAPS' and Dr. Doblin's history of work in the area of

[20] The Court deferred ruling on Respondent's relevancy objection at the hearing. Respondent now renews this objection.

sponsoring exploration of medical benefits of psychedelic substances corroborates that this effort is completely legitimate.

B. Dr. Craker Has Demonstrated He Has And Will Comply With Applicable State And Local Law.

The second factor in §823(a) directs the Attorney General to consider "compliance with applicable State and local law." 21 U.S.C. §823(a)(2). The evidence is undisputed that Dr. Craker and the University of Massachusetts at Amherst have complied with all applicable State and local law, and intend to continue to comply. The Administration of this reputable research university has been involved in every step (despite the urging of DEA agents not to do so (Tr. at 43)) and is willing to do what is required of them. Thirty-eight Massachusetts and federal lawmakers have notified this Court that they support Dr. Craker's application. Resp. Ex. 50. Indeed, officials from the state of Massachusetts had previously asked Dr. Craker to consider cultivating medical marijuana for the state of Massachusetts. Tr. at 212. During the process of applying for the DEA license, Dr. Craker discussed with Massachusetts state investigators the security requirements and the requisite state permits. Tr. at 45-46. The state investigators informed Dr. Craker that the state permit would be granted if the federal permit were obtained. Tr. at 45-46. Dr Craker is prepared to and intends to comply with state and federal laws relating to the growing of any marijuana that he is allowed to grow and any other applicable state and local law. Tr. 73-74. This factor clearly weighs in favor of granting the application.

C. Dr. Craker Has Demonstrated That His License Will Promote Technical Advances In The Art Of Manufacturing Marijuana And Will Facilitate The Development Of New Substances.

The third relevant factor is "promotion of technical advances in the art of manufacturing these substances and the development of new substances." 21 U.S.C. §823(a)(3). Licensing Dr. Craker to become a bulk manufacturer of marijuana would promote technical advances both in growing techniques and in alternative delivery forms for medical botanical marijuana.

As is fully set forth in the factual findings, licensing Dr. Craker would promote scientific and technical advances in four different ways. First, because Dr. Craker proposes to grow medical marijuana indoors, rather than outdoors, as NIDA's crop is grown, he can establish much more comprehensive control over environmental factors. Granting Dr. Craker's application would therefore result in advances in growing techniques creating more precise knowledge about and consistency in the chemical composition of the plant.

Second, one of the reasons Dr. Craker seeks to grow marijuana is specifically for use in research to develope a vaporizer as an alternative delivery system to smoked marijuana. Although MAPS has tried to obtain a small amount of NIDA marijuana for a researcher seeking to determine what percentages of different cannabinoids are present in the vapor, and to develop the preliminary information necessary to FDA approval of that device. NIDA has refused to provide marijuana for this purpose. Dr. Craker has agreed to provide marijuana for this indisputably legitimate purpose to properly licensed facilities identified by MAPs if his registration is approved. Thus, granting the license would promote the technical advancement in the delivery of medical marijuana.

Third, as Dr. Craker noted, the rigorous practice of science requires validation and replication of scientific discoveries and techniques. An alternative source to Dr. ElSohly's marijuana would provide materials to validate and confirm both the results he claims as well as the results of tests done by others with his product Findings, H(2).

And fourth, granting the application would promote scientific advances as it would enable research into possible clinical uses of marijuana, such as for AIDS-wasting, that have not been studied because NIDA refused to provide the marijuana for such a study.

Finally, although the number of patents an applicant has can often be relevant under this factor, the Court should not find here that the lack of patents relating to growing marijuana weighs against Dr. Craker. Where only one person has been allowed to grow medical marijuana legally for 30 years, others can hardly be expected to have developed patents or particular growing techniques relating to marijuana. Interestingly, although Dr. ElSohly has patents, they all relate to processes, such as extracting THC, or products, such as his suppositories, none of which are relevant to growing a particular botanical marijuana product requested by researchers. Tr. at 1331-34. He does not have any patents on plants, or on any growing processes. Thus, because manufacturing marijuana, unlike most other products, involves horticultural expertise, the number of patents held by an applicant is far less relevant here than in a chemical or other process-oriented manufacturing application.

