

**UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

In the Matter of)	Docket No. 05-16
)	
LYLE E. CRAKER, Ph.D.)	Respondent’s Supplemental Brief in
)	Support of Request Under 5 U.S.C.
Denial of Bulk Application for)	§ 556(e) To Respond to New Officially
Registration as Bulk Manufacturer)	Noticed Evidence and Motion for
of Marijuana)	Reconsideration
_____)	

Pursuant to the Deputy Administrator’s February 9, 2009 Order, Respondent Dr. Lyle E. Craker submits this supplemental filing and attached documents in support of his Request Under 5 U.S.C. § 556(e) to Respond to Officially Noticed Evidence and Motion for Reconsideration.¹

INTRODUCTION AND STATEMENT OF THE CASE

On June 26, 2001, University of Massachusetts, Amherst, Professor of Plant, Soil, and Insect Sciences Dr. Lyle E. Craker applied for DEA registration to grow marijuana for scientific research. Dr. Craker seeks his registration in order to provide a new source of marijuana for FDA- approved and DEA-licensed researchers seeking to take marijuana through the FDA approval process and make it available as a prescription medicine. DEA Administrative Law Judge (“ALJ”) Mary Ellen Bittner, after extensive legal hearings involving numerous witnesses, found, pursuant to the relevant statutory criteria, that licensing Dr. Craker would be in the public interest. The ALJ therefore recommended that Dr. Craker’s application be granted.

As uncontroverted testimony before the ALJ established, the National Institute on Drug Abuse (“NIDA”) has long held a monopoly on the supply of marijuana—but no other drug—that

¹ In accordance with the Deputy Administrator’s order, this filing supplements Respondent’s January 30, 2009 motion papers. Respondent therefore incorporates by reference the arguments made, and documents referred to, in those papers, much of which is elaborated upon herein. In this Supplemental Pleading, Dr. Craker is responding, in large part, to the new evidence and new arguments that were not introduced before the ALJ. However, it is important to put those arguments and evidence into context, so this Supplemental Pleading discusses them in the broader context of the rationales of the Deputy Administrator’s ruling. Although Dr. Craker here responds to some specific errors in that ruling, he has not attempted here to raise all errors in that ruling, and reserves his right to raise these and other issues both before the agency and on appeal, if necessary.

can legally be used in medical research. NIDA's monopoly, created by DEA's failure to license any additional bulk manufacturer, has directly resulted in a complete dearth of privately-funded medical marijuana research for over 40 years. Absent a government-funded initiative to take marijuana through the FDA approval process—which is highly unlikely, since virtually all investigational-new-drug research in the United States is privately funded by pharmaceutical companies—only privately-funded research can hope to accomplish that goal. Therefore, until DEA ends the NIDA monopoly by registering another bulk manufacturer, such as Dr. Craker, to produce marijuana for privately-funded researchers, there simply cannot be an adequate and uninterrupted supply of marijuana for research intended to gain 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 medicine because the FDA has not approved its medicinal use. Yet NIDA has blocked the very research necessary to allow FDA to decide, on the basis of scientific inquiry into safety and efficacy, whether and under what circumstances marijuana should be available to patients. NIDA's monopoly is not mandated by Congress or administrative regulation. Instead, it results from DEA's failure to register an additional manufacturer to produce marijuana for privately-funded researchers. NIDA and DEA have made clear that they oppose marijuana becoming available as a prescription medicine.² That decision, however, properly lies not with NIDA or DEA, but rather with FDA, which in turn has never been able to answer the question because the research necessary to evaluate it simply cannot take place under the current system of supply.

² See, e.g., the DEA website at <http://www.usdoj.gov/dea/ongoing/marijuana.html>.

Within his first week in office, the new President explicitly directed a move away from an era in which “[r]igid ideology has overruled sound science.”³ Then on March 9, 2009, the White House issued a Memorandum for the Heads of Executive Departments and Agencies concerning “Scientific Integrity”⁴ stating, *inter alia*,

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 Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised Each agency should adopt such additional procedures . . . as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decisionmaking or otherwise uses or prepares.

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. At the very least, DEA must hear all relevant evidence before making potentially life-and-death decisions about the future course of medical research into the risks and benefits of the medical uses of marijuana.

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 is the agency that certifies that proposed studies have scientific merit and are safe, and FDA permission is a prerequisite to initiate clinical studies.

³ This comment, made by President Obama in announcing a change in national policy toward states that seek to set stricter automobile emissions standards than the federal government, is reported at <http://abcnews.go.com/Politics/Economy/Story?id=6732327&page=3> (Jan. 26, 2009), and attached hereto as Exhibit A, at 4.

⁴ Available at http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/, attached hereto as Exhibit B.

