UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of	)	Docket No. 05-16
	)	
LYLE E. CRAKER, Ph.D.	)	**Respondent's Second Supplemental Brief**
	)	**in Support of Motion for Reconsideration**
Denial of Bulk Application for	)	
Registration as Bulk Manufacturer	)	
of Marijuana	)	
	)	

Pursuant to the Deputy Administrator's December 2, 2010 Order,[1] Respondent Dr. Lyle E. Craker submits this supplemental filing and attached documents in support of his Motion for Reconsideration. This filing supplements Dr. Craker's January 30, 2009 and March 11, 2009 motion papers. Dr. Craker incorporates by reference the arguments made, and documents referred to, in those papers, some of which are elaborated upon herein. Although Dr. Craker here responds to some of the points raised in the DEA's January 14, 2009 and December 2, 2010 Orders, he has not attempted here to raise all issues implicated in these rulings, and reserves his right to raise these and other issues both before the agency and on appeal.

PRELIMINARY STATEMENT

This case is about a decade-long battle of politics versus science in the field of medical marijuana. Specifically, this case exposes the heads-I-win, tails-you-lose logic of the federal government's policy toward medical marijuana research: the government claims that marijuana offers no medical benefit to patients, and yet the government is simultaneously cutting off access to research material for scientific studies that seek to determine what medical benefit marijuana might have. The result is that the federal government remains willfully blind to the possibility of scientific results that do not match its political preconceptions.

[1] *See In re Lyle E. Craker, Order Regarding Respondent's Request Under 5 U.S.C. § 556(e) To Respond to Officially Noticed Evidence and Motion for Reconsideration* , No. 05-16 (Dec. 2, 2010) (hereinafter "Dec. 2 Order"), at 27.

Research into the possible medical benefits of marijuana is more important now than ever: fifteen states (Alaska, Arizona, California, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Jersey, New Mexico, Oregon, Rhode Island, Vermont, and Washington) and the District of Columbia have all decriminalized the possession and use of marijuana for medical purposes, but the federal government is effectively obstructing the scientific research necessary to help resolve the ongoing debate over what, if any, medical benefits marijuana offers to patients. The federal government's official policy is that marijuana has no medical benefit. But the government is unwilling to put its policy to the test of science: instead, the government exercises monopoly control over the nation's supply of marijuana that may be used for scientific purposes, by allowing an agency whose mission is to explore the consequences of the *abuse* of marijuana—the National Institute on Drug Abuse (NIDA)—to determine what research may go forward regarding marijuana's *beneficial* medical uses. The result is that, as explained in more detail below, marijuana alone out of all potential medicines is subject to a special and obstructive process that places politics over science.

This case is an effort to open up that process in order to advance scientific and medical knowledge about a substance that appears to be providing relief to thousands of patients notwithstanding the federal government's classification of marijuana as a substance that has "no currently accepted medical use."

The existing regulatory system for the approval of new medications works like this: approval from the Food and Drug Administration (FDA) is required to create a medicine that is sanctioned under federal law; FDA approval is granted only to new medicines that have been proven effective in rigorous clinical testing; and FDA, Drug Enforcement Administration (DEA) and State approval are all required to perform the necessary clinical testing on controlled

substances such as marijuana.[2] This is the system for all medicines licensed in the United States, and it is a sensible one.

But for marijuana only, an additional agency is involved: NIDA. In the case of marijuana, the DEA has licensed only one bulk manufacturer of research marijuana, at the University of Mississippi. Access to research material from the University of Mississippi is dependent on approval by a Public Health Service/NIDA protocol review process (hereafter simply "NIDA review"), in addition to approval by FDA, DEA and State authorities.

This case is about whether the DEA should license a second manufacturer, whose distribution of the marijuana would be subject to the standard, rigorous regulations of the FDA, the DEA and State authorities, but not the additional NIDA review, which exists only for marijuana but no other controlled substance. In February 2007, DEA Administrative Law Judge ("ALJ") Mary Ellen Bittner held that licensing a second manufacturer was in the public interest. In January 2009, the DEA rejected this finding and denied the application. Respondent Dr. Craker respectfully requests reconsideration of that decision.

STATEMENT OF THE CASE AND FACTS

On June 26, 2001, University of Massachusetts, Amherst, Professor of Plant, Soil, and Insect Sciences Dr. Lyle E. Craker applied for Drug Enforcement Administration registration to grow marijuana for scientific research. Dr. Craker seeks this registration in order to provide a new source of marijuana for privately-funded, government-licensed researchers seeking to study marijuana's potential medical uses through the FDA drug development process in order to make it available as a prescription medicine.

[2] FDA regulations also require review by an independent "Institutional Review Board" (IRB). *See* 21 C.F.R. §§ 56.101 *et seq*. Here and throughout this brief, references to FDA review or approval include review or approvals by an IRB where required under FDA regulations.