For all these reasons, this third statutory factor weighs strongly in favor of granting the application.

D. Dr. Craker Has No Prior Conviction Record Relating To Marijuana Or Any Other Controlled Substance Offense.

Section 823(a)'s fourth factor is "the prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances" shall be considered. 21 U.S.C. § 823(a)(3). Other than one speeding ticket, Dr. Craker has never been convicted of any crime, including any relating to the manufacture, distribution, or dispensing of marijuana. Findings § H(5). This factor weighs in favor of granting the application.

E. Dr. Craker Has Experience That Supports His Application.

The fifth factor in determining whether a registration is consistent with the public interest is "past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion." 21 U.S.C. §823(a)(5). Although Dr. Craker does not have past experience in the manufacture of controlled substances, no one other than Dr. ElSohly at the University of Mississippi, the sole legal manufacturer of marijuana in the country, could possibly have the relevant experience in manufacturing marijuana legally. Moreover, as the evidence indicated, the FDA has only recently issued guidelines for developing botanicals as medicine. Gov't Ex. 92A (Guidance for Industry -- Botanical Drug Product, issued in June 2004). Therefore, few, if any, applicants with the necessary expertise in growing botanicals would also have experience in the chemical manufacture associated with many controlled substances. Growing medical marijuana requires experience cultivating and propagating plants, and Dr. Craker has significant expertise in that field.

Indeed, as Dr. ElSohly quickly conceded, Dr. Craker has ample experience cultivating and propagating medicinal plants under specific conditions, including work funded through government grants and agencies, like the Department of Agriculture and the Environmental Protection Agency. Findings § H(1). Moreover, Dr. Craker is also familiar with security requirements in plant research, as he did classified botanical research for the U.S. military in a secure facility. Dr. Craker's extensive experience working with other medicinal plants establishes him as a qualified applicant whose experience will advance the public interest. Finally, as DEA agents have agreed that the facility can easily be secure, and as Dr. Craker has agreed to implement the necessary security measures, the evidence is clear that the proposed manufacturing facility will have effective controls. Thus, this factor also weighs in favor of granting the application.

F. All other considerations relevant to public health and safety weigh in favor of registering Dr. Craker as a bulk manufacturer.

The last factor enumerated in §823(a) is "such other factors as may be relevant to and consistent with the public health and safety." As an initial matter, it is important to note that this factor cannot be used to reconsider evidence related to a factor described in the other five specific categories under some different standard. Whatever "other factors" may mean, it cannot mean reconsideration of the first five factors that are specifically described. Thus, DEA cannot rely on this factor to re-frame any arguments about marijuana being a drug subject to abuse, for example, and thus unsuitable for additional registration.

However, other factors do weigh in favor of granting the application. As noted above, thirty-eight members of Congress have notified this Court that they support Dr. Craker's application and the effort to increase competition for medical marijuana,

especially through private initiative rather than increasing the taxpayer expense. Resp. Ex. 50. In addition, Dr. Robert's testimony established that political opposition in the government to the development of botanical marijuana as medicine is real (Tr. at 339, 343-44), and that opposition constricts medical research through constricting the supply. Permitting one non-government source of marijuana would allow access to medical marijuana for those researchers whose goals may not be in alignment with the DEA's or NIDA's, so that science, not politics, can decide whether medical botanical marijuana should be available to sick people.