DEA is the agency that ensures controlled-substance researchers do not facilitate unauthorized drug use through drug diversion. 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 marijuana for research. 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 NIDA. Importantly, this additional and unique layer of NIDA review for marijuana research is not mandated by statute, but rather exists solely through the interaction of distinct NIDA and DEA regulations, and specifically through DEA's failure to register a bulk manufacturer, like Dr. Craker, to provide marijuana for non-NIDA-approved research. Under 21 U.S.C. § 823 and DEA regulations, DEA has registered Professor 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 research projects that NIDA has approved. No statute or regulation requires a privately-funded researcher with FDA permission for a clinical research project to obtain NIDA approval for the research. That requirement arises only because DEA has refused to register any manufacturer of marijuana other than Dr. ElSohly, who manufactures marijuana only for NIDA-approved research.

But NIDA's mission is to study drug *abuse*, not to research beneficial medical uses for controlled substances, much less to facilitate research conducted under an FDA Investigational New Drug ("IND") application seeking to take 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. In the words of NIDA's Director Dr. Nora Volkow, "It is not . . . NIDA's mission to study the medicinal use of marijuana or to advocate for the establishment of facilities to support this research." Resp. Ex. 13. Dr. Craker established at his hearing that because of

NIDA's institutional view of what research should be conducted with its product, 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. On this basis, ALJ Bittner found the current supply of marijuana for research to be inadequate.

Even if privately-funded sponsors of medical marijuana research could be assured access to NIDA's marijuana for all FDA-approved and all DEA-licensed studies, NIDA's monopoly would still result in an inadequate supply, because a privately-funded research sponsor would lack a crucial prerequisite for the development of a new drug: assurance of an uninterrupted supply to provide to patients once FDA approval has been obtained. As NIDA's own contractor testified, NIDA is not in the business of supplying research material for drug development. The evidence adduced at the ALJ hearing demonstrates that private companies would be unwilling to invest the millions of dollars for clinical studies required to gain FDA approval of marijuana as a prescription medicine if the supply cannot be guaranteed; therefore, NIDA's unwillingness to supply drug-development studies results in the existing supply being inadequate for this type of research. Moreover, even if NIDA would permit its sole-source supplier to sell marijuana for use by patients with prescriptions, a pharmaceutical company seeking to provide patients with the drug would be required to negotiate with NIDA's supplier for purchase of the material, who could charge literally whatever he wanted due to his monopoly power.

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 in 21 U.S.C. § 823. *See In re Craker*, No. 05-16 (Feb. 12, 2007) (hereinafter "ALJ Op.").

Importantly, the ALJ found that the evidence adduced at the hearing established one of Dr. Craker's key contentions: 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. *See id.* at 84.

But after waiting nearly two more years, and on the eve of the change in Presidential Administration, DEA Deputy Administrator Leonhart rejected the ALJ recommendation and denied Dr. Craker's application. *See Denial of Craker Application*, No. 05-16 (published Jan. 14, 2009), 74 Fed. Reg. 2101-03 (hereinafter "Leonhart Order"). Relying on new evidence that was not in the record and which Dr. Craker did not have the opportunity to rebut, the Deputy Administrator denied the application for three reasons: first, she found that the lone current manufacturer, growing under exclusive contract with NIDA, produces an adequate supply under adequately competitive conditions; second, in spite of the ALJ's legal conclusion to the contrary, the Deputy Administrator believed that granting the application would violate an international treaty, the Single Convention on Narcotic Drugs ("Convention"); and third, the president of an organization that would sponsor Dr. Craker's production facility admitted at the ALJ hearing that he has used marijuana recreationally. *See id.* at 117.

Each of these rationales is either unsupported by the record, contrary to applicable law, or both. The Deputy Administrator misapplied the statutory factors in large part based on new evidence that was never presented at the hearing and which Dr. Craker has never had an adequate opportunity to rebut. Under basic principles of due process, "when an agency takes official or administrative notice of facts, a litigant must be given an adequate opportunity to respond." *Heckler v. Campbell*, 461 U.S. 458, 469 (1983). Dr. Craker seeks an evidentiary hearing to present live testimony rebutting the new evidence upon which the Deputy

Administrator relied, as well as to present additional oral argument to urge the Deputy Administrator to grant reconsideration of her order based on this new evidence, the evidence already in the record, and applicable law.

ARGUMENT

The registration requirements in the Controlled Substances Act direct that the “Attorney General *shall* register an applicant to manufacture controlled substances in Schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.” 21 U.S.C. § 823(a) (emphasis added). In defining the “public interest,” the statute instructs the Attorney General 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.” 21 U.S.C. § 823(a)(1). The statute lists four other factors, including “the existence . . . of effective control against diversion,” *id.* § 823(a)(5), that the Attorney General must consider in determining whether to grant a license, and then instructs the Attorney General to consider “such other factors as may be relevant to and consistent with public health and safety,” *id.* § 823(a)(6).

