UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

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

RESPONDENT'S RESPONSE TO THE GOVERNMENT'S EXCEPTIONS TO OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

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INTRODUCTION

In a thorough and exhaustive 87-page opinion, Judge Bittner carefully reviewed the relevant evidence from the two-week hearing. She evaluated the credibility of witnesses and gave careful consideration to weighing the factors listed in the statute. Based on the largely undisputed evidence, she concluded that the current NIDA manufacture and distribution system results in indisputably legitimate, FDA-approved research being denied access to marijuana, and that the current system does not provide an adequate supply, as required under 21 U.S.C. § 823(a)(1).

Judge Bittner concluded, based on the undisputed evidence, that although MAPS, as sponsor of the facility, would make the *allocation* decisions as to which registered, approved and legitimate researchers would be provided with the medical marijuana Professor Craker would grow, MAPS would at no time have physical possession or control of that marijuana, and that Professor Craker would send the medical marijuana only to researchers holding the proper DEA registrations and FDA approval. Thus, Judge Bittner properly concluded that there was minimal risk of diversion of the 25 pounds of marijuana Professor Craker intends to grow. In addition, the record shows that Professor Craker has significant expertise and decades of experience in medicinal plant growth and development, that DEA agents agreed that the proposed manufacturing facility on campus could be made secure enough to satisfy them, and that Professor Craker's has a record of compliance with all laws. In light of these facts, there is no evidentiary basis for any finding other than the one Judge Bittner made: Respondent's registration to cultivate marijuana for medical research purposes would be in the public interest. [1]

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[1] Respondent excepts only to two parts of Judge Bittner's thorough opinion. First, as we will show, there was significant evidence that Professor Craker's registration will indeed promote technical advances. *See* Part III.C. Second, Judge Bittner indicated (probably inadvertently) that under the Single Convention special categories of stocks, Professor Craker's

In a brief long on rhetoric and short on facts and relevant authority, the government attacks Judge Bittner and her recommendations. Though its arguments are somewhat scattershot, the government appears to argue primarily that:

(1) because Judge Bittner did not explicitly and redundantly re-state the burden of proof when she discussed, in turn, each statutory factor, she applied the wrong standard;

(2) because MAPS, an organization that has sponsored significant FDA-approved and DEA-licensed research, conducted without diversion, into the medical uses of a variety of schedule I substances, did not specifically name particular researchers who will use Professor Craker's medical marijuana, the attempt to obtain the bulk manufacturer registration is merely a "front" and that this whole exercise is some sort of nefarious scheme to spend more than six years and hundreds of thousands of dollars in pursuing the registration and developing a secure facility so that MAPS (apparently through Dr. Doblin) can somehow divert some or all of the 25 pounds of marijuana from Professor Craker's facility, ignoring the undisputed facts that MAPS' long-standing goals are to develop marijuana into an FDA-approved prescription medicine and that Professor Craker will distribute the marijuana only to FDA-approved and properly DEA-licensed researchers;

(3) because Professor Craker did not specify every detail as to the security procedures he would adopt, the registration should not be granted, despite the uncontested evidence that DEA agents have agreed that Professor Craker can provide adequate security to meet DEA concerns and that Professor Craker has agreed to implement the reasonable security arrangements DEA calls for;

(4) because NIDA conducts a competitive bidding process for both growing marijuana and conducting large scale testing of street marijuana, the supply is adequate, despite undisputed evidence that that at least two eminent researchers whose studies were approved by the FDA, were unable to conduct their studies because NIDA refused to provide marijuana for the study;

(5) because HHS regulations require NIDA/PHS approval before NIDA will allocate HHS's contractually-grown marijuana to researchers, these regulations somehow prohibit DEA from registering Professor Craker as a bulk manufacturer, despite the fact that the HHS regulation the government cites requires FDA, not NIDA or PHS approval, as a condition of a practitioner-researcher registration; and

(6) although NIDA's contractor, Professor ElSohly, concededly has a registration to bulk manufacture marijuana wholly *outside* of the NIDA contract, and although that privately-grown marijuana is wholly outside HHS/NIDA control, and although Professor ElSohly's activities apparently do not violate the Single Convention since they have been carried out with full awareness and approval of DEA and NIDA, registering Professor Craker to grow marijuana

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might be "special stocks" (for which there is little evidence) rather than "retail stocks," for which there is substantial evidence. *See* Part II.C.

outside a NIDA contract, though within DEA registration limits and quota limits, would somehow violate the Single Convention.

None of these arguments is new. The government made them at the hearing and in its previous post-hearing briefing, and merely rehashes them here. The evidence at the hearing conclusively refutes each of them. As Judge Bittner concluded after weighing all the evidence, Professor Craker has established by a preponderance of the evidence that registering him as a bulk manufacturer of marijuana for medical research is in the public interest. None of the exceptions the government articulates undercut that conclusion in the slightest, because each is based on a misunderstanding of the law, a misstatement of the facts, or both. For the reasons articulated in Judge Bittner's recommendation and in Professor Craker's Proposed Findings of Fact and Conclusions of Law, Professor Craker urges the Deputy Administrator to adopt Judge Bittner's well-supported and well-reasoned Opinion and Recommended Ruling recommending granting his application to be registered as a bulk manufacturer of marijuana.

I. JUDGE BITTNER PROPERLY FOUND THAT REGISTERING PROFESSOR CRAKER WOULD NOT VIOLATE HHS POLICY.

As an initial matter, it is necessary to address a flawed argument the government raises over and again. Throughout its exceptions, the government repeatedly suggests that Judge Bittner's decision was wrong because, it says, registering Professor Craker would allow distribution of marijuana to medical researchers in violation of HHS policy. It claims, incorrectly, that *all* research involving *any* medical marijuana research must be approved by PHS and NIDA as delegates of HHS authority. *See* Government's Exception to Opinion and Recommended Ruling ("Gov't Br.") at 7, 8, 10 ("the Recommendation appears to incorrectly equate FDA approval with HHS approval," and researchers without "HHS approval" are not "legitimate" researchers to whom any marijuana could be legally distributed). *See also id.* at 3,

9, 11, 21. Thus, the government appears to claim that if Professor Craker's registration were granted such that he could distribute medical marijuana to FDA-approved and DEA-registered researchers, that distribution would be in violation of HHS policy.