DEA Administrative Law Judge Mary Ellen Bittner, after extensive legal hearings involving numerous witnesses, issued a thorough 87-page opinion finding, pursuant to the relevant statutory criteria, that licensing Dr. Craker would be in the public interest. Specifically, the ALJ found that

> granting Respondent's application would not be inconsistent with the [U.S. international treaty obligations], that there would be minimal risk of diversion of marijuana [to unauthorized uses] resulting from Respondent's registration, that there is currently an inadequate supply of marijuana available for research purposes, that competition in the provision of marijuana for such purposes is inadequate, and that Respondent has complied with applicable laws and has never been convicted of any violation of any law pertaining to controlled substances.[3]

The ALJ therefore recommended that Dr. Craker's application be granted.

As uncontroverted testimony before the ALJ established, the National Institute on Drug Abuse has long held a monopoly on the supply of marijuana—but no other drug—that can legally be used in medical research. NIDA's monopoly, created by DEA's refusal to license any additional bulk manufacturer, has resulted in a dearth of privately-funded medical marijuana research for over 40 years. Until DEA ends the NIDA monopoly by registering another bulk manufacturer, such as Dr. Craker, to produce marijuana for privately-funded researchers, there cannot be an adequate and uninterrupted supply of marijuana for research intended to obtain FDA approval of marijuana as a prescription medicine.

Under the current system, medical marijuana patients and their advocates face the archetypal catch-22: marijuana cannot be made available as a prescription medicine because the government (specifically, the FDA) has not approved its medicinal use. Yet at the same time the government (specifically, NIDA) has blocked the very research necessary to allow the FDA to decide, on the basis of scientific inquiry into safety and efficacy, whether marijuana should be available to patients. NIDA's monopoly is not mandated by Congress. Instead, it results from

[3] *In re Craker*, No. 05-16 (Feb. 12, 2007) (hereinafter "ALJ Op."), at 87.

DEA's failure to register additional manufacturers to produce marijuana for privately-funded researchers. NIDA and DEA have made clear that they oppose marijuana becoming available as a prescription medicine.[4] That decision, however, properly lies not with NIDA or DEA, but rather with the FDA, which in turn has never been able to answer the question because the drug development research necessary to evaluate it is fundamentally obstructed under the current system of supply.

Within his first week in office, President Obama explicitly directed a move away from an era in which "[r]igid ideology has overruled sound science."[5] More formally, on March 9, 2009, the White House issued a Memorandum for the Heads of Executive Departments and Agencies concerning "Scientific Integrity" stating:

> Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health . . . . The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions . . . .[6]

To date, NIDA's and DEA's approach to medical marijuana has been to deny its potential benefits and obstruct the privately-funded research necessary for FDA to decide whether or not it should be approved as a prescription medicine. Dr. Craker's application seeks to end this obstruction and let these important questions be answered by science, not politics.

A. The Federal Regulatory Structure

Research with controlled substances is subject to a host of regulations and to the authority of two main regulatory agencies: FDA permission is a prerequisite to initiate clinical studies, and DEA is the agency that ensures controlled-substance researchers do not divert drugs to

---

[4] *See, e.g.,* U.S. Drug Enforcement Admin., "Exposing the Myth of Smoked Medical Marijuana," *at* http://www.usdoj.gov/dea/ongoing/marijuana.html (last visited Jan. 25, 2011).
[5] *See* Ex. A to Resp. Supp. Br. (Mar. 11, 2009).
[6] *See id.*, Ex. B, *available at* http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/ (last visited Mar. 2, 2011).

unauthorized use. But it is a third government agency, NIDA, that holds the contract with, and controls the research material from, the only currently licensed manufacturer of research marijuana in the nation. Thus, unlike research with any other controlled substance, if a proposed research project involves marijuana, the research cannot take place unless approval has been obtained not only from FDA and DEA, but also from a redundant NIDA review process. This additional and unique layer of NIDA review for marijuana research is not mandated by statute, but rather exists because of the confluence of NIDA-related regulations and DEA's failure to register an additional manufacturer, like Dr. Craker, to provide marijuana for privately-funded research. The DEA has registered Professor Mahmoud ElSohly at the University of Mississippi as the nation's only bulk manufacturer of marijuana. NIDA has contracted with Dr. ElSohly to provide marijuana *only* to NIDA, only for research projects that NIDA has approved. Importantly, this additional NIDA review applies not only to NIDA-funded or other government-funded research, but even to privately-funded research with FDA-approved protocols.

NIDA's mission is to study drug *abuse*, not to research beneficial medical uses for controlled substances. It is certainly not to facilitate taking marijuana through the FDA approval process. That is what Dr. Craker's non-profit sponsor seeks to do, and why Dr. Craker seeks DEA registration. Dr. Craker established at the hearing that because of NIDA's entrenched view of what research should be conducted, NIDA has denied research material to, and thereby effectively blocked, several medical marijuana research projects even though the projects have met the FDA standards for scientific merit and safety and would have been conducted in accordance with DEA controls against unauthorized use. In the words of NIDA's Director Dr. Nora Volkow, "It is not . . . NIDA's mission to study the medicinal uses of marijuana or to

advocate for the establishment of facilities to support this research."[7] On this basis, ALJ Bittner found the current supply of marijuana for research to be inadequate.