Under these criteria, the Deputy Administrator rejected the ALJ recommendation and denied Dr. Craker’s application for three reasons: first, because she found that the lone current manufacturer produces an adequate supply under adequately competitive conditions; second, because the Deputy Administrator concluded that granting the application would violate the Single Convention on Narcotic Drugs; and third, because the president of an organization that sponsors Dr. Craker has used marijuana recreationally. *See id.* at 117. Because these

conclusions were founded on errors of law and on new evidence that was not in the record and arguments not made below, to which Dr. Craker did not have the opportunity to respond, Dr. Craker submits documents here, and asks that his Motion To Reconsider be granted and that either the ALJ's recommendation be adopted or the administrative hearing reopened so that he may produce additional live testimony to rebut the new evidence upon which the Deputy Administrator relied.

I. The Current Source of Research Marijuana Does Not Produce An Adequate Supply Under Adequately Competitive Conditions, And Dr. Craker Can Rebut The Administrator's New Evidence To The Contrary.

As the Deputy Administrator herself 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 uninterrupted" or the supply does not ensure "adequately competitive conditions." *See* Leonhart Order 103, 108. As the Administrative Law Judge who heard nine days of live testimony found, 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/or DEA-licensed studies that propose to explore the benefits of marijuana as medicine. While the Leonhart Order points to other marijuana research that NIDA has allowed, the fact remains that several research projects have been blocked by NIDA in spite of FDA-approved protocols. Nor does the Leonhart Order's reference to past approval of other research recognize the key distinction between general research into marijuana's medicinal uses, *see, e.g.*, Leonhart Order 16-17, and research efforts like those Dr. Craker seeks to facilitate which are aimed at developing the marijuana plant into an FDA-approved prescription medicine. The NIDA monopoly on supply 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. The Deputy Administrator relied on new evidence to dismiss evidence in the record about proposed research that was not supplied with marijuana because of NIDA policy, so Dr. Craker now seeks a hearing and reconsideration to adduce rebuttal evidence in support of his examples of stymied projects and the proper analysis of adequacy of competition under 21 U.S.C. § 823.

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, 21 U.S.C. § 393(b), and in fulfilling this important responsibility the FDA reviews protocols submitted by researchers, 21 U.S.C. § 355, and conducts "an assessment of the scientific quality of the clinical investigations." 21 C.F.R. § 312.22(a). But the effect of the NIDA 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 preferences or its 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 use of marijuana or to advocate for the establishment of facilities to support this research." Resp. Ex. 13. To the limited extent NIDA has been willing to permit medical marijuana research with the only available marijuana product in the country, that research must conform to the agency's own views about how marijuana could be medically useful. For example, NIDA accepts the possibility that *cannabinoid components* of marijuana can become prescription medicine, but it specifically rejects whole-plant smoked or vaporized medical

marijuana. *See, e.g.*, Gov't 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.”). 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.” Tr. 1463.

NIDA contends its additional review is necessary to ensure scientific value, but as NIDA’s own guidelines reflect, the FDA approval process already does this. Gov. 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))). 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 own prejudgments.⁵

⁵ But for DEA’s refusal to register an additional bulk manufacturer of marijuana for research purposes (such as Dr. Craker), NIDA’s biased review process would not in and of itself block research with contrary goals; for example, though NIDA provides funding for much scientific research, it can and does choose to fund some research but not other research, consistent with its own policy inclinations. Virtually all investigational-new-drug research in the United States is privately funded by pharmaceutical companies. Even when that research requires obtaining Schedule I substances, such companies need not obtain NIDA approval or funding for their research; they simply must obtain the appropriate DEA licenses to handle the substances, FDA permission for any clinical use of the substances, and then either manufacture the substance themselves or obtain the substances from any number of private DEA-registered manufacturers. Only with marijuana does DEA refuse to register additional bulk manufacturers, creating the anomalous NIDA monopoly over supply and resulting complete control over which categories of research may—and may not—occur.

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 supply them with marijuana.” ALJ Op. 84. 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.” Tr. 1694.

But the Deputy Administrator dismissed Dr. Craker’s examples of such researchers—Dr. Donald Abrams, Dr. Ethan Russo, and Chemic Laboratories⁶—on the basis of new evidence that Dr. Craker has not had the opportunity to rebut. This issue is of crucial significance because the Deputy Administrator ruled that Respondent’s failure “to demonstrate that the long standing existing system in the United States of producing . . . research-grade marijuana under the oversight of HHS [the Department of Health and Human Services] and NIDA is inadequate . . . weighs heavily against granting his application.” Leonhart Order 117. Dr. Craker is prepared to rebut each of the Deputy Administrator’s reasons for rejecting evidence concerning Dr. Abrams, Dr. Russo, and Chemic.