But this argument is meritless. The government confuses and conflates two wholly separate processes: (1) the process by which DEA registers *practitioner-researchers* to conduct research using schedule I substances, and (2) the process by which HHS/NIDA allocates the marijuana it grows with taxpayer money for research purposes.

A. The DEA Process Under 21 USC § 823(f) to Register Research-Practitioners Requires Review By The FDA, Not By NIDA or PHS.

The sole authority the government cites for its somewhat confusing argument is 21 U.S.C. § 823(f). But that provision relates not to the bulk-manufacturer registration at issue in this proceeding, but to the DEA process for registering practitioners doing research using scheduled substances. When a practitioner applies for a DEA registration to conduct research with substances listed on schedule I, § 823(f) provides that such applications "shall be referred to the Secretary [of HHS], who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol."[2]

The government tries to suggest (without citing any authority whatsoever) that § 823(f) therefore requires NIDA/PHS to review research protocols whenever marijuana is distributed for medical research. But this suggestion is demonstrably wrong. In fact, HHS review under § 823(f) has nothing to do with NIDA or PHS. Instead, as a simple review of the delegation of authority under the statute makes clear, the Secretary of Health and Human Services has specifically re-delegated his functions under § 823(f) to the *Food and Drug Administration*---not to NIDA or to PHS. FDA Staff Manual Guides, Volume II, 1410.10(a)(8) (the Secretary

[2] The term "Secretary" is defined as the Secretary of Health and Human Services. 21 U.S.C. § 802(24).

delegates to the FDA "[f]unctions vested in the Secretary pertaining to . . . 21 U.S.C. § 823(f), which relate to the merits of the research protocol and the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act.") (available at www.fda.gov/smg/141010.html).[3] And this delegation of authority makes sense, because as the agency whose primary function every day is reviewing and evaluating research protocols relating to medical substances, the FDA is the agency with the most obvious expertise in such reviews. Thus, HHS has specifically provided that § 823(f) protocol and researcher review is done by the FDA, and not by NIDA or PHS, as the government tries to argue here.

B. HHS Requires NIDA/PHS Approval *Only* When NIDA Makes Decision About Allocating Its Supply of Marijuana.

Wholly separate from the process of DEA registration is the process by which HHS/NIDA, which contracts to have marijuana grown for it in limited amounts at taxpayer expense, decides to *allocate* its marijuana among researchers. That process—which does include the PHS review and NIDA approval the government keeps referencing—is articulated in the 1999 HHS Guideance that the government introduced at the hearing. Gov't Ex. 24. But both that document and the government's own NIDA witness agree that NIDA's allocation process (with the requisite PHS review) applies *only* when a researcher seeks to use NIDA marijuana (or to obtain NIDA funding) to carry out a research project. The Guidance explicitly stated, "This procedure will apply to the provision, *through NIDA*, of marijuana . . . ." Gov't Ex. 24 at 4 (emphasis added). And the government's witness, Dr. Steven Gust, confirmed that limitation in

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[3] This delegation of authority was originally codified at 21 C.F.R. 5.10(a)(8). By final agency action in 2004, the FDA removed these delegations of authority from the Code of Federal Regulations. The Agency stated, "Because FDA makes information on delegation of authority available on FDA's Internet Web site, the regulations on delegations of authority are no longer necessary." 69 Fed. Reg. 17285 (April 2, 2004).

his discussion of that document: "[w]e only provide the peer review [process set out in the 1999 HHS Guidance] for materials that are provided by the government. So if somebody has materials that are not provided by the government, NIH or NIDA, PHS wouldn't get involved." Tr. at 1648:20 - 1649:2. Dr. Gust later reiterated, "As I said, only proposals that are requesting material provided by the government would need to go through the NIH--or funding--would need to go through the NIH, PHS, or ad hoc review process.[4] Tr. at 1652:18-22.

Thus, as Judge Bittner properly concluded, the undisputed evidence established that the PHS review for the NIDA allocation process applies *only* when a researcher seeks NIDA marijuana (or funding) for the research. That NIDA allocation process simply has no relevance to how non-NIDA marijuana, like that Professor Craker proposes to grow, could be allocated. Instead, researchers requesting marijuana from Professor Craker would be required first to obtain FDA approval for any clinical research, and then obtain a proper DEA registration to conduct the research with a schedule I substance. Of course, to register a practitioner-researcher, DEA would have to ensure that the FDA had first provided the necessary HHS review under 21 U.S.C. section 823(f). Thus, no DEA-registered researcher could possibly lack HHS (through the FDA)

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[4] Moreover, as it is entitled to do when it is dealing with limited, taxpayer-funded resources, HHS has decided to allocate the NIDA marijuana according to certain criteria. For example, the Guidance establishes that the goal of any research using the NIDA marijuana "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. This provision plainly excludes research aimed at developing smoked or vaporized whole plant marijuana as medicine, although such research would plainly be legitimate if it were approved by the FDA. Thus, HHS will allow its marijuana to be used for *some* legitimate research, but not for *all* legitimate research. Indeed, as NIDA's Dr. Gust 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. Where the government chooses to allocate those resources to some, but not all, legitimate research, it cannot then reasonably object to other providers filling in the gaps.

review. For this reason, the government's argument that if DEA were to register Professor Craker, he would distribute marijuana without the required HHS approval under § 823(f) is simply nonsensical.

Judge Bittner plainly understood, and properly rejected the government's argument on this point in her Recommendation:

> The Government contends that granting Respondent's application would amount to circumventing the Department of Health and Human Services' policy with respect to providing marijuana to researchers, and that the DEA has no legal authority to do so. But, as quoted above, the NIH Guidance by its own terms applies to marijuana that the Department of Health and Human Services makes available, not marijuana that might be available from some other legitimate source.

ALJ Op. at 86. Her finding on that point is compelled by the government's own evidence; any finding to the contrary would be contrary to both statutory and agency law.