At the hearing, the government tried to suggest that this license application was premature, since Dr. Craker does not have orders in hand from researchers, or since the facility is not yet fully prepared, or since there is not NDA pending at the FDA. But there is no support for this notion in the CSA or in DEA regulations. *See NORML v. DEA*, 559 F.2d 735 (1977) (rejecting argument that petitioner must file an NDA before seeking rescheduling under the CSA when no indication Congress required one to precede the other). In addition, that argument wholly ignores the realities of research, and of the DEA licensing process. There is no requirement whatsoever that a facility like the University of Massachusetts first invest substantial time and money into preparing the facility or contracting researchers before knowing whether it will have a product to manufacture and offer. By far the most unsettled question of this whole process is whether DEA will issue a license to allow a second bulk manufacturer where a single one has been operating under monopoly conditions for more than 30 years. If the license is granted, Dr. Craker has testified he intends to begin planting marijuana to set up the various processes for growing the product MAPS identifies for the researchers who will

use it. Likewise, there is no requirement that MAPS have medical marijuana researchers lined up before it pursues obtaining a source of supply to allow its drug development efforts to move forward. Indeed, if Dr. Craker or MAPS had lined up researchers before Dr. Craker submitted his application in 2001, there is little likelihood those researchers would still be interested after the five years the licensing process has already taken, or the potentially several more it could take. Moreover, as Dr. Geiringer testified, the CMCR apparently had little trouble finding researchers – indeed, they have exhausted the resources provided by the state of California without funding all the eligible projects. Tr. at 416. Thus, seeking the license first shows good prudence, not prematurity. *See Johnson Massey*, 67 Fed. Reg. 39041, 39045 (rejecting argument that license cannot issue until company can demonstrate it is immediately prepared to start processing materials and orders).

The consequence of registering Dr. Craker to become a bulk manufacturer of marijuana is that FDA-approved medical and DEA-licensed scientific researchers who do not meet NIDA's allocation standards will still be able to conduct their research for legitimate medical or scientific purposes, and that the quality of the medical marijuana available from all sources may improve under somewhat more competitive conditions. Additionally, adding a second supplier to a field of one would "reduce the risk of supply problems in the event of regulatory recall, fire, flood, or other natural disaster." *Johnson Matthey*, 67 Fed. Reg. at 39045. Any research or development done with marijuana from Dr. Craker's facility will have the appropriate DEA licenses, and, for clinical research, FDA approval. Further, because most research institutions require approval of their own or outside institutional review boards, that research will likely have several

other layers of review as well. Thus, there is no greater likelihood that Dr. Craker's medical marijuana product will be used in illegitimate or sham research than is NIDA's. In short, the ready availability of a second source, with a better quality of marijuana product to conduct valid scientific research approved by the DEA and FDA can only benefit the important FDA process of determining whether it is in the public interest for botanical marijuana to be available in some form as a medicine, by providing the necessary reliable scientific data to inform that decision. Granting this license is in the public interest.

II. Registering Dr. Craker as a Bulk Manufacturer of Marijuana Is Consistent With All Laws, Treaties, and Conventions

Section 823(a) requires the Attorney General to register a manufacture of controlled substances if the registration is "consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971." The relevant treaty is the United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol (collectively, the Single Convention). Resp. Ex. 2. DEA declares that registering Dr. Craker would violate the Single Convention because "the Federal Government has to limit marijuana available for clinical research to one source" and HHS and NIDA determine which "one enterprise will be allowed to cultivate marijuana." ALJ Exhibit 1 at ¶8(c). This reading of the Single Convention is without basis.

The Single Convention defines "cannabis" as the flowering or fruiting tops of the plant, including leaves when not detached, (Resp. Ex. 2, Single Convention, Art. 1, § 1(b)). and "cannabis resin" as any resin extracted from the plant. *Id.* Art. 1, § 1(d).

Under Article 28, nations may "permit[] the cultivation of the cannabis plant for the production of cannabis or cannabis resin," so long as the nation "adopt[s] such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant," and so long as it "appl[ies] thereto the system of controls as provided in article 23 [of the Single Convention on Narcotic Drugs] respecting the control of the opium poppy."[21] Resp. Ex. 2, Single Convention, Art. 28 §§ (1) & (3).