B. The ALJ Recommendation and the DEA Final Order

ALJ Bittner held a nine-day hearing in 2005 and then on February 12, 2007 recommended that Dr. Craker's application be granted under the multi-factor analysis prescribed by the Controlled Substances Act as codified in relevant part at 21 U.S.C. § 823.[8] Importantly, the ALJ found that the evidence at the hearing established that the existing supply of marijuana for medical and scientific research is not adequate because NIDA has exercised its control over that supply to obstruct legitimate FDA-approved research by DEA-licensed researchers.[9]

In 2009, after almost two years of delay and days before the inauguration of President Obama, the DEA rejected the ALJ recommendation and denied Dr. Craker's application.[10] (All further references to DEA's position will be references to its 2009 Order, except as noted.) Dr. Craker filed a Motion for Reconsideration and sought an opportunity to respond to evidence that was judicially noticed in the DEA's January 2009 decision but to which Dr. Craker had not been given an opportunity to respond. At the DEA's request, Dr. Craker proffered a list of witnesses he would call if permitted. On December 2, 2010, after almost two years of additional delay, the DEA issued an order rejecting Dr. Craker's request to call witnesses, but the DEA did take notice of certain documents and invited this one final brief in support of reconsideration.

ARGUMENT

The Controlled Substances Act directs that the federal government "*shall* register an applicant to manufacture controlled substances in Schedule I or II if . . . such registration is

---

[7] *See* Resp. Hrg. Ex. 13 (Volkow letter to Rick Doblin).
[8] *See* ALJ Op.
[9] *See id.* at 84.
[10] *See Denial of Craker Application*, No. 05-16 (published Jan. 14, 2009), 74 Fed. Reg. 2101-03 (hereinafter "DEA Order").

consistent with the public interest and with United States obligations under international treaties[.]"[11] In defining the "public interest," the statute instructs the government to "limit[] 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*."[12] The statute lists four other factors, including "the existence . . . of effective control against diversion,"[13] that should be considered in determining whether to grant a license, along with "such other factors as may be relevant to and consistent with the public health and safety."[14]

Under these criteria, the DEA rejected the ALJ recommendation and denied Dr. Craker's application for three reasons: first, because it found that the lone current manufacturer produces an adequate supply under adequately competitive conditions; second, because the DEA concluded that granting the application would violate an international treaty, the Single Convention on Narcotic Drugs; and third, because the executive director of the organization that sponsors Dr. Craker has used marijuana recreationally.[15] Because each of these conclusions is unsupported by the record, legally erroneous, or irrelevant, Dr. Craker requests that his Motion To Reconsider be granted and that the ALJ's recommendation be adopted by DEA.

I. The Current Source of Research Marijuana Does Not Produce An Adequate Supply Under Adequately Competitive Conditions.

As the DEA has recognized, the public interest as defined in 21 U.S.C. § 823(a)(1) requires granting Dr. Craker's applications if either the current supply is not "adequate and

[11] 21 U.S.C. § 823(a) (emphasis added).
[12] *Id.* § 823(a)(1) (emphasis added).
[13] *Id.* § 823(a)(5).
[14] *Id.* § 823(a)(6)
[15] *See* DEA Order, 74 Fed. Reg. at 2126-27, 2133.

uninterrupted" or the supply does not ensure "adequately competitive conditions."[16] The Administrative Law Judge who heard nine days of live testimony found that the current supply of research-grade marijuana and competition for that supply are inadequate because NIDA's monopoly results in the denial of research material to legitimate, FDA-approved and DEA-licensed studies that propose to explore the benefits of marijuana as medicine.[17] Though the DEA points to other marijuana research that NIDA has allowed,[18] none of these studies aimed to develop marijuana into a legal prescription medicine. And the fact remains that several research projects have been blocked by NIDA in spite of FDA-approved protocols. The NIDA monopoly renders the supply inadequate because entire categories of legitimate medical research are effectively foreclosed; as a result, the scientific debate is slanted in favor of NIDA's preferred position that marijuana has no legitimate medical uses. (It should be noted that the specific instances of researchers being denied research material do not indicate the full extent of the problem: Dr. Craker proffered additional testimony regarding the chilling effect these instances have had on other researchers who have been dissuaded from even submitting protocols to the FDA, but the DEA denied Dr. Craker the opportunity to present this testimony.)

By statute, Congress has delegated to the FDA, and not to NIDA, the responsibility of evaluating the efficacy and safety of all new drug products.[19] In fulfilling this important responsibility the FDA reviews protocols submitted by researchers,[20] and conducts "an assessment of the scientific quality of the clinical investigations."[21] But the effect of the NIDA

[16] *See id.* at 2113.
[17] *See* ALJ Op. 84, 87.
[18] *See*, *e.g.*, DEA Order, 74 Fed. Reg. at 2105-06.
[19] 21 U.S.C. § 393(b).
[20] 21 U.S.C. § 355.
[21] 21 C.F.R. § 312.22(a).

monopoly perpetuated by DEA is that NIDA, instead of the FDA, determines which medical marijuana research goes forward and which does not.