II. THE ALJ PROPERLY FOUND THAT REGISTERING PROFESSOR CRAKER AS A BULK MANUFACTURER IS CONSISTENT WITH THE SINGLE CONVENTION.

Under Section 823(a), the Attorney General must register a manufacturer of a controlled substance 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 parties agree that the only relevant treaty, convention, or protocol is the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol. Resp. Ex. 2. Professor Craker's burden as to this provision of Section 823(a), therefore, is a light one: he had merely to show that nothing in the Single Convention was inconsistent with his registration. He has amply met that burden.

Judge Bittner found that Professor Craker's registration would be consistent with the Single Convention for two separate reasons: first, nothing in the Single Convention required the government to take physical possession of Professor Craker's crop of cultivated marijuana; and second, Professor Craker's crop would not be considered a "stock" under the Single Convention which the United States would have the exclusive right to maintain.[5] ALJ Op. at 86; *see also* Resp. Ex. 2, Single Convention, Art. 23, § 2(d)-(e). The text of the statute, and the evidence adduced at the hearing that the DEA has registered Professor ElSohly as a bulk manufacturer of private, non-NIDA marijuana over which the government has no physical control, make clear that Judge Bittner's holdings were supported—indeed, compelled by—the evidence.

A. The Single Convention Framework As To Cultivation Of Marijuana

The Single Convention states that a signatory 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, an illicit traffic in, the leaves of the cannabis plant," and, specifically, "appl[ies] thereto a system of controls as provided in article 23." Resp. Ex. 2, Single Convention, Art. 28 §§ (1) & (3). Article 23, in turn, requires that the signatory create a government agency to control cultivation by (a) designating where the product may be cultivated, (b) licensing any cultivators, and (c) purchasing and taking possession of the crop.[6] Resp. Ex. 2, (Single Convention, Art. 23 §§ 1 & 2). This section also requires that the government agency have

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[5] The government, in its Order to Show Cause, asserted that the Single Convention required it to license no more than one cultivator. Gov. Ex. 2, ¶ 8(a). The government has never explained this assertion, did not raise it at the hearing or in its Exception, and appears to have waived it. To whatever extent this assertion remains at issue, it has no merit, as the plain text of the Single Convention is to the contrary.

[6] As Judge Bittner noted, the government did not make clear whether the single agency responsible under the Convention is DEA or NIDA .

> the exclusive right of importing, exporting, wholesale trading and maintaining of [marijuana] stocks other than other than those held by manufacturers of [marijuana] alkaloids, medicinal [marijuana] or [marijuana] preparations. [The government agency] need not extend this exclusive right to medicinal [marijuana] and [marijuana] preparations.

Single Convention, Art. 23 § 2(e). The word "stocks" does not include material held: "(iv) By retail pharmacists or other authorized retail distributors and by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions, or (v) As "special stocks." *Id.*, Art. I § 1(x).

B. The Single Convention Does Not Require Physical Possession By the Government.

Judge Bittner correctly held that Article 23 § 2(d) does not require the government to take physical possession of Professor Craker's crop. As Judge Bittner noted, neither NIDA nor the DEA takes physical possession of Professor ElSohly's enormous, private, non-NIDA crop, which demonstrates that the government does not itself interpret the Single Convention as requiring such possession. ALJ Op. at 82. Indeed, at the time of the hearing, Professor ElSohly stored approximately 1,000 kilograms of marijuana stock under this private, non-NIDA registration, over which the government had no actual or constructive control. *Id.* And the DEA more recently allowed him to grow 4500 kilograms of non-NIDA, for-profit marijuana over which the government will have no control. Gov't Ex. 79.

In addition, as Judge Bittner also noted, there was also corroborating evidence that other signatories to the Single Convention also do not require physical possession. The United Kingdom, a signatory to the Single Convention, has addressed Article 23 § 2(d) by creating a system of constructive possession for *all* registered manufacturers. Resp. Ex. 51, Ex. A. Despite the government's bluster about that evidence (Gov't Br. at 2), it is clear that Judge Bittner simply looked at British practice as a helpful guide to interpret the treaty language. Given that the

United Kingdom's approach, like the DEA's, does not require the government to take physical possession, Judge Bittner's finding is the only one consistent with the evidence.

C. Professors Craker's Crop Will Have A Medicinal Purpose Or Will Not Be "Stocks."

Judge Bittner alternatively held that the Single Convention did not preclude Professor Craker's registration because the marijuana would qualify as "medicinal" under the treaty. ALJ Op. at 82. Under the Single Convention, the government has "the exclusive right of...maintaining stocks *other than* those held by manufacturers of...medicinal [marijuana]." Resp. Ex. 2 (Single Convention, Art. 23 § 2(e)) (emphasis added). The Single Convention defines "medicinal" marijuana as that "which has undergone the process necessary to adapt it for medicinal use." *Id.* at Art. I 1(o).

The government asserts that because marijuana "has no currently accepted medical use" there can be no medicinal marijuana. Gov't Br. at 4. But this argument fails.[7] First, as the government itself has stipulated, there is ongoing research into the medical uses of marijuana. ALJ Ex. 2. As a matter of common sense, marijuana used for that medical research is clearly used for medicinal purposes. Second, the marijuana used in FDA-approved research, as Professor Craker's will be, has clearly undergone processes necessary to adapt it for medicinal use. The FDA has rigorous standards for drugs that it permits to be used in FDA-approved clinical research. The marijuana will have to have been grown under consistent and thoroughly documented procedures, processed to remove most of the stems and seeds, and standardized as to

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[7] Whether marijuana has "currently accepted medical uses" under the Controlled Substances Act is not the issue under the Single Convention, which clearly anticipates research being performed with both all substances. And, as the evidence in the hearing established, some doctors do prescribe marijuana for medical use in states where it is legal under state law, others would if they legally could, and the government itself distributes marijuana *for medical use* to various patients under a "Compassionate Use" program. Tr. 492, 561-63; *and see Gonzales v. Raich*, 545 U.S. 1, 3 (2005).