Regarding Dr. Abrams, the Deputy Administrator officially noticed a letter dated April 19, 1995 from a NIDA official purporting to explain the reasons NIDA denied researcher Dr. Abrams’ request for marijuana to conduct medical research. *See* Leonhart Order 23-24 n. 24; *id.*

⁶ 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.

at 86 n. 84. But NIDA's actual motivations for denying marijuana to researchers were vigorously contested at the hearing before ALJ Bittner. Ignoring all this evidence without resolving the conflict, the Deputy Administrator simply *assumed the veracity* of the reasons proffered in NIDA's letter that the Deputy Administrator plucked from a website. Dr. Craker seeks to rebut this evidence with testimony from Dr. Abrams and/or the author of the NIDA letter, Alan Leshner, and/or others familiar with these events about the actual reasons for the denial of Dr. Abrams' initial protocol. Notably, NIDA approved Dr. Abrams' subsequent application only after he revised his protocol to explore potential *harms* of marijuana use by his AIDS patients instead of potential *benefits* of marijuana use in treating AIDS wasting syndrome.

Regarding Dr. Russo, the Deputy Administrator relied on a distinction—introduced in her decision for the first time, after years of litigation—between applications for research marijuana *before* the issuance of a set of guidelines by NIDA in 1999, and applications made *after* those guidelines were in place. Concluding, based on this new position, that all NIDA denials before these 1999 Guidelines were irrelevant, the Deputy Administrator dismissed the compelling evidence regarding Dr. Russo's application because she found Dr. Craker's evidence did not clearly demonstrate that the application was denied under the 1999 Guidelines. Leonhart Order 24-26 (noting testimony was that the witness "thought" the denial was in 1999.) Had this argument been raised at the hearing, or had DEA counsel questioned the date, Dr. Craker could easily have demonstrated what is in fact true: that NIDA denied Dr. Russo's request under the 1999 Guidelines. Indeed, as the Deputy Administrator has already shown herself willing to reach outside the record to take official notice of letters from NIDA to Dr. Abrams found on a non-government website, Leonhart Order 23-24 n. 24, she should take official notice of a letter

from NIDA to Dr. Russo, found on the very same website only one link away from the very same page as the link to the NIDA letter to Dr. Abrams on which she relied.

Given the Deputy Administrator's new argument that the Guideline date is wholly determinative, Dr. Craker must be allowed the chance to respond. At a hearing, Dr. Craker can provide evidence, in addition to the NIDA letter of which the Deputy Administrator should take official notice, that NIDA notified Dr. Russo on February 1, 2000 that his application was denied after a special review committee's consideration in November 1999.⁷ In addition, Dr. Craker seeks to introduce testimony to rebut the Deputy Administrator's new position that only post-Guideline denials of researchers are relevant for determining whether NIDA's supply is adequate. This evidence would include testimony of other researchers, including Dr. John Halpern of Harvard Medical School, that NIDA's policies toward marijuana research at odds with NIDA's mission are widely perceived in the medical scientific community as much the same both before and after the adoption of the 1999 Guidelines: such research will not be supported by NIDA, and such researchers will not be able to obtain NIDA marijuana for their research.

Regarding Chemic Labs, the Deputy Administrator officially noticed two reports from Chemic and a non-profit newsletter concerning testing of a device known as the Volcano Vaporizer, for which Chemic sought research marijuana. *See* Leonhart Order 27 n. 30; *id.* at 29 n. 32. The Deputy Administrator infers from these officially noticed documents that, "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."

⁷ Available at <http://www.maps.org/mmj/russo1199/02010001.html>; <http://www.maps.org/mmj/russo1199/119901.html>, and attached hereto as Exhibit C.

Leonhart Order 29 n. 33. Again, the Deputy Administrator's new evidence led her to an erroneous factual conclusion that Dr. Craker could easily have rebutted if this evidence had been offered at the hearing. Specifically, Dr. Craker seeks to introduce testimony recounting the extensive efforts to pursue remedies for NIDA's denial of research marijuana. These efforts include a lawsuit 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 rejected the new protocol for reasons that were contrary to some of NIDA's reasons for rejecting Chemic's earlier research request.⁸

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. If, in spite of the foregoing evidence, these three examples are deemed insufficient, Dr. Craker is also prepared to present additional testimony that other researchers, such as the aforementioned Dr. John Halpern of Harvard Medical School, were discouraged from even *proposing* marijuana research because of the widely-recognized likelihood NIDA would block it by denying research material.

