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January 30, 2009

BY FACSIMILE TRANSMISSION

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Ms. Michele M. Leonhart
Deputy Administrator
ATTN: Mr. James Crowley
Office of the Deputy
Administrator
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA

Dear Mr. Crowley and Ms. Leonhart:

Attached please find a copy of Respondent Professor Lyle Craker's Request for Opportunity Under 5 U.S.C.A. § 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration, and his brief in support of that request. Per your instructions in your letter of Jan. 22, 2009, I am faxing it to the attention of Mr. James I. Crowley at 202-307-4540 before 5:00 pm on January 20, 2009.

Because you indicate that filing is complete on receipt in your office, and because I have no contact information for anyone in your office, I request that someone in your office call me at 202-639-6029 when the document is received, so that we will know filing is complete. Thank you for this courtesy.

Sincerely,

Julie M. Carpenter

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

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

This Request and Motion is made by Professor Lyle E. Craker (Respondent) for an opportunity to respond to, refute, and show the contrary of material new evidence that does not appear in the record of this proceeding, but which was nonetheless officially noticed by DEA in arriving at its January 7, 2009, Denial of Application for Registration as Bulk Manufacturer of Marijuana ("Leonhart Order"). Such evidence so officially noticed is set forth in the Leonhart Order and consists of the following:

1) A letter dated April 19, 1995 from the National Institute for Drug Abuse ("NIDA") to Dr. Donald Abrams. *See* Leonhart Order 23 n. 24; *id.* at 86 n. 84.

2) Two reports from Chemic Laboratories concerning testing of a device known as the Volcano Vaporizer. *See id.* at 27 n. 30; *id.* at 29 n. 32.

3) A 2003 newsletter from the Multidisciplinary Association for Psychedelic Studies ("MAPS") concerning studies of the Volcano Vaporizer. *See id.* at 27 n. 30.

4) FDA Guideline for Drug Master Files (Sept. 1989). *See id.* at 35 n. 41.

5) The 2005 International Narcotics Control Board ("INCB") Annual Report. *See id.* at 53 n. 56.

6) INCB press release issued on February 8, 2008. *See id.* at 53 n. 57.

7) 2008 Edition of FDA's "Orange Book." *See id.* at 54 n. 58.

8) 2004 letter from Assistant Attorney General William Moschella to Congressman Souder. *See id.* at 108 n. 111.

Respondent has had no opportunity to present evidence to dispute this evidence and the inferences DEA has drawn from it, or to argue its immateriality. If provided the opportunity, Respondent can and wishes to present evidence, both oral and documentary, and show authority to refute the evidence officially noticed.

Respondent notes that this new evidence has been asserted by DEA more than two years after the conclusion of the administrative hearing in this matter, and that DEA has provided respondent eighteen days from receipt of the Leonhart Order in which to file this Request and Motion.[1] That time period included two weekends and a federal holiday, leaving Respondent thirteen business days in which to file.

Because the Leonhart Order itself is 118 pages long and the new officially noticed evidence is voluminous—consisting of hundreds of pages—Respondent has not had sufficient time to assess this new material in comprehensive detail and amass all of the available evidence and authority refuting it. Indeed, two of the officially noticed documents are simply not available at the location or citation provided by the Deputy Administrator. First, the INCB press release issued on February 8, 2008, is not available at the URL address cited in the order. *See* Leonhart Order 53 n. 57 (taking notice of this document). Second, Respondent has been unable to locate the 2004 letter from Assistant Attorney General William Moschella to Congressman Souder. *See* Leonhart Order 108 n. 111 (citing this document although it does not appear in the

[1] The Leonhart Order is dated January 7, 2009. Counsel for Respondent did not receive a copy of the Order until it was delivered via regular mail on January 12. In the Order, the Deputy Administrator provided that Respondent had fifteen days in which to file a Motion to Reconsider, but also provided that the fifteen days was to commence with "the mailing of the Order," which apparently took place on January 8. Under that timeline, Respondent's Motion to Reconsider would have been due by January 22. The Deputy Administrator subsequently extended the due date to January 30.

record).[2] The citation provided in the Leonhart Order, "108th Cong. 208 (2004)" is not a standard citation of which counsel is aware. Respondent is thus placed in the Kafkaesque position of being required to respond to "officially noticed" extra-record material that he is unable to obtain or review.