potency and stability. Tr. Furthermore, the marijuana must have been grown, harvested, and processed in accordance with an FDA Drug Master File which must contain detailed descriptions of the procedures for growing and processing the marijuana, along with analytical data about its potency and stability, all of which the FDA must have reviewed and accepted. ALJ Op. 28-33. Professor Craker will grow a defined medical cannabis product, with specific levels of THC and other cannabinoid content based on requests from MAPS' researchers. Thus, like any botanical that is being grown according to specification, harvested, and prepared for medical research purposes, the medical marijuana Professor Craker grows will indeed have undergone the process necessary to adapt it for medicinal use. Otherwise, the FDA would not allow it to be used in testing. Third, the government's argument that a bulk manufacturer cannot be registered under the Single Convention to grow marijuana for medical uses is wholly undermined by DEA's own treatment of the 1000 kilograms of cannabis grown and maintained *privately* by Professor ElSohly under his private, non-NIDA, bulk manufacturer's registration for use in privately-developed medical products. Gov. Ex. 75, 76, 79 at 1; Tr. at 1463.

DEA's past practice as to Professor ElSohly plainly demonstrates its policy that it can, consistent with the Single Convention, register a bulk manufacturer who will "maintain" crops not controlled by NIDA or DEA. This may be because (whatever its litigation position now), the government understands that medical research is a medicinal purpose within the meaning of the Single Convention, or it may be that the government considers these crops to fall within one of the exceptions to the Single Convention definition of "stocks." As Judge Bittner explained, "retail stocks" and "special stocks," as they are defined by Article 1 § 1(x) are not "stocks" at all within the meaning of the Convention. ALJ Op. at 11.

Judge Bittner alternatively concluded that Professor Craker's medical marijuana would fall outside the Single Convention's exclusive government right to maintain stocks because that crop could be "special stocks." ALJ Op. at 82. As "special stocks" are those held "by the government...for special government purposes and to meet exceptional circumstances," Respondent does not maintain that his stocks would be "special stocks." Gov't Br. at 4. But it is evident that Judge Bittner simply inadvertently referenced the wrong term from Article 1 § 1(x), because both Professor ElSohly's crops and Professor Craker's crops *do* fit neatly into the definition of "retail" stocks: stocks held by retailers *or* "by institutions or qualified persons in the duly authorized exercise of therapeutic or scientific functions." Professor Craker, a plant and soil scientist at the University of Massachusetts Amherst, breeding and cultivating a defined product for medical research is an institution or qualified person in carrying out scientific and therapeutic functions. Once registered, Professor Craker will qualify for this exception just as Professor ElSohly does now.

For these reasons, registering Professor Craker as a bulk manufacturer of marijuana for medical research is consistent with the treaty obligations of the United States.

III. JUDGE BITTNER PROPERLY CONSIDERED AND WEIGHED THE STATUTORY FACTORS WHICH SUPPORT HER RECOMMENDATION THAT REGISTERING PROFESSOR CRAKER IS IN THE PUBLIC INTEREST.

A. Section 823 (a) (1)

1. Granting Professor Craker's Registration Does Not Impair Effective Controls Against Diversion.

21 U.S.C. § 823(a) requires the DEA to register an applicant to manufacture a Schedule I controlled substance if that registration is consistent with relevant treaties and in the public interest. The first factor relevant to the public interest is

> maintenance of effective controls against diversion . . . into other than legitimate medical, scientific, research, or industrial channels, by limiting . . . [manufacturing] 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). The District of Columbia Court of Appeals has explained, "The stated purpose of section 823(a)(1) is to effectively control against diversion and it 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 (D.C. Cir. 2004) (emphasis added). Thus, because Professor Craker's registration would not interfere with DEA's maintenance of effective diversion controls, the registration should be granted without regard to whether the current system is adequately competitive to ensure an adequate and uninterrupted supply to legitimate researchers.

In considering this factor, Judge Bittner evaluated the undisputed evidence that the DEA agents who visited the facility approved of Professor Craker's plans and told him they thought the proposed facility could be made secure. Judge Bittner also noted the undisputed evidence that Professor Craker's plans are to grow approximately 25 pounds in the first year of cultivation. In addition, there was undisputed evidence that Professor Craker has previous experience in classified military-funded agricultural research in secure facilities, and he recognized the importance of security in growing medical marijuana. Tr. at 366:14 - 367:12. Moreover, he stated that he would implement any further protections against diversion DEA requires. Tr. at 189:6-13 ("We would certainly want to go according to any of the instructions from the Drug Enforcement Administration [as to seed control]). Without any information from the government to the contrary, Judge Bittner concluded that the risk of diversion from the proposed facility at the University of Massachusetts-Amherst is minimal. ALJ Op. at 84.

The evidence was also undisputed, as Judge Bittner concluded, that Professor Craker would "send marijuana only to researchers who hold DEA registrations and, therefore, have the requisite approval from the Department of Health and Human Services, including findings that the researcher is qualified and competent, that the research protocol is meritorious, and that the research project has procedures in place to adequately protect against diversion of the marijuana." ALJ Op. at 84. As we have explained fully in Part I above, the government's argument that granting Professor Craker's registration here will result in distributing medical marijuana without the necessary "HHS" approval is simply meritless.

Judge Bittner also considered the likelihood of diversion after the medical marijuana leaves Professor Craker's plant laboratory. She noted that Dr. Doblin personally disagrees with DEA's positions on the dangers of marijuana use. However, she also noted that the undisputed record established that although MAPS, as the sponsor of the facility, would have the authority to allocate the medical marijuana to various research projects, only Professor Craker would have physical possession of the crop, and Professor Craker would distribute that marijuana only to properly DEA-registered researchers. Thus, she concluded that risk was also minimal. ALJ Op. at 84.