Finally, the Deputy Administrator relied on evidence not introduced at the hearing to reject the ALJ's finding that the current NIDA monopoly on the supply of marijuana for research in the United States does not allow for "adequately competitive conditions." Specifically, the Deputy Administrator cited to an attachment to a letter submitted to Congress by Assistant Attorney General William E. Moschella in response to questions posed by the House

⁸ Chemic's November 5, 2008 letter to NIDA is attached hereto as Exhibit D. Additionally, Chemic's revised research protocol can be found at http://www.maps.org/mmj/vaporizer_protocol/2696A.MAPS.volcanofinal1-16-08.NIDAmaterial.pdf. Chemic's other actions in this matter, described in the text, would be the subject of the testimony Dr. Craker seeks to introduce in response to the Deputy Administrator's new evidence.

Subcommittee on Criminal Justice, Drug Policy and Human Resources. *See* Leonhart Order 108 n. 111. Among his answers, Moschella asserted that “[i]t is possible that there can be adequate competition within the meaning of Section 823(a) with just a single manufacturer [of a single drug], provided that manufacturer can produce the substance in sufficient quantity and quality . . . without charging unreasonable prices.”⁹ The question of what constitutes an “unreasonable price”—and whether that criterion applies only to a manufacturer’s bid on a U.S. government manufacturing contract or also to the prices potential researchers must pay the manufacturer—is one of the key factors in dispute over whether NIDA’s sole-manufacturer system produces “adequately competitive conditions.” The Deputy Administrator found that it does because NIDA “put[s] the contract [to grow research marijuana] up for competitive bidding at periodic intervals then supplying the marijuana to researchers for free or at NIDA’s cost.” Leonhart Order 80.

If the DEA counsel had introduced this DOJ letter at the hearing, Dr. Craker would have rebutted this evidence, and he is entitled to do so now. At a reopened hearing, Dr. Craker will rebut this position by presenting the testimony of a leading economist, Harvard University Professor Frederic M. Scherer, establishing that adequate competition does not exist when, as here, some legitimate, FDA-approved and/or DEA-licensed buyers are shut out of the market entirely; for these buyers, such as Drs. Abrams and Russo and Chemic Labs, the cost of the research material they need is effectively infinite, not “for free or at NIDA’s cost” as the Deputy Administrator suggests. *Id.*¹⁰

⁹ Letter of William E. Moschella, Asst. Att’y Gen., to Cong. Mark Souder, Chairman, House Subcomm. on Crim. J., Drug Policy and Human Resources, Attachment at 5 (Oct. 13, 2004), *available at* <http://www.access.gpo.gov/congress/house/pdf/108hrg/96746.pdf> (page 208-215 of the 356-page PDF file).

¹⁰ A written proffer of Professor Scherer’s testimony is attached hereto as Exhibit E.

Due process requires that Dr. Craker be permitted an opportunity to present his evidence in response to the agency's new evidence and to respond to arguments never raised below. *See Heckler v. Campbell*, 461 U.S. 458, 469 (1983). As the foregoing argument and proposed testimony reflects, that response is considerable and comprehensive, and demonstrates that the Deputy Administrator erred in concluding that NIDA's contract with the University of Mississippi ensures an "adequate and uninterrupted supply" under "adequately competitive conditions."

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

The Attorney General 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." 21 U.S.C. § 823(a). The only relevant treaty is the Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407, T.I.A.S. No. 6298 (hereinafter "Convention"), which requires that signatory nations supervise the legitimate use and manufacture of controlled substances.

The Convention requires signatories that "permit[] the cultivation of the cannabis plant . . . shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy." Convention, Art. 28(1). The Convention thereby applies *all* of the opium poppy controls in Article 23 to the control of marijuana. Article 23, in turn, requires that signatories establish a government agency to exert the following controls over opium poppy, and by reference in Article 28, over marijuana as well:

- a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of [marijuana] . . . shall be permitted.
- b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.

- c) Each license shall specify the extent of the land on which the cultivation is permitted.
- d) All cultivators of [marijuana] shall be required to deliver their total crops of [marijuana] to the Agency. The Agency shall purchase and take physical possession of such crops . . .
- e) The Agency shall, in respect of [marijuana], have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of . . . medicinal [marijuana]... Parties need not extend this exclusive right to medicinal [marijuana].

Convention, Art. 23(2).

The Deputy Administrator's interpretation of the Convention rests on several erroneous factual premises, derived in part from new evidence, about the types of government controls the Convention mandates for the production of marijuana and how those controls are implemented in the United States. The Convention calls for a single government agency to take possession of all marijuana. The Deputy Administrator 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 DEA-licensed manufacturer, who has been permitted by DEA to grow large amounts of marijuana *outside* of the NIDA contract for personal financial gain, disproves the Deputy Administrator's 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 and under what circumstances, 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 Deputy Administrator's assertions about the treaty. Finally, the Deputy

Administrator refused to adopt relaxed requirements for medical marijuana equivalent to the exemptions for medical opium (as required by the Convention’s plain text) because she claims, relying on new evidence, that there is no such thing as medical opium. But Dr. Craker can demonstrate that the Deputy Administrator’s new evidence about medical opium is simply incorrect as a factual matter. Dr. Craker requests a hearing so he may produce live testimony to rebut the Deputy Administrator’s new evidence regarding the Convention and show that current U.S. and international implementation of the Convention is consistent with granting his application.