In spite of these significant limitations, Respondent provides in the attached brief, filed in support of this Request and Motion, a summary of evidence he has identified thus far that he would seek to present in opposition to the officially noticed material.

For the reasons stated above and in the attached brief, Respondent therefore requests that DEA withdraw the Final Order in this matter (published January 14, 2009 and appearing at 74 Fed. Reg. 2101-03) in order to provide Respondent 60 days in which to present additional documentary evidence, live testimony and argument refuting and in opposition to the evidence officially noticed.

DATED: January 30, 2009

Respectfully Submitted,

Allen Hopper (by JMC)

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[2] While the Deputy Administrator does not explicitly state that she took official notice of this letter, it is certainly not part of the administrative record and, as noted in the text, Respondent cannot locate it from the citation provided by the Deputy Administrator and has therefore never read it and cannot possibly be deemed to have been given an adequate opportunity to respond to it.

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of LYLE E. CRAKER, Ph.D. Denial of Bulk Application for Registration as Bulk Manufacturer of Marijuana	Docket No. 05-16 **Brief in Support of Request Under 5 U.S.C. § 556(e) for Opportunity To Show Facts Contrary to Facts Officially Noticed and Motion for Reconsideration**

STATEMENT OF THE CASE

More than seven and a half years ago, on June 26, 2001, Professor Lyle E. Craker (Respondent) submitted to DEA by first class mail his Application for Registration as a Bulk Manufacturer of Marijuana. Respondent seeks this registration in order to provide an alternate source of research-grade marijuana to FDA- and DEA-approved researchers seeking to undertake the research necessary to allow FDA to determine whether marijuana should be approved as a medicine available by prescription. Currently, only one manufacturer is registered by DEA; that source is under contract with the National Institute of Drug Abuse ("NIDA"), and the terms of that contract permit distribution of marijuana only to research projects approved by NIDA and the Public Health Service ("PHS").

After three-and-a-half years of delay, on December 10, 2004, DEA issued an Order to Show Cause proposing denial of Professor Craker's application—and this only after he filed a petition for review in the Court of Appeals for the D.C. Circuit alleging unreasonable agency delay, and after the Court ordered DEA to file a response explaining the delay. *See In re Craker*, No. 04-1246 (D.C. Cir. Nov. 22, 2004) (per curiam). Rather than explain to the Court this extraordinary delay, DEA simply denied Respondent's application. After an administrative

hearing in August and December 2005, Administrative Law Judge Mary Ellen Bittner ("ALJ Bittner") issued a decision on February 12, 2007, recommending that DEA grant Respondent's application. Importantly, ALJ Bittner found that the evidence adduced at the hearing established that the existing supply of marijuana for medical and scientific research is not adequate because NIDA has exercised its monopoly over that supply to obstruct legitimate research by refusing to provide marijuana to some of the researchers who hold DEA registrations and FDA approval for their research. *See In re Craker*, No. 05-16 (Feb. 12, 2007) (ALJ decision) (hereinafter "ALJ"), at 84.

Now, after nearly two years of additional delay, Deputy Administrator Leonhart has published in the Federal Register her final order rejecting the ALJ recommendation and denying Professor Craker's application. *See Denial of Craker Application*, No. 05-16 (published Jan. 14, 2009), 74 Fed. Reg. 2101-03 (hereinafter "Leonhart Order").

Because the Deputy Administrator relied upon evidence that was not part of the administrative record and of which she took official notice, her Order specifically instructed that Respondent could file a motion for reconsideration within fifteen days of the date the order was mailed. Leonhart Order 23 n. 24. Pursuant to that instruction and pursuant to 5 U.S.C. § 556(e) and 21 C.F.R. 1316.59(e), Respondent hereby submits this Request for Opportunity to Show Facts Contrary to Facts Officially Noticed and Motion for Reconsideration, along with this supporting brief.