The government quibbles about whether Professor Craker related sufficient detail about the security procedures he would follow with regard to employee screening, inventory controls, quotas, reporting in-transit losses and the like. Gov't Br. at 5. But Professor Craker could not have said more clearly he would follow DEA requirements on security, as well as on procedures for controlling seeds and access. *E.g.,* Tr. at 189:6-13. He was not required to detail every step, particularly since the DEA agents have not yet finalized the particular steps they would require. Moreover, much of that detail is already articulated in DEA regulations, which Professor Craker

has stated he will follow. *See, e.g.* 21 C.F.R. § 1302 (regulations relating to labeling and packaging requirements); § 1303 (regulations relating to quotas); § 1304 (regulations about records and reports); § 1305 (regulations relating to orders and reports to DEA about the orders); § 1301 (regulations relating to security requirements); 1301.90 (regulations relating to employee screening procedures). Since these DEA regulations are presumably known to the DEA, its position that Professor Craker should have presented each regulation as part of his case to detail the steps he will need to follow is disingenuous, at best.

The government also contends that Dr. Doblin's admission that he previously used marijuana recreationally, and his personal view about the legalization of marijuana, somehow creates a risk that Professor Craker's medical marijuana—from a facility sponsored by MAPS, not Dr. Doblin—will be diverted. Gov't Br. at 5. Apparently stymied by its own inability to dispute the evidence that led Judge Bittner to conclude that neither MAPS nor Dr. Doblin would have physical control of the medical marijuana at any time, and that Professor Craker would distribute the marijuana he grows only to DEA-registered and FDA-approved researchers, the government can only look to *ad hominem* attacks and an implied "agency" theory that compares Dr. Doblin to Pablo Escobar and MAPS to the Medellin Cartel. But this absurd comparison could only begin to approach reality if the DEA and the FDA were to register and approve every Medellin customer before the Medellin growers would distribute their products.

In short, the evidence at the hearing amply supports Judge Bittner's conclusion that the risk of diversion from registering Professor Craker is minimal.

2. Granting Professor Craker's Registration is Necessary To Create the "Adequate and Uninterrupted Supply" of Medical Marijuana Under "Adequately Competitive Conditions For Legitimate Medical,

Scientific, Research, And Industrial Purposes" Required By Congress.

Based on the undisputed evidence relating to Dr. Abrams and Dr. Russo, two eminent researchers with FDA-approved research protocols that were indisputably "legitimate research" under 21 U.S.C. § 823(a)(1), Judge Bittner concluded, as the evidence compelled her to do, that NIDA's system for allocating taxpayer-funded marijuana for research purposes resulted in some legitimate researchers being unable to conduct their research. ALJ Op. at 84. In addition, the evidence also showed that the NIDA supply was inadequate because a pharmaceutical developer could not reasonably rely on NIDA marijuana to take marijuana through the FDA new drug approval process. Tr. at 437-440, Tr. at 550-554. And it is further inadequate because, as the evidence shows, some requests for NIDA marijuana are effectively denied simply by being ignored as they languish for months or years without decision. Ex. 14, Tr. at 535-539. She therefore concluded that the existing supply of marijuana is not adequate under §823(a)(1).

The government excepts to this finding, once again on the mistaken notion that FDA-approved research is not "legitimate" research under HHS policies. As we explained at length in Part I, *supra,* this argument is meritless, since any researcher receiving Professor Craker's medical marijuana will necessarily have both FDA approval (if the research involves clinical research), and a DEA license for that research which includes HHS/FDA approval. The government also complains that by considering the record as a whole and making a finding about the preponderance of the evidence, the ALJ somehow erred because some of that evidence was submitted by DEA rather than by Professor Craker. Gov't Br. at 8. This argument is similarly meritless. The ALJ is certainly entitled to consider all the evidence submitted, including evidence the government chose to submit.

The government also takes exception to Judge Bittner's recommendation on the theory that registering Professor Craker would result in a "shelf registration." In addition to its now-familiar—though utterly wrong—claim that the only "legitimate" researchers are NIDA/PHS-approved researchers, which we have addressed in Part I above, the government also suggests that because Professor Craker has not identified the particular researchers or companies who will use his product, the registration should be denied. But Judge Bittner properly noted that Professor Craker is only required to show that registration will be used to "produce marijuana that will be used in legitimate research." ALJ Op. at 84. Given the undisputed evidence that some FDA-approved, legitimate researchers have not been able to obtain NIDA marijuana, given MAPS' previous experience sponsoring FDA-approved and DEA-licensed research, and given the undisputed evidence of interest in researching the medical uses of marijuana demonstrated by the studies in the California-financed Center for Medicinal Cannabis Research (CMCR), there is ample showing that Professor Craker's medical marijuana will be used in legitimate research.

Finally, the government takes exception to Judge Bittner's finding that NIDA's actions of soliciting competitive bids every five years for one contract that includes both growing the NIDA marijuana and analyzing large quantities of samples of marijuana for law enforcement provides "adequate competition" as required by 21 U.S.C. § 823(a)(1). ALJ Op. at 85. The government argues that because this process results in competition as to price, that is all that is required. However, as Judge Bittner pointed out, the question is whether competition results in "marijuana [being] made available to all researchers who have a legitimate need for it in their research." ALJ Op. at 85. Plainly, given the evidence relating to Dr. Abrams and Dr. Russo, NIDA's competitively bid contract does not yield that result. To the contrary, for researchers, it results a monopoly. Moreover, the bidding process does not create competition as to quality, services,

variety of product, or even price for researchers. More fundamentally, the process results in a monopoly that blocks legitimate research by FDA-approved researchers. The end-result of the competitive bidding process, for whomever wins the contract, is to grow marijuana for the government monopoly. In contrast, Professor Craker is seeking to grow marijuana for use in privately-funded pharmaceutical research aimed at developing marijuana, smoked and/or vaporized, into an FDA-approved prescription medicine, a use for which HHS policy says that NIDA will not provide marijuana. Should Professor Craker have bid on and obtained the NIDA contract, NIDA would still own the marijuana he grew and would still refuse to provide any for privately-funded research aimed at developing marijuana, smoked and/or vaporized, into an FDA-approved prescription medicine. Thus, there is simply no evidence that would justify a finding that NIDA's bid process provides "adequate competition" that will produce an adequate and uninterrupted supply for all legitimate research.