The current supply of research marijuana is not "adequate and uninterrupted" because NIDA selectively denies research material to studies not in keeping with its policy predispositions regarding whether and how marijuana can be medically useful. The undisputed evidence indicates that NIDA does not seek to facilitate research into marijuana as medicine: as NIDA's Director has explained, "It is not . . . NIDA's mission to study the medicinal uses of marijuana or to advocate for the establishment of facilities to support this research."[22] To the limited extent NIDA has been willing to permit medical marijuana research, that research has conformed to the agency's own views about how marijuana could be medically useful. For example, NIDA accepts the possibility that *certain components* of marijuana can become prescription medicine, but it specifically rejects whole-plant smoked or vaporized medical marijuana.[23] (By contrast, the FDA has officially stated that it will consider new botanical drugs and has in fact published a formal guide for making such request.[24]) In addition, NIDA does not support taking marijuana medications through the FDA approval process for marketing as a new drug. As Dr. ElSohly, the researcher with whom NIDA has contracted to manufacture marijuana at the University of Mississippi, explained, "if somebody wants to develop a commercial product with marijuana, they could not use the NIDA marijuana."[25]

---

[22] Resp. Ex. 13 (Volkow letter to Rick Doblin).
[23] *See, e.g.*, Gov't Hrg. Ex. 24 at 2 (1999 NIDA Guidelines for supplying marijuana to an FDA-approved research) ("[T]he goal . . . *must be* to determine whether *cannabinoid components* of marijuana . . . can meet the standards [to become] a medical product." (emphasis added)); *id.* ("[T]he purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug.").
[24] *See* U.S. Dep't of Health & Human Servs., Food & Drug Admin., Guidance for Industry: Botanical Drug Products (June 2004), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070491.pdf.
[25] Tr. of ALJ Hrg. 1463.

The government contends NIDA's additional review is necessary to ensure scientific value, but as NIDA's own guidelines reflect, the FDA approval process already does this.[26] Thus the additional layer of NIDA review, which applies only to marijuana and not to any other Schedule I controlled substance, appears aimed at screening out studies based on something other than scientific value: NIDA's political judgments.

Consistent with NIDA's institutional biases, a number of researchers with FDA-approved protocols have been denied access to research marijuana because NIDA did not approve of their research goals. Specifically, as the ALJ found, "NIDA's system for evaluating requests for marijuana . . . has resulted in some researchers who hold DEA registrations and requisite approval from the Department of Health and Human Services [i.e., FDA] being unable to conduct their research because NIDA has refused to provide them with marijuana."[27] As DEA witness and NIDA Special Assistant to the Director, Steve Gust, conceded, "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."[28]

In its January 2009 Order, the DEA dismissed Dr. Craker's examples of such researchers—Dr. Donald Abrams, Dr. Ethan Russo, and Chemic Laboratories.[29] This issue is crucial because the Deputy Administrator ruled that Dr. Craker's failure to demonstrate that the current system is inadequate "weighs heavily against granting his application."[30] Dr. Craker has offered to rebut each of the DEA's reasons for rejecting evidence concerning Dr. Abrams, Dr. Russo, and Chemic.

---

[26] *See* Gov't Hrg. Ex. 24 at 3-4 (noting that FDA review "include[s] 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" (citing 21 C.F.R. § 312.22(a)).
[27] ALJ Op. 84.
[28] Tr. of ALJ Hrg. 1694.
[29] Because of the nature of Chemic's research, FDA approval was not required, but Chemic did have DEA registration to handle controlled substances including marijuana.
[30] DEA Order, 74 Fed. Reg. at 2133.

The DEA's December 2, 2010 response to Dr. Craker's proffer was mixed. The DEA refused to reopen the hearing to discuss the matter of Dr. Abrams and other researchers who have not even submitted protocols because of the futility of doing so in light of NIDA's institutional biases.[31] But the DEA's taking of judicial notice of certain evidence undermines the DEA's original reasoning in dismissing the examples of Dr. Russo and Chemic relied upon by the ALJ. The DEA originally rejected the relevance of Dr. Russo because the DEA believed NIDA's rejection of his protocol occurred prior to the adoption of new NIDA guidelines in 1999.[32] But now that DEA has agreed to take judicial notice of a letter proving that the 1999 Guidelines did apply to Dr. Russo,[33] the DEA's rationale for dismissing the example of Dr. Russo has been undermined. As to Chemic, the DEA's 2009 Order rejected this example in part based on the assumption that if Chemic had had any legitimate grievance with NIDA's rejection of its study, it would have sought relief in the courts.[34] The DEA's December 2, 2010 Order has indicated it would take official notice of correspondence Dr. Craker requested, if it is submitted now. These materials are attached to this brief as Exhibits A-K, and show Chemic's dogged pursuit of its research protocol even in the face of NIDA's denial of research marijuana. Chemic's efforts include a lawsuit against NIDA filed by Chemic's non-profit sponsor in the D.C. Circuit for unreasonable delay, extensive correspondence between Chemic and NIDA in which Chemic tried to persuade NIDA to grant its request for research material, Chemic's submission of a new research protocol in 2008, and Chemic's protestations to NIDA when NIDA

[31] *See* Dec. 2 Order 16-20.
[32] *See* DEA Order, 74 Fed. Reg. at 2108.
[33] *See* Dec. 2 Order 25; *see also* Resp. Br. of Mar. 11, 2009, Ex. C.
[34] DEA Order, 74 Fed. Reg. at 2109 n. 33 ("If Chemic had a valid basis to challenge HHS's denial of its request for marijuana, it presumably had remedies available to challenge that agency action either within HHS or in the courts . . . . Respondent produced no evidence showing that Chemic has pursued any such remedies.").

rejected the new protocol for reasons that were contrary to some of NIDA's reasons for rejecting Chemic's earlier research request.[35]

Dr. Craker asserted, and the ALJ agreed, that his evidence regarding the experiences of Dr. Abrams, Dr. Russo, and Chemic sufficed to demonstrate that the current research supply is inadequate.[36] It should be sufficient for the DEA now.