ARGUMENT

A. Respondent Is Entitled to an Adequate Opportunity to Respond.

1. The DEA Has Not Allowed Adequate Time to Respond.

The new officially noticed evidence is extensive—indeed, the new extra-record sources cited in the Leonhart Order comprise, cumulatively, hundreds of pages of material. Respondent is now required to carefully review the 118-page Order and all of the extra-record material, along with the entire administrative record and the ALJ's recommended decision, to evaluate the veracity and relevance of the new evidence and the inferences DEA has drawn from it, and then marshal any available facts and argument to refute the officially noticed information. DEA has granted Respondent only thirteen business days in which to file this Request and Motion. That time is plainly inadequate for Respondent to meaningfully and comprehensively respond to all of the new material. *See Heckler v. Campbell*, 461 U.S. 458, 469 (1983) ("[W]hen an agency takes official or administrative notice of facts, a litigant must be given an adequate opportunity to respond."). Respondent therefore requests that DEA withdraw or amend the Leonhart Order and provide Respondent 60 days in which to present additional documentary evidence, live testimony and argument refuting the facts officially noticed. Absent such withdrawal or amendment of the Order, Respondent must file a petition for review in the Court of Appeals within 30 days of publication of the Order—two weeks from this filing. *See* 21 U.S.C. § 877. Rendering the Final Order without providing Respondent a meaningful opportunity to evaluate and respond to the new, officially-noticed evidence would be arbitrary and capricious and constitute an abuse of discretion.

2. The Deputy Administrator's Selective Use of "Official Notice" Undermines the Fairness of the Hearing.

Official notice is the agency equivalent of judicial notice, a doctrine by which "the finder of fact [may] waive proof of facts *that cannot seriously be contested.*" 2 Am. Jur. 2d Admin. Law § 349 (emphasis added) (citing *Galina v. I.N.S.*, 213 F.3d 955, 958 (7th Cir. 2000)). This criterion cannot reasonably be applied to the extra-record material noticed by the Deputy

Administrator. For example, the Deputy Administrator officially noticed a letter from a NIDA official purporting to explain the reasons NIDA denied researcher Dr. Donald Abrams' request for marijuana to conduct medical research, even though NIDA's actual motivations for denying marijuana to researchers was vigorously contested at the hearing before ALJ Bittner. Taking official notice of NIDA's purported reasons for denying Dr. Abrams' request and *assuming the veracity* of those proffered reasons, is a far cry from, for instance, taking official notice that NIDA did in fact refuse to provide marijuana to Dr. Abrams. Because, as discussed more fully below, much of the evidence the Deputy Administrator officially noticed and inferences she drew from that evidence are "seriously contested," Respondent must be given a meaningful opportunity to contest them.

The Deputy Administrator's treatment of evidence on the Multidisciplinary Association for Psychedelic Studies ("MAPS") website concerning Dr. Ethan Russo illustrates how significantly the fairness of these proceedings has been undermined by the extensive reliance on extra-record material not subjected to the adversarial process. The Deputy Administrator dismissed evidence about Dr. Russo's inability to obtain NIDA marijuana for FDA-approved research because she concluded Respondent failed to establish that the denial occurred after the adoption of new procedures implemented by the agency on May 21, 1999. *See* Leonhart Order 25-26. She so concluded because witness Dr. Rick Doblin stated, "I think it [the NIDA refusal] was 1999." *Id.* at 25. The Deputy Administrator obviously spent time on the MAPS website, as she took official notice of a NIDA letter to Dr. Abrams found there. *Id.* at 23 n. 24. However, on that same website, on the very same page and directly below the Abrams link, is a link labeled "Dr. Russo's cannabis in migraine treatment study." *See* http://www.maps.org/mmj/. Clicking on that link takes one immediately to a page, the first sentence of which states, "On December 6,

1999, Dr. Ethan Russo, U. Montana, heard that NIDA's special review committee *convened in November 1999* [after the new procedures were in effect] rejected his MAPS-supported, IRB-and FDA-approved protocol." *See* http://www.maps.org/mmj/mjrusso.html (emphasis added). One click away is the actual letter from NIDA to Dr. Russo dated February 1, 2000, denying his request for marijuana for FDA-approved research. *See* http://www.maps.org/mmj/russo1199/02010001.html.