B. 21 U.S.C. § 823(a)(2). Compliance with State and Local Law.

Judge Bittner properly found that there is neither evidence nor contention that Professor Craker has not complied with applicable laws and therefore, this factor weighed in favor of granting the registration. ALJ Op. at 85. In its brief, the government agrees with the ALJ's finding that there is no evidence Respondent has not complied with state law. However, the government takes exception with the ALJ weighing this factor in favor of the Respondent because "an expectation by Respondent that the required state license will ineluctably follow the granting of a DEA registration and a promise to comply with state and local law in the future simply renders this factor irrelevant... ." Gov't Br. at 12. Contrary to the government's assertion, the law does not require that state licenses be granted as proof of compliance with the law. Rather, a lack of evidence of non-compliance with applicable laws is ample evidence to

support a finding that weighs this section in favor of the applicant. *See*, *Johnson Matthey*, 67 FR 39041, 39044 (2002). All parties agree that the record reveals a lack of evidence of non-compliance and therefore supports a finding that this section weighs in favor of the applicant.

Moreover, there is ample evidence to refute even the government's musings about whether Professor Craker will be able to comply with state law in the future since he does not yet have a state license. First, the University of Massachusetts at Amherst, a state-run facility, has been involved in every step of the application process and given its stamp of approval. Second, thirty-eight Massachusetts and federal lawmakers have notified the Court that they support Professor Craker's application. Resp. Ex.50. Third, officials from the Commonwealth of Massachusetts had previously asked Professor Craker to consider cultivating medical marijuana for the Commonwealth of Massachusetts. Tr. at 212. And finally, the evidence was undisputed that Professor Craker has met with Massachusetts investigators about the requirements for a state license, and those investigators indicated that if the federal permit was granted, the state permit would be granted as well. Tr. at 45-46.

Because an applicant need only show that he has not violated any local or state laws to weigh this factor in favor of the applicant, and because the applicant here has shown far more, the undisputed record supports Judge Bittner's conclusion that this section weighs in favor of Professor Craker.

C. Section 823(a)(3). Technical Advances.

Judge Bittner found that insufficient evidence existed in the record to support a finding that Professor Craker's registration would promote technical advances, though she noted his expertise in cultivating medicinal plants "might" promote technical advances. ALJ Op. at 86. Oddly, the government excepts to Judge Bittner's finding of insufficient evidence, apparently on

the ground that Judge Bittner should not have even noted the possibility of technical advances. In addition, the government argues there was no evidence of technical advances, and that Judge Bittner should have stated that this factor weighed against the application.

The government is simply wrong when it insists that there is no evidence that Professor Craker's application will promote technical advances. The government confuses using existing methodologies to grow marijuana with *promoting* scientific and technical advances. In *Roxane Laboratories, Inc.*, 63 FR 55891 (1998), the Acting Deputy Administrator found that a mere marketing scheme, which capitalized on a previously existing delivery method for cocaine, would promote scientific and technical advances, and thus weighed the factor in favor of the applicant. Here, Professor Craker will be the first privately-funded marijuana manufacturer in the United States manufacturing, by cultivation, a product designed to meet the FDA new drug approval requirements for a botanical medical marijuana product. This manufacture is a necessary first step to developing marijuana as an FDA-approved product, since as witnesses for both sides testified, the first thing a pharmaceutical developer needs is a reliable and consistent source of the product it seeks to develop. Tr. at 117-120; 437, 2026, 2033.

Moreover, one of Professor Craker's explicit goals is to provide marijuana for use in testing and developing a non-smoked marijuana vaporization delivery system for botanical medical marijuana, a new device which is in the early stages of development and has been approved for use in FDA-approved clinical researchSuch a delivery system would certainly constitute a technical advance, and registering Dr. Craker, who will grow marijuana specifically for that purpose will certainly promote that technical advance. Finally, Professor Craker will be the first registrant in the United States to use an indoor controlled method of production which provides more precise knowledge about, and consistency in, the chemical composition of the

plant. Indeed, this undisputed evidence should compel the Deputy Administrator, on review, to conclude that registering Professor Craker would promote scientific and technical advances in the area of marijuana as a botanical medicine, and that this factor weighs strongly in favor of granting the application.

D. Section 823(a)(4). Applicant's Prior Conviction Record.

21 U.S.C. § 823 (a)(4) provides that a further factor in determining the public interest is "prior conviction record of applicant under federal and state laws relating to the manufacture, distribution, or dispensing of such substances." It is undisputed that Professor Craker is the applicant in this proceeding, and it is further undisputed that Professor Craker has never been convicted of violating any law pertaining to controlled substances. It is therefore not surprising that Judge Bittner concluded that Professor Craker carried his burden as to this element, and it should weigh in his favor. ALJ Op. at 86.

The government, however, manages to except to this finding, as well. Specifically, it objects to defining the statutory term "applicant" as "the applicant for the registration." Instead, the government argues that the "applicant" must also include all other parties who are "interested" in the proceeding. Having expanded the definition of "applicant" beyond its commonsense meaning, the government then seeks to rely on evidence relating to Dr. Doblin's personal views about marijuana use, and his admitted past recreational use of marijuana. But these exceptions are groundless.

First, the plain meaning of "applicant" is the entity applying for the registration. In this case, Professor Craker is the individual applicant and the evidence was undisputed that he, and not Dr. Doblin or anyone from MAPS would be in charge of the operations involved in manufacturing marijuana. Professor Craker, not Dr. Doblin or anyone from MAPS, is

responsible for maintaining a secure facility and ensuring the appropriate security measures are met. Indeed, the evidence was undisputed that neither MAPS nor Dr. Doblin would have physical possession of the marijuana at any time, and that Professor Craker would send it only to FDA-approved and DEA-registered researchers. Thus, the government's argument is wholly contrary to the undisputed facts.