Moreover, even if a researcher could obtain NIDA approval for research into medical marijuana and pursue an FDA-approved drug, efforts to bring the drug to market would be blocked by the University of Mississippi's monopoly control over the supply for research marijuana. As the only federally-authorized source in the entire country, Dr. ElSohly at Mississippi faces no competition and therefore could charge an exorbitant price for his product. Additionally, Dr. ElSohly might have a market interest in blocking the development of medicinal marijuana: he acknowledges he works with certain "pharmaceutical partners"—i.e. drug companies—seeking to develop "pharmaceutical products that are based on naturally-occurring THC."[37] Such products would almost certainly be in competition with any marijuana medication that other researchers might seek to take through the FDA approval process. Mississippi's monopoly over the nation's supply of research marijuana thus deters marijuana research at the outset and thereby presents an additional obstacle to the development of a marketable drug. It doesn't take an economist to recognize that a monopoly is the very antithesis of the "adequately competitive conditions" envisioned by Congress for the supply of research material.[38]

---

[35] *See* Exs. A-K; *see also* Cmpt. at 1-2, *In re Multidisc. Assoc. for Psych. Studies*, No. 04-1246 (D.C. Cir. filed July 22, 2004).
[36] *See* ALJ Op. 84 ("The record does establish, however, that NIDA's system for evaluating requests for marijuana for research has resulted in some researchers who hold DEA registrations and requisite approval from the Department of Health and Human Services being unable to conduct their research because NIDA has refused to provide them with marijuana. I therefore find that the existing supply of marijuana is not adequate.").
[37] Tr. of ALJ Hrg. at 1465-66.
[38] 21 U.S.C. § 823(a)(1).

The problem is therefore broader than the experiences of Dr. Abrams, Dr. Russo and Chemic: in the current system, there is only one source for research marijuana, and that source is subject to the policy biases of the NIDA review process and further obstructed by the market power of a monopoly. Without a second bulk manufacturer—such as Dr. Craker—who can be independent of NIDA's decisionmaking process (though always conforming, of course, to the FDA, DEA, and State regulations that apply to all other drugs), NIDA's politically-motivated institutional biases will continue to constrict the field of marijuana research in the United States. This is precisely what the ALJ found after a nine-day hearing, and her difficult and diligent evaluation of the facts should not be brushed aside. As the ALJ found, the current supply—i.e., the NIDA monopoly overseen by the University of Mississippi—is not sufficient to ensure an "adequate and uninterrupted supply" under "adequately competitive conditions."[39]

DEA should take a stand for the primacy of science, not politics, as the touchstone for marijuana research decisions in the United States. Put another way, if a research protocol is good enough for the FDA, it should be good enough to be carried out, NIDA or no NIDA. It is this simple principle for which Dr. Craker has been fighting for a decade, and it is for this reason that the DEA should reconsider its January 2009 Order.

II. Dr. Craker's Registration Is Consistent With The United States' International Treaty Obligations.

The government must register a controlled substance manufacturer if that registration "is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols."[40] The only relevant treaty is the Single Convention on Narcotic

[39] *Id.*
[40] 21 U.S.C. § 823(a).

Drugs (hereinafter "Convention"),[41] which requires that signatory nations supervise the legitimate use and manufacture of controlled substances.

The Convention's Article 28 requires countries to apply "the system of controls as provided in article 23 respecting the control of the opium poppy" to "the cultivation of the cannabis plant."[42] In other words, the Convention applies all of the opium poppy controls in Article 23 to the control of marijuana.

As discussed in detail below, the DEA Order's interpretation of Articles 23 and 28 of the Convention rests on several erroneous factual premises about the types of government controls the Convention mandates for the production of marijuana and how those controls are implemented in the United States.

First, the DEA (as of its most recent, December 2, 2010 Order) refuses to apply the relaxed requirements for medical marijuana equivalent to the exemptions for medical opium (as required by the Convention's plain text) because, as the DEA notes, medical marijuana has not yet been licensed by the U.S. government.[43] This catch-22 logic—that the research necessary to show whether there could be a medical use for marijuana cannot occur because the medical use of marijuana has not yet been demonstrated according to the government—is precisely the type of anti-scientific barrier to legitimate research that Dr. Craker is trying to eliminate with his present application.

If the medical exception does not apply, the Convention calls for a single government agency to take possession of all marijuana. The DEA Order asserts that the United States agency designated for this purpose is NIDA—an assertion never previously made by DEA and flatly contradicted by testimony from NIDA personnel. Additionally, the conduct of the one currently

[41] Mar. 30, 1961, 18 U.S.T. 1407, T.I.A.S. No. 6298.
[42] Convention, Art. 28(1).
[43] *See* Dec. 2 Order 12.