A. Dr. Craker’s Registration Would Be Consistent With the Convention Because Sufficient Government Controls—DEA Regulations—Will Oversee His Activities.

Article 23 requires that signatory nations designate a “government agency” to control and supervise marijuana cultivation in several ways. The Deputy Administrator doubly erred in finding that Dr. Craker’s registration would violate these Convention requirements. First, the Deputy Administrator 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 Deputy Administrator incorrectly identified which U.S. “agency” fulfills the Convention requirements, in part because she ignored her own agency’s rules and regulations.

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 signatories to the Convention do not—and need not—read this clause literally to require the agency to take actual possession. On previous occasions, the DEA itself has not read or 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. Tr. 1093-94; ALJ Op. 46. 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. Nor are they commissioned or later purchased by any government agency. Tr. 1472; ALJ Op. 39-40. Nonetheless, the DEA has renewed ElSohly’s license to cultivate marijuana multiple times, thus establishing (as the ALJ correctly concluded) that the DEA does not interpret or apply Article 23(2)(d) literally. ALJ Op. 19. Despite this precedent, the Deputy Administrator found 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 her own agency’s prior interpretations of the Convention, without a reasoned explanation for the complete rejection of past practice, is arbitrary and capricious. *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[.]’”).¹¹

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 hearing showed, the British non-government company GW Pharmaceuticals Ltd. (“GW”) cultivates marijuana pursuant to a license from the British Home Office that establishes “a form

¹¹ The Deputy Administrator 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. The Deputy Administrator’s explanation is therefore not a reasonable basis on which to treat UMass differently than UMiss.

of constructive purchase and possession” from GW to the Agency in order to satisfy the Convention requirements. ALJ Op. 74 (citation and internal quotation marks omitted). GW and the Home Office have had this arrangement for multiple 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. INCB 2001 Annual Report 25, ¶ 158. The Deputy Administrator relied on new evidence, not introduced at the hearing, to dismiss the evidence relating to international practice under the Convention. The Deputy Administrator’s new evidence, a selective quote from the 2005 INCB Annual Report, reiterates that signatories must have a national cannabis agency even if they only allow marijuana cultivation for research. Leonhart Order 52-53. Dr. Craker is entitled to respond to this new evidence and argument. Indeed, if DEA counsel had tried to introduce this evidence, Dr. Craker would have responded by introducing the INCB 2001 Annual Report as well as others. Now that several additional years have passed, Dr. Craker can also point to the 2006, 2007, and 2008 Reports, all of which were made with full knowledge of the GW arrangement in Britain, but none of which suggests that this arrangement constitutes a Convention violation. In sum, Dr. ElSohly’s repeatedly renewed DEA license, the arrangement between GW and the British Home Office, and multiple INCB reports establish that Article 23(2)(d) does not bar Dr. Craker’s registration, and the Deputy Administrator’s contrary finding is erroneous.

Reconsideration of the Leonhart 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. This mistake led the Deputy Administrator to mischaracterize Dr. Craker’s

argument, ignore the position of NIDA itself at the hearing, and ignore a host of her own agency's relevant regulations. Specifically, the Deputy Administrator identified NIDA/HHS as the U.S. "agency" responsible for implementing the Convention-required controls over marijuana. Leonhart Order 49-50. Accordingly, the Deputy Administrator 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. While it is certainly true Dr. Craker seeks to cultivate marijuana outside of *NIDA's* monopoly, the Deputy Administrator was entirely mistaken that Dr. Craker seeks to cultivate marijuana outside the strictures of *any government regulation*. Throughout her discussion of the Convention, the Deputy Administrator repeatedly demonstrated a fundamental misunderstanding of Dr. Craker's application: according to the Deputy Administrator, "it is this 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." Leonhart Order 53.¹² To the contrary, and as demonstrated by his compliance with the DEA throughout this process, Dr. Craker and his non-profit sponsor are in 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. DEA regulations control all aspects of the registration of manufacturers, distributors, and dispensers of controlled substances. *See* 21 C.F.R. § 1301 *et seq.* For example, these regulations specify research protocols, law enforcement exemptions, DEA's right to revoke or suspend registrations, physical security

¹² *See also id.* at 49-50 (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 50 ("[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 57 ("[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.").

requirements, and employee screening procedures to prevent diversion. *See* 21 C.F.R. §§ 1301.18, 1301.24, 1301.36, 1301.71, 1301.91. 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.” Tr. 1732. Thus, the Deputy Administrator’s refrain that Dr. Craker’s application is fundamentally inconsistent with the Convention obligations because he would not be subject to NIDA control is simply incorrect: Dr. Craker’s activities would always be subject to government control, through extensive DEA regulations. The Deputy Administrator’s overarching concern about Dr. Craker’s escaping government regulation is not only unfounded, but is conclusively disproved by her own agency’s rules.

Finally, it is important to note also that Dr. Craker and his non-profit sponsor are not seeking to evade HHS regulations. HHS regulations and control are implemented and exercised by the FDA. Granting Dr. Craker’s application would enable privately-funded researchers to conduct research even when NIDA does not sanction it, but FDA regulations ensuring safety, efficacy and scientific merit of research protocols would remain. For example, Dr. Craker adduced testimony and other evidence in the hearing establishing that his non-profit sponsor has funded and sponsored numerous clinical research studies with other Schedule I substances including MDMA, LSD, psilocybin and mescaline, all in compliance with FDA and DEA regulations.

B. The Deputy Administrator’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.” Convention, Art. 23(2)(e). The record demonstrates that if the Attorney General registers Dr. Craker, the crops he cultivates will be used to research and develop the medicinal uses of marijuana. Tr. 551, 580, 647; ALJ Op. 58. Thus, the Convention provides that some 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 Deputy Administrator erroneously found that Dr. Craker’s marijuana would not qualify as “medicinal.” Relying again on new evidence, the Deputy Administrator essentially excised the medicinal exemption from Article 23(2)(e) of the Convention. On the ground that “[t]here is also no listing of any opium-containing product in the latest edition (2008) of FDA’s ‘Orange Book,’ which lists each drug product currently approved for marketing under the FDCA based on a determination by the FDA that the drug is safe and effective,” Leonhart Order 54 n. 58, the Deputy Administrator decided that the term “medicinal opium” in Article 23(2)(e) “is now obsolete,” and the “term’s obsolescence itself provides ample reason to disregard it.” Leonhart Order 55. Because Article 28 prescribes for marijuana the same controls that exist for opium, she then concluded that there was no medicinal marijuana exemption either.

Dr. Craker is entitled to an opportunity to respond to both this new evidence, and the new argument based upon it, neither of which was raised at the hearing. Dr. Craker can establish

through documentary and expert testimony that opium tincture—which contains opium—is currently produced, marketed, and prescribed as a medication with FDA approval.¹³

Dr. Craker is also entitled to respond on the record to the Deputy Administrator’s argument that she has authority to rely on the new Orange Book to justify “disregard[ing]” the plain text of the Convention. Just as judges cannot execute a statutory repeal absent “clear and manifest” legislative intent, *United States v. Borden Co.*, 308 U.S. 188, 198 (1939), the Deputy Administrator of an agency cannot simply decide on her own initiative that part of an international treaty is obsolete and can be disregarded. Moreover, the Deputy Administrator’s reliance upon the Orange Book at all in this context is arbitrary. Given the opportunity, Dr. Craker will present testimony and argument to establish that the Orange Book lists only drugs that were approved by the FDA after certain requirements to prove safety and efficacy were put into place. The Orange Book does not purport to list legal drugs such as medicinal opium that were approved *before* these requirements were put into place. Thus looking for medicinal opium in the Orange Book makes no sense, and its absence from that source cannot be the basis upon which to employ a never-before-asserted interpretation of the Convention that requires “disregard[ing]” its plain text.

The Deputy Administrator also exceeded her authority in concluding that “there is currently no such thing in the United States as ‘medicinal cannabis.’” Leonhart Order 56-57. Article 28 of the Convention—“Control of Cannabis”—explicitly and plainly applies *all* of the Article 23 provisions to marijuana: a Party “shall apply . . . the system of controls as provided in article 23 respecting the control of the opium poppy.” Convention, Art. 28(1). Nowhere does the Convention indicate that Article 23’s medicinal exemption does not apply to marijuana.

¹³ See http://www.fda.gov/cder/drug/MedErrors/opiumTincture_paregoric.pdf, attached hereto as Exhibit F; <http://www.drugs.com/ppa/opium-tincture-paregoric.html>, attached hereto as Exhibit G; http://www.medicinenet.com/tincture_of_opium-oral_liquid/article.htm, attached hereto as Exhibit H.

Rather, Article 28 fully adopts the Article 23 controls and applies them to marijuana cultivation with no exception or modification. Thus, it is not within the Deputy Administrator's interpretive authority to selectively refuse to apply Article 23 to marijuana. *Cf. Moran v. Ashcroft*, 395 F.3d 1089, 1093 (9th Cir. 2004) (explaining that when one statute cross-references another, it is necessary to "[t]ranslat[e]" the cross-referenced provision by "replac[ing] references" to the cross-referenced concepts with references to the new concept in order to interpret the statute in the new context).