Second, the caselaw the government cites is wholly inapposite because those cases each involve a corporate entity applicant. Because a corporation is a legal fiction, not a real person, and because the corporation cannot act without real persons, the DEA reasonably understands that the actual persons who will in fact control the activities under the license are also the applicants. This is especially true where, as in the cases cite by the government, the business in question is a retail store, in which employees, owners, and others with control have physical access to the controlled substances. *Big T Pharmacy Revocation,* 47 FR 51830 (1982). *See Market Street Market*, 67 FR 11142 (2002) (where applicant was convenience store owned and operated by Mr. and Mrs. Kim, any convictions of Mr. and Mrs. Kim were appropriately considered); *Planet Trading, Inc.* 71 FR 11055 (2007) (applicant was corporation owned and operated by its president, justifying consideration of his record); *Georgia Convenience Wholesale* 72 FR 9969 (2007) (applicant was corporation owned and operated by Mr. Yaqoob and Mr. Omar whose records were therefore considered).

In sharp contrast, here, Professor Craker *is* the key person who will carry out the activities at the University under the registration. Neither MAPS nor Dr. Doblin will be in the lab, nor will they have access to the premises. Neither case law nor common sense support the notion that a geographically distant research sponsor without access or physical control can be considered the registration "applicant." Thus, the government's assertion that Dr. Doblin and

MAPS are the "real parties in interest" because Dr. Doblin assisted Professor Craker in the application process and because MAPS has agreed to sponsor Professor Craker's production facility as well as research using the marijuana Professor Craker seeks to manufacture, must fail.

Finally, even if MAPS and Dr. Doblin were key operators in the manufacturing process Professor Craker proposes (and they clearly are not) such that they could be considered "applicants," the evidence is undisputed that neither Dr. Doblin nor MAPS have any prior convictions. Trying to get around this hurdle, the government posits the "obvious reality that MAPS, an organization which supports the legalization of drugs for recreational use is seeking to set up the University of Massachusetts program as a front organization . . . ." Gov't Br. at 15. But this "reality" is wholly fabricated by the government—there was no such evidence adduced at the hearing. MAPS has taken no position on the legalization of drugs of abuse for recreational use, and the government introduced no evidence that it has. To the contrary, the undisputed evidence is that MAPS' organizational mission is to develop Schedule 1 drugs into FDA approved prescription medicines and to educate the public about the risks and benefits. Tr. at 473:18. Moreover, the government wholly ignores the undisputed evidence that MAPS has sponsored numerous DEA-registered researchers in a variety of FDA-approved Phase I and Phase II drug trials involving controlled substances, including MDMA, psilocybin, ibogaine, ketamine, and marijuana and that it currently holds a Master Drug File for MDMA. Tr. at 482-491. Indeed, when NIDA denied MAPS permission to purchase psilocybin for its sponsored researchers to use in FDA-approved research, MAPS purchased its own supply from a commercial laboratory to carry out MAPS-sponsored research, all without a hint of the sort of

diversion the government suggests is behind the "front" of medical research.[8] Tr. at 15. And finally, while in response to a direct question from the government, Dr. Doblin expressed his personal views about marijuana legalization, Tr. at 638, Dr. Doblin, like MAPS, will have no possession or control over Professor Craker's medical marijuana except to determine which duly FDA-approved and DEA-registered researchers will receive it from Professor Craker.

The ALJ properly concluded that this factor weighs in favor of the granting Professor Craker's application.

E. Section 823(a)(5). Prior experience.

The ALJ properly ruled that lack of experience handling a controlled substance is not sufficient to weigh this factor against Professor Craker. ALJ Opinion p. 86. Because Professor Craker has significant and extensive experience cultivating and propagating medicinal plants, (including in secure research facilities), Judge Bittner properly found that this statutory factor weighs in favor of granting his application.

The government argues that experience relevant to this factor is limited to controlled substances and states, "[i]n no case involving applications to handle controlled substances, has 'prior experience' with non-controlled substances ever been considered as support for granting an application." But this argument is simply wrong. In *Chattem Chemicals Inc.,* 71 FR 9834, 9838 (2006), for example, a case cited by the government, the applicant had no prior experience in processing opium alkaloids, the controlled substance for which it sought a manufacturer's

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[8] The government never articulates why it speculates MAPS intends to divert Dr. Craker's marijuana, other than to hint it could be used for personal recreational use. And it also never explains why MAPS would invest over six years and, once the license is granted, spend hundreds of thousands of dollars in (1) funding Dr. Craker's facility to manufacture a defined medical marijuana project (2) funding FDA-approved studies (3) developing an FDA master drug file designed to take marijuana through the FDA new drug approval process, simply to have a chance at diverting the 25 pounds of medical marijuana Dr. Craker proposes to grow.

registration. Nonetheless, based on evidence that the applicant's experience handling "alkaloid-like materials" was relevant experience, and on the evidence that the process for extracting the alkaloids "is not a new or complex process," the Deputy Administrator concluded that the prior experience factor weighed in the applicant's favor. *Chattem,* 71 FR at 9838. Similarly, here, the process for cultivating marijuana is not a "new or complex process," and Professor Craker's experience in cultivating other medicinal plants is directly applicable to the process of manufacturing marijuana.

The government's argument also ignores the important interrelationship of the "prior experience" factor and the danger of diversion. The case law cited by the government illustrates that an applicant's lack of prior experience handling controlled substances is significant where that lack of experience translates into an increased risk of diversion. *See* Gov't Brief at 18. In *Prodim Denial of Application* (64 FR 15809 (1999), for example, the applicant was an individual proposing to export drugs for his volunteer work in Honduras. He had no experience with or even knowledge of any steps necessary to avoid the risk of diversion. In fact, the Deputy Administrator could not determine who would be responsible for the controlled substances, what controls against diversion would be in place during the shipment of any controlled substances, or the identity or location of the agencies with physical custody of the controlled substances. Not surprisingly, the Deputy Administrator weighed this factor against the applicant. In contrast, here, Professor Craker has agreed to implement the DEA security requirements and to send the medical marijuana only to properly registered and approved researchers.