The system of controls mandated in Article 23 require principally that a nation create a government agency to operate controls, and that the agency designate the land where the drug will be cultivated, license the drug's cultivators, purchase and take possession of the drug crop, and maintain "the exclusive right of importing, exporting, wholesale trading and maintaining stocks [of the drug] other than" those stocks held by manufacturers of "medicinal" preparations, defined as a substance which has "gone

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[21] Article 23 provides, in total:

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.

2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:

    (a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
    (b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
    (c) Each license shall specify the extent of the land on which the cultivation is permitted.
    (d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and shall take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
    (e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

through the processes necessary to adapt it for medicinal use." Resp. Ex. 2, (Single Convention, Art. 23 §§ 1 & 2).

A. The Single Convention on Narcotic Drugs Plainly Permits More Than One Cultivator to Cultivate Marijuana.

The plain language of the Convention refers repeatedly to the plural word "cultivators." "Only *cultivators* licensed by the agency . . . ." Resp. Ex 2, Art. 23(2)(a). "*All cultivators* of the opium poppy shall be required to deliver *their* total crops . . . ." *Id.*, Art. 23(2)(d). Nowhere does the Convention even suggest that only one cultivator may be permitted under the treaty. By its terms, the Convention certainly contemplates that more than one cultivator or bulk manufacturer may be licensed by the member nation's licensing agency, and the DEA's position in the Show Cause order is factually and legally wrong.

B. Registering Dr. Craker Would Be Consistent With the Single Convention.

Registering Dr. Craker as a bulk manufacturer of marijuana would not violate the Single Convention. The evidence is clear that there is currently a single cultivator of medical marijuana in the United States. Although it is somewhat unclear whether the "agency" designated in the U.S. is DEA or NIDA, it is clear that for Single Convention purposes, there is a United States agency that fulfills that role, or Dr. ElSohly's registrations could not have been granted and repeatedly renewed.[22]

[22] The evidence seems to strongly suggest that DEA, not NIDA, is the "Agency" designated in the U.S. pursuant to the Single Convention. DEA carries out the licensing process, designates the land in the license and specifies the extent of the land that may be cultivated. Moreover, Dr. Gust, the NIDA representative who testified during the hearing, confirmed that NIDA is not the government entity responsible for discharging these requirements of the Single Convention. Tr. at 1730-32.

Should DEA grant Dr. Craker's application for registration, Dr. Craker and the University of Massachusetts would be subject to the same regulation that Dr. ElSohly is subject to. Like Dr. ElSohly, Dr. Craker would be licensed by the DEA to engage in the cultivation and would only do so in areas approved by the DEA for such use. Like Dr. ElSohly, Dr. Craker would only cultivate the amount authorized by the DEA in accordance with any Memorandum of Understanding establishing the yearly quota.

Moreover, because Dr. Craker's crop would be medical marijuana, grown and processed to be adapted for medicinal use, it is not subject to the agency's "exclusive right" for "maintaining stocks." Art. 23(2)(c) provides:

> The Agency shall, in respect of [marijuana], have the exclusive right of importing, exporting, wholesale trading and maintaining stocks *other than* those held by manufacturers of [marijuana] alkaloids, medicinal [marijuana] or [marijuana] preparations. Parties need not extend this exclusive right to medicinal [marijuana] and [marijuana] preparations.

(emphasis added). Thus, there is no Single Convention requirement that Dr. Craker's medicinal marijuana stocks be "maintained" by the agency, just as Dr. ElSohly's private, non-NIDA marijuana stocks grown under his private, non-NIDA bulk manufacturer's license are not "maintained" by NIDA or DEA.[23] And it is worth noting that Dr. Elsohly anticipates he will grow for private purposes more than five times the amount he grew last year, or will grow for NIDA, without turning over those stocks to any government agency. If Dr. ElSohly's license conforms with the Single Convention, granting Dr. Craker a similar license will conform as well.