DEA-licensed manufacturer, who has been permitted by DEA to grow large amounts of marijuana *outside* of the NIDA contract, disproves the theory that marijuana grown for any purpose other than to supply NIDA-approved research would violate the Convention. In fact, the comprehensive regime of DEA regulations that control who may produce and possess marijuana, demonstrates that it is DEA, not NIDA, that is the single government agency overseeing the use of research marijuana in the United States for purposes of the Convention. Because Dr. Craker seeks to grow marijuana under a DEA license and subject to DEA regulation, granting his request would be entirely consistent with the Convention. Moreover, international implementation of the Convention is inconsistent with the assertions about the treaty contained in the DEA Order.

A. The DEA's Analysis of the Convention's Medicinal Marijuana Exemption Is Flawed.

Because Dr. Craker is applying for a license to manufacture marijuana for medicinal purposes, he is exempt from certain Convention controls that would otherwise apply. Specifically, the Convention explicitly exempts "medicinal [marijuana]" from being subject to a signatory government agency's "exclusive right of importing, exporting, wholesale trading and maintaining stocks."[44] The record demonstrates that if the government registers Dr. Craker, the crops he cultivates will be used to research and develop the medicinal uses of marijuana.[45] Thus, the Convention provides that the exclusive rights that the government holds over non-medicinal marijuana need not extend to Dr. Craker's medicinal marijuana.

Despite the plain language in the Convention, the DEA has floated various and shifting arguments that Dr. Craker's marijuana would not qualify as "medicinal." The January 2009 Order suggested that since there is no such thing as "medicinal opium" (the drug named in the

[44] Convention, Art. 23(2)(e).
[45] Tr. of ALJ Hrg. 551, 552, 580, 647; ALJ Op. 58.

Convention provision cross-referenced by the medical marijuana provision), the term is "obsolete" and therefore should be "disregard[ed]" in the Convention: in other words, because Article 28 prescribes for marijuana the same controls that exist for opium, if "medicinal opium" does not exist then neither can "medicinal marijuana."[46] Perhaps recognizing the anti-textual and illogical nature of this position, the DEA has now posited an alternative rationale: medical marijuana might exist, but only "theoretically," contingent upon FDA approval for such a drug.[47] This logic puts medical marijuana researchers—and, of greater concern to the public heath, their patients—in the archetypal catch-22. Medical marijuana does not exist, according to the DEA, unless it is an FDA-approved medicine, but Dr. Craker's license to supply marijuana for the research necessary to test such a medicine and secure FDA approval cannot be granted because medical marijuana does not yet exist. Surely creating this type of insuperable barrier to the advancement of medical science does not further the "public interest" that the DEA is instructed to consider in deciding whether to grant Dr. Craker's application.[48]

B. Dr. Craker's Registration Would Be Consistent With the Convention Because Government Controls—DEA Regulations—Will Apply.

Article 23 (applicable to marijuana as provided in Article 28) requires that nations designate a "government agency" to control and supervise marijuana cultivation in several ways.[49] The DEA doubly erred in finding that Dr. Craker's registration would violate these Convention requirements. First, the DEA misinterpreted a Convention provision in a manner wholly at odds with the uniform past practice followed not only by other Convention signatories but by the DEA itself. Second, the DEA incorrectly identified which U.S. "agency" fulfills the Convention requirements.

[46] DEA Order, 74 Fed. Reg. at 2116.
[47] Dec. 2 Order 12.
[48] 21 U.S.C. § 823(a).
[49] Convention, Art. 23(2).

Article 23(2)(d) requires that the government agency responsible for regulating marijuana cultivation "purchase and take physical possession" of all crops. However, both domestic and international practices indicate that nations do not—and need not—read this clause literally so as to require the agency to take actual possession. On previous occasions, the DEA itself has not applied the requirement of purchase and physical possession literally. The record demonstrates that the marijuana Dr. ElSohly grows at the University of Mississippi pursuant to his NIDA contract never comes into the literal physical possession of a government agency.[50] The record also demonstrates that Dr. ElSohly grows additional marijuana *outside* his contract with NIDA, and that these crops are never taken into any kind of possession—physical or constructive—by any U.S. agency.[51] Nonetheless, the DEA has renewed Dr. ElSohly's license to cultivate marijuana multiple times, thus establishing (as the ALJ correctly concluded) that the DEA does not apply Article 23(2)(d) literally.[52] Despite this precedent, the DEA found in this case that Dr. Craker's registration would violate the Convention because no government agency would purchase or take literal physical possession of his crops. This departure from its own prior interpretations of the Convention without a reasoned explanation is "arbitrary and capricious" and therefore contrary to law.[53]

Evidence of international practice and findings by the Convention's compliance body also indicate that this clause need not be applied literally. As the undisputed evidence at the