Moreover, even when substantial misconduct constitutes an applicant's prior experience, leading the ALJ to weigh this factor against the applicant, the DEA has nevertheless granted registration to such applicants where the evidence indicates little likelihood of diversion. Thus,

in *Johnson Matthey, Inc.*, 60 FR 26050 (1995), despite finding that applicant's misconduct was sufficient to deny the entire application, the ALJ recommended and the Deputy Administrator agreed to grant the application because the applicant had no relevant prior convictions or history of noncompliance with state and local law, security systems were adequate to handle controlled substances, and the applicant showed a satisfactory history of handling other substances. Here, while Professor Craker concedes he has had no experience handling marijuana—and indeed, there is only one grower in the entire nation, Professor ElSohly, who can claim that experience legally—there is also no record of "substantial misconduct" or failure to control for diversion that can properly be weighed him. Nor does that lack of experience suggest any increased risk of diversion where the record is undisputed that Professor Craker has agreed to implement the DEA's security requirements and that he will distribute the medical marijuana only to those researchers who have the necessary approvals and requirements under federal law.

The government also suggests that cases relating to distribution of List I chemicals are analogous to this one. But because those cases involve distribution largely or only to "grey market" convenience stores, they are entirely inapposite to this case, which involves distribution only to medical researchers with FDA approval and an appropriate DEA license. For example, the government cites cases involving List I chemicals commonly used as precursors in the illicit manufacture of methamphetamine. Gov't Br. at 19. There, the lack of experience in distributing List I chemicals weighed against granting a registration because "[v]irtually all of the Respondent's customers, consisting of gas station and convenience stores, are considered part of the gray market, in which large amounts of listed chemicals are diverted to the illicit manufacture of amphetamine and methamphetamine." *Xtreme Enterprises, Inc.*, 67 FR 76195 (2002). In the other cases, a lack of experience in distributing List I chemicals weighed against applicants who

failed to display even the most rudimentary knowledge regarding the milligram strengths of the listed chemical products or what would constitute a suspicious order. *Jay Enterprises*, 70 FR 24620, 24621 (2005) ; *ANM Wholesale*, 69 FR 11652, 11653 (2004); *Taby Enterprises of Osceola, Inc.*, Denial of Application 71 FR 71557, *71558.

That minimal past experience with list chemicals is weighed more heavily where the applicant will be distributing those precursor chemicals through "grey market "channels most likely to be used by illicit manufacturers does not suggest a lack of that past experience with marijuana should be weighed the same here, where Professor Craker will simply be developing the product in a secure facility at the University of Massachusetts and distributing it only to FDA-approved and DEA-licensed researchers. And, unlike the applicants in the methamphetamine precursor cases, Professor Craker has significant experience with the science involved in manufacturing medicinal plants, and that science applies to cultivating marijuana.

The record supports the ALJ's finding weighing the "prior experience" factor in favor of granting Professor Craker's application. Indeed, Professor ElSohly acknowleged that when he first applied for his bulk manufacturing license, he lacked experience and expertise in security measures relating to controlled substances, and conceded that the experience required for his first license was experience in "the plant and soil sciences and the development of medicinal plants." Tr. at 1346:13-20. Like Professor ElSohly, Professor Craker has no negative history with controlled substances, DEA agent agreement that he can to control for diversion, and the scientific experience to cultivate a defined medical marijuana product. Thus, like Professor El ElSohly's, Professor Craker's prior experience supports his application for the registration.

F. Section 823(a)(6)

The final factor in the public interest analysis is "such other factors as may be relevant to and consistent with the public health and safety." 21 U.S.C. § 823(a)(6). Having dealt with all the factors the government raised in its post-trial briefing elsewhere, Judge Bittner concluded that there were no other factors to be considered. ALJ Op. at 86. The government again excepts to this conclusion and argues that the ALJ erred by failing to consider Dr. Doblin's attitude toward marijuana under this section. Gov't Br. at 20. But as Judge Bittner plainly observed, she dealt with that evidence earlier, and there was no need to consider it again under this "catch-all" factor. ALJ Op. at 86.

The government also raised one last time its flawed argument that HHS policy requires NIDA/PHS approval for researchers to obtain marijuana from sources other than NIDA, so registering Professor Craker would violate HHS allocation policy. Gov't Br. at 21. As we have debunked that argument in Part I, we will not repeat it here.

Finally, the government objects because Judge Bittner did not conclude that this factor should be weighed against Professor Craker. Gov't Br. at 21. But this is nonsense -- if there are no factors to consider under the catch-all factor, the factor is simply neutral.

CONCLUSION

For all these reasons, and for the reasons articulated in Respondent's Post-Hearing brief, Judge Bittner properly concluded that registering Dr. Craker as a bulk manufacturer of marijuana was consistent with the public interest and not precluded by treaty. We urge the Deputy Administrator, after reviewing the record, to accept Judge Bittner's well-documented findings and conclusions and to adopt her recommendation.

In March 1992, then-DEA Administrator Robert Bonner stated, "Those who insist that 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." Federal Register Vol. 57, No. 59 / Thursday March 26, 1992, p. 10503. MAPS has been working for more than 15 years to sponsor such legitimate scientific research, only to see its researchers blocked from obtaining access to marijuana to conduct that research. Registering Professor Craker to cultivate a defined medical marijuana product will open the door for the research Administrator Bonner suggested. More fundamentally, it will bring the supply of marijuana for legitimate medical research into compliance with the system Congress has statutorily required DEA to ensure.

Respectfully submitted,

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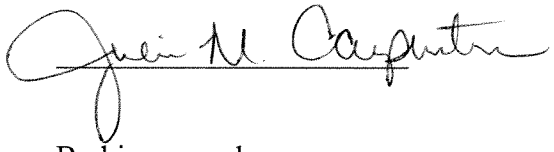

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2007, I caused a copy of the foregoing Respondent's Response to Government's Exception to Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge to be served on the following by hand-delivery:

Brian Bayly, Esq.
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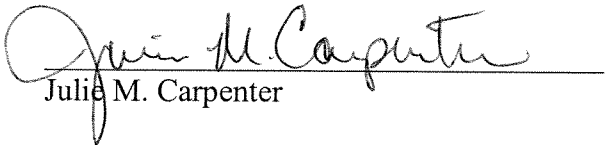
In addition, the original and two copies were delivered by hand to the DEA Office of Administrative Law Judges on March 26, 2007.



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