The Deputy Administrator's finding that Dr. Craker's marijuana would not fall under the Convention's medicinal exemption to the government's exclusive rights is based on unsound interpretation not advanced below, and on and false inferences drawn from new evidence not introduced at the hearing. Dr. Craker is entitled to an opportunity to rebut both.

III. The Deputy Administrator'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 Her Other Findings.

In finding that Dr. Craker's registration would be contrary to the public interest because of a sponsoring organization's president's personal conduct, the Deputy Administrator contradicted herself and again selectively ignored her own agency's regulatory controls precluding Dr. Craker from distributing the marijuana to anyone but DEA-licensed researchers for particular FDA-approved research. The governing statute expressly directs the Deputy Administrator to consider "the existence in the establishment of effective control against diversion," 21 U.S.C. § 823(a)(5). After listing this and four other factors to be weighed, the statute authorizes consideration of "such *other* factors as may be relevant." 21 U.S.C. § 823(a)(6) (emphasis added). The Deputy Administrator correctly found in her analysis of 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.” Leonhart Order 89-90. However, the Deputy Administrator then invoked the catch-all clause “such other factors” to flatly contradict her own prior finding by asserting that Dr. Craker’s sponsoring organization’s president’s personal use of marijuana creates a risk of diversion. Despite the statute’s plain language instructing the Deputy Administrator to consider *other* factors—i.e., factors not already expressly enumerated in the statute—she considered the risk of diversion *again* and came to a different conclusion. But the term “other” cannot be read out of the statute. *See, e.g., Beck v. Prupis*, 529 U.S. 494, 506 (2000) (recognizing “the longstanding canon of statutory construction that terms in a statute should not be construed so as to render any provision of that statute meaningless or superfluous”). Because the Deputy Administrator’s diversion is explicitly prescribed as a consideration under a separate factor, *see* 21 U.S.C. § 823(a)(5), and as noted, the Deputy Administrator found that Dr. Craker would have effective controls against diversion, she cannot reintroduce the specter of diversion through the back door by relying on the catch-all language “such *other* factor[] as may be relevant,” 21 U.S.C. § 823(a)(6) (emphasis added).

Moreover, the Deputy Administrator’s “other factors” analysis is substantively flawed insofar as it results from the Deputy Administrator’s apparent disregard of her own agency’s regulations. The Deputy Administrator found that Dr. Craker’s registration would pose an unacceptable risk of diversion because of Dr. Craker’s sponsoring organization’s president’s personal history with marijuana. Leonhart Order 93-94. But this concern ignores the comprehensive DEA and FDA regulations that will apply to Dr. Craker’s crops if his registration is granted. *See* 21 C.F.R. § 1301 *et seq.* As the evidence at the hearing demonstrated, and as the ALJ held, Dr. Craker’s registration would not authorize the sponsoring organization’s president 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.” ALJ Op. 84. 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 non-clinical scientific research. Tr. 73. Absent evidence from which the Deputy Administrator could conclude that Dr. Craker would be likely to violate DEA regulations and provide the marijuana he grows to unlicensed or unauthorized persons, the conclusion that a third party who will fund FDA-approved research poses a threat of diversion is entirely untethered to fact. Further, the Deputy Administrator’s concern about the president’s “role in deciding to whom [Dr. Craker] will supply the marijuana” to is also unwarranted. Leonhart Order 91. Under DEA regulations, Dr. Craker could not supply anyone with his marijuana unless they are 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, 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. 84. 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 Deputy Administrator’s finding that Dr. Craker will have adequate controls against diversion in place—the Deputy Administrator’s concern about a sponsoring organization’s president is unjustified. Therefore the Deputy Administrator’s “other factors” analysis should be reconsidered.

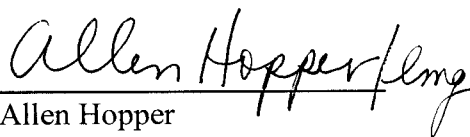
CONCLUSION

Due process requires that Dr. Craker be given an opportunity to respond to new evidence, and to arguments never raised below. This is particularly true where, as here, the party seeking that opportunity can identify ample rebuttal evidence to present regarding the new evidence underlying some of the decisionmaker's most important conclusions. Additionally, or in the alternative, the Leonhart Order's incorrect factual and legal premises make reconsideration of that order appropriate.

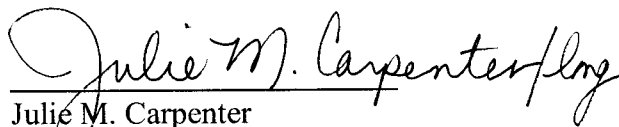
For all these reasons, the agency should grant Dr. Craker's Motion To Reconsider and adopt the ALJ's well-reasoned opinion, or in the alternative reopen the administrative hearing so that he may produce additional live testimony and oral argument to rebut the Deputy Administrator's new evidence.

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