Thus, the Deputy Administrator selectively took official notice of one NIDA letter she believed supported a conclusion unfavorable to Respondent while ignoring another NIDA letter, linked to the very same page of the very same extra-record source, that supported another conclusion more favorable to Respondent. This selective use of the discretion to officially notice new facts highlights the crucial importance of permitting Respondent an adequate opportunity to carefully review and respond to all of the extra-record sources officially noticed in the Leonhart Order. Simple fairness requires the Deputy Administrator not to reach conclusions she finds, *by her own research*, to be contrary to the facts.

Presumably, the Deputy Administrator found the information presented by DEA to ALJ Bittner at the hearing to be an insufficient basis upon which to disregard Judge Bittner's thorough 87-page Opinion and Recommendation. Otherwise, there would have been no need to rely on hundreds of pages of extra-record material from eight different sources. Such extensive reliance upon extra-record material fundamentally undermines the fairness of these proceedings. The purpose of the administrative hearing process is, of course, to permit a party aggrieved by agency action an opportunity to "present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. § 556(d). The Deputy Administrator's official notice

of extensive extra-record evidence, without allowing Respondent a meaningful opportunity to substantively respond, denies Respondent this basic Due Process right. Indeed, had the DEA counsel sought to put this evidence in the record under the procedural rules of the adversarial hearing (which the agency had ample opportunity to do), counsel for Respondent could have objected to the documents, or introduced other documents or testimony to rebut them. And an adjudicator would have listened to arguments from both sides as to whether they should be admitted—unlike here, where the decision-maker is the very party seeking to rely on new evidence. Respondent is entitled to the same processes now that the Deputy Administrator has essentially re-opened the hearing by introducing, without notice, hundreds of pages of new evidence.

B. Initial Proffer of Evidence To Respond to New Evidence.

As a matter of simple fairness, Respondent seeks withdrawal or modification of the Leonhart Order and an additional 60 days in which to develop the factual basis to refute the extra-record material on which that order relies. Even given the abbreviated timeframe for him to prepare and submit this motion, Respondent can already sketch out a rudimentary summary of the type of evidence he would present to controvert the officially noticed evidence. For a full and fair opportunity to develop this evidence and adduce additional similar evidence, Respondent believes a 60-day time frame is both necessary and reasonable.

1. Proffer of additional evidence Respondent would present to respond to the Deputy Administrator's official notice of letter dated April 19, 1995 from NIDA to Dr. Donald Abrams.

The Deputy Administrator officially noticed a letter dated April 19, 1995 from NIDA to Dr. Donald Abrams. *See* Leonhart Order 23 n. 24; *id.* at 86 n. 84. This letter is significant because Respondent presented evidence which the ALJ found established 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." ALJ at 84. Based on that showing, the ALJ found that the existing supply of marijuana is inadequate. *Id.* Rejecting this conclusion, the Deputy Administrator ruled that Respondent failed "to demonstrate that the long-standing existing system in the United States of producing research-grade marijuana under the oversight of HHS and NIDA is inadequate," and found that this failure "weighed heavily against granting his application." Leonhart Order 117.

But the Deputy Administrator's concerted effort to reach outside the record to rebut Respondent's evidence about researchers who were denied marijuana from NIDA misses the point. In effect, the Deputy Administrator found that NIDA had adequate reasons *under the criteria imposed by the current system* to deny marijuana to these researchers. Respondent, however, adduced evidence at the hearing establishing that it is the current system's singular treatment of marijuana, among all other Schedule I drugs, that renders the current supply inadequate. Respondent presented ample evidence to support his argument that the current supply is inadequate because the additional layer of review imposed for marijuana, but no other Schedule I