[50] Tr. of ALJ Hrg. 1093-94; ALJ Op. 46.
[51] Tr. of ALJ Hrg. 1472; ALJ Op. 39-40.
[52] ALJ Op. 19.
[53] *See, e.g., ANR Pipeline Co. v. FERC,* 71 F.3d 897, 901 (D.C. Cir. 1995) ("[W]here an agency departs from established precedent without a reasoned explanation, its decision will be vacated as arbitrary and capricious."); *Huntington Hosp. v. Thompson,* 319 F.3d 74, 79 (2nd Cir. 2003) ("While an agency is not locked into the first interpretation of a statute it embraces, it cannot simply adopt inconsistent positions without presenting 'some reasoned analysis[.]'"). The DEA attempts to justify its departure by pointing out that the DEA permits Dr. ElSohly to *distribute* non-NIDA marijuana only in extract rather than whole plant form. But this argument fails to address the relevant issue, which is that the DEA permits Dr. ElSohly to *manufacture* whole plant marijuana outside his NIDA contract and without taking possession of it.

hearing showed, the British for-profit company GW Pharmaceuticals Ltd. cultivates marijuana pursuant to a license from the British Home Office that establishes "a form of constructive purchase and possession" by the Agency in order to satisfy the Convention requirements.[54] GW and the Home Office have had this arrangement for many years, and the Convention's compliance body—the International Narcotics Control Board ("INCB")—has never indicated that this arrangement violates the United Kingdom's treaty obligations. To the contrary, the 2001 INCB Annual Report *commended* the U.K. for its medical marijuana research; GW conducted this research with marijuana it cultivated privately.[55] In its December 2, 2010 Order, the DEA now takes the position that international practice is irrelevant.[56] But the DEA's January 2009 Order itself looks to the 2005 INCB Annual Report for support, thus suggesting that the view of the international community *is* relevant to how the treaty should be understood.[57] The DEA cannot have it both ways. Instead, the DEA should adhere to its initial position that international practice is relevant and adopt the ALJ's thorough analysis of that practice.

Reconsideration of the January 2009 Order is necessary also because its Convention analysis relies on a mistake concerning which U.S. "agency" is responsible for carrying out the treaty requirements. According to the January 2009 Order, NIDA (via its parent agency, the Department of Health and Human Services) is the U.S. "agency" responsible for implementing the Convention-required controls over marijuana.[58] This position ignores not only DEA's own regulations but the position of NIDA itself. It is DEA, not NIDA, that is the U.S. agency responsible for implementing Convention-required controls. DEA regulations control all aspects

[54] ALJ Op. 74 (citation and internal quotation marks omitted).
[55] INCB 2001 Annual Report 25, ¶ 158.
[56] *See* Dec. 2 Order 8.
[57] *See* DEA Order, 74 Fed. Reg. at 2115-16.
[58] *See id.* at 2114-15.

of the registration of manufacturers, distributors, and dispensers of controlled substances.[59] For example, these regulations specify research protocols, law enforcement exemptions, DEA's right to revoke or suspend registrations, physical security requirements, and employee screening procedures to prevent diversion.[60] Even NIDA's own representative confirmed at the ALJ hearing that NIDA is *not* the U.S. agency responsible for implementing Convention obligations. When asked which agency is responsible for regulating and monitoring Convention-required rules, Dr. Gust, the Special Assistant to the Director of NIDA, responded unequivocally: "It's not NIDA."[61]

Further, the DEA erroneously reasoned that registering Dr. Craker to produce marijuana outside of the NIDA monopoly would violate the Convention because he would escape government agency regulation entirely.[62] This is flatly incorrect. It is certainly true Dr. Craker seeks to cultivate marijuana outside of *NIDA's* monopoly, but it does not follow that Dr. Craker seeks to cultivate marijuana outside the strictures of *any government regulation*. According to the DEA's Order, "it is [] control of the cultivation and production of cannabis by a national agency of the United States to which Respondent is fundamentally opposed, thereby demonstrating the inconsistency between his application and the Single Convention."[63] This statement fundamentally mischaracterizes Dr. Craker's position. As demonstrated by his compliance with the DEA throughout this process, Dr. Craker and his non-profit sponsor are in

[59] *See* 21 C.F.R. § 1301 *et seq*.
[60] *See* 21 C.F.R. §§ 1301.18, 1301.24, 1301.36, 1301.71, 1301.91.
[61] Tr. of ALJ Hrg. 1732.
[62] *See* DEA Order, 74 Fed. Reg. at 2115, 2116.
[63] *Id.* at 2116; *see also id.* at 2115 (characterizing Dr. Craker's "proposed purpose for gaining authorization" as enabling his non-profit sponsor "rather than HHS/NIDA" to "control distribution of the marijuana"); *id* at 2115 ("[T]he central theme of Respondent's argument . . . is that the very Government monopoly . . . that the Single Convention demands is the primary evil that Respondent seeks to defeat through obtaining a DEA registration."); *id.* at 2117 ("[T]he national agency must control the production and distribution of the raw marijuana material used for research or any other permissible purpose. Respondent's unwillingness to accept this principle illustrates how his proposed registration is fundamentally at odds with the treaty.").

no way opposed to the regulation of marijuana by the government agency that has been established to do so. But that agency is DEA—not NIDA. Thus, the DEA's refrain that Dr. Craker's application is fundamentally inconsistent with the Convention obligations because he would not be subject to NIDA control is a straw man: as the ALJ found, Dr. Craker's activities would always be subject to government control, both through extensive DEA and State regulation of who may access marijuana and through FDA regulation over the safety, efficacy and scientific merit of research protocols.[64] DEA's concern about Dr. Craker's escaping government regulation entirely is thus wholly unsupported by the record.