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[23] At the hearing, Dr. ElSohly agreed that he never delivered his non-NIDA marijuana crops to NIDA or DEA. He indicated he believed there was an exception to the treaty that allowed private marijuana cultivation if the marijuana was going to be used to "develop a product." Tr. at 1557. Respondents are unaware of any amendment or provision in the treaty that excepts cultivators from the treaty requirements solely on the ground that they are creating a product, but if that is so, Dr. Craker should certainly be excepted as well, since by processing the plant into a form suitable for medical use, he will also be creating a medical product.

C. The DEA's Licensing of Dr. ElSohly Demonstrates that Cultivators Can Grow Marijuana Outside NIDA's Control Without Violating the Single Convention.

Even if there were some colorable semantic argument that the language of the Single Convention would prohibit licensing Dr. Craker because he would not be growing under NIDA's control (and there is not), the undisputed evidence established that DEA has issued several bulk manufacturer licenses to Dr. ElSohly, and that under those licenses, Dr. ElSohly has grown, and continues to grow substantial quantities of marijuana outside the NIDA contract. Gov't Ex. 75, 76, 79 at 1; Tr. at 1463. Presumably, the DEA would not have issued those licenses had they violated the Single Convention. DEA cannot selectively interpret the Single Convention.

Pursuant to a non-NIDA-related bulk manufacturer's license, Dr. ElSohly grows marijuana not subject to NIDA's control. Tr. 1682-83. He is able to conduct his own research with this marijuana (and has developed a number of patents through that research), and prepares marijuana extracts that the University then sells to pharmaceutical companies to develop products (though he cannot, according to his testimony, distribute it in other than extract form.) Findings, § I. Thus, DEA's past practice plainly demonstrates its policy that it can, consistent with the Single Convention, license a bulk manufacturer whose crop is not controlled by NIDA though it is licensed by DEA.

D. Other Signatory Countries Like England Demonstrate How Multiple Cultivators Comply With the Single Convention.

DEA may also argue that the Single Convention precludes this license because the application does not specify that the "Agency" would "purchase and take possession" of all crops. But this argument cannot stand. First, the example of Dr. ElSohly and his non-

NIDA manufacturer's license makes clear that DEA has issued that license without requiring such provisions. Indeed, if all goes according to the Memorandum of Understanding between the DEA and the University of Mississippi, the vast majority of what Dr. ElSohly will grow this year is for commercial use and will certainly not be purchased nor ever possessed by NIDA or by DEA. Gov't Ex. 78. Nor can the government suggest that everything grown by Dr. ElSohly is somehow under NIDA's constructive possession and control, since Dr. ElSohly testified that only the NIDA material was under NIDA's control. Indeed, Dr. ElSohly carefully pointed out that the University has two vaults, one paid for by NIDA, and one paid for by U.Miss. In the U.Miss vault, Dr. ElSohly stores the 1000 kilos of plant material he generally maintains for the University, outside of the NIDA contract. Tr. at 1472.

However, the notion of DEA establishing constructive possession through the manufacturing license, as it establishes the other necessary controls in the Single Convention, may explain why DEA does not object to Dr. ElSohly storing 1000 kilos of plant material grown outside the NIDA contract at the University of Mississippi. Respondent introduced evidence showing that England, a signatory to the Single Convention has addressed the issue of maintaining stocks by creating a system of constructive possession for all licensed manufacturers. Resp. Ex. 51, Ex. A. Thus, England's regulations implementing the Convention provides that once the marijuana manufacturing license is issued, "a form of constructive purchase and possession will be deemed to have taken place between the Agency and the producer." *Id.* at Ex. A. DEA has certainly introduced no evidence that England has violated the Single Convention;

thus, the evidence is persuasive that the Single Convention does not requires member parties to limit cultivation to one source.

CONCLUSION

Based on the evidence presented at the hearing, Dr. Craker has carried his burden of showing, by a preponderance of the evidence, that granting his application for a license to become a bulk-manufacturer of medical marijuana is in the public interest.

Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on May 8, 2006, I caused a copy of the foregoing Respondent's Findings of Fact, Conclusions of Law, and Argument, as well as a copy of the Non-Record Sources Cited in Respondent's Brief, to be served on the following by hand-delivery:

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