III. The DEA's Finding That The Personal Conduct Of A Third Party Warrants Denial of Dr. Craker's Application Is Unsupported By The Evidence And Is Contradicted By Its Other Findings.

The third reason for which the DEA denied Dr. Craker's registration was the personal conduct of Dr. Craker's sponsoring organization's executive director. In relying on this reason, the DEA contradicted its own prior reasoning in its own opinion and selectively ignored its own regulatory controls precluding Dr. Craker from distributing the marijuana to anyone but DEA- and State-licensed researchers for particular FDA-approved research.

The governing statute directs the government to consider "the existence in the establishment of effective control against diversion."[65] After listing this and four other factors to be weighed, the statute authorizes consideration of "such *other* factors as may be relevant."[66] The DEA correctly found regarding the "diversion" factor that Dr. Craker "has met his burden of demonstrating that, if the registration were granted, he would have in place effective controls against diversion."[67] However, the DEA then invoked the catch-all clause "such other factors" to

[64] *See* ALJ Op. 84
[65] 21 U.S.C. § 823(a)(5).
[66] 21 U.S.C. § 823(a)(6) (emphasis added).
[67] DEA Order, 74 Fed. Reg. at 2126.

flatly contradict its own prior finding by asserting that Dr. Craker's sponsoring organization's executive director's personal use of marijuana creates a risk of diversion. Because the diversion is explicitly prescribed as a consideration under a separate factor,[68] and as noted, the DEA found that Dr. Craker would have effective controls against diversion, the agency cannot reintroduce the specter of diversion through the back door by relying on the catch-all language "such *other* factors as may be relevant."[69]

Moreover, the DEA's "other factors" analysis is substantively flawed insofar as it assumes the insufficiency of its own controls and ignores the comprehensive DEA and FDA regulations that will apply to Dr. Craker's crops if his registration is granted.[70] As the evidence at the hearing demonstrated, and as the ALJ held, Dr. Craker's registration would not authorize the sponsor's executive director to have any contact with the marijuana: "the record . . . establishes that [the sponsoring organization and its president] would not at any time have physical possession of that marijuana."[71] The uncontroverted evidence adduced at the hearing established 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 scientific research.[72] And, as should be obvious, the licensee here is Dr. Craker, not a third-party who wishes only to fund research. Absent evidence from which the DEA could conclude that *Dr. Craker* would be likely to violate DEA regulations and provide the marijuana he grows to unlicensed or unauthorized persons—and there was no such evidence in the record—the conclusion that a third party who will fund FDA-approved

[68] *See* 21 U.S.C. § 823(a)(5).
[69] 21 U.S.C. § 823(a)(6) (emphasis added).
[70] *See* 21 C.F.R. § 1301 *et seq.*
[71] ALJ Op. 84.
[72] Tr. of ALJ Hrg. 73.

research poses a threat of diversion is entirely untethered to fact and amounts to little more than guilt by association.

Further, the DEA's concern about the executive director's "role in deciding to whom [Dr. Craker] will supply the marijuana" is also unwarranted.[73] Under DEA regulations, Dr. Craker could not supply marijuana to anyone not DEA-licensed and FDA-approved:

> [T]he record [] establishes . . . that Respondent would send marijuana only to researchers who hold DEA registrations and, therefore, have the requisite approval from the Department of Health and Human Services [i.e., the FDA], 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.[74]

It is Dr. Craker, and not any other individual, who seeks registration; without some indication that he will provide marijuana to persons not authorized to have it—which is, again, contrary to the DEA's contemporaneous finding that Dr. Craker will have in place adequate controls against diversion—the concern about a sponsor's executive director is unjustified. Therefore the DEA's "other factors" analysis should be reconsidered, and the DEA should abandon the use of guilt-by-association logic to raise the specter of diversion when no such risk appears on the record.

CONCLUSION

In accordance with presidential directives, the time has come for science to prevail over politics. A neutral Administrative Law Judge held a nine-day hearing and found that granting Dr. Craker's license and ending NIDA's monopoly on the supply of medical marijuana for FDA-regulated research in the United States was in the public interest. The DEA rejected the ALJ's opinion based on a series of factually or legally incorrect premises. The DEA should now reconsider its initial order and grant Dr. Craker's license in order to permit this nation's strong

[73] DEA Order, 74 Fed. Reg. at 2126.
[74] ALJ Op. 84.

tradition of scientific research and free market principles to prevail over the narrow political calculus of the past.

March 7, 2011

Respectfully Submitted,

Scott Michelman
American Civil Liberties Union Foundation
1101 Pacific Avenue, Suite 333
Santa Cruz, CA 95060
Tel: (831) 471-9000
Fax: (831) 471-9676

Allen Hopper
ACLU Foundation of Northern California
39 Drumm Street
San Francisco, CA 94111
Tel: (415) 621-2493
Fax: (415) 255-8437

Julie M. Carpenter
Jenner & Block LLP
601 Thirteenth Street, N.W.
Suite 1200 South
Washington, DC 20005-3823
Tel: (202) 639-6029
Fax: (202) 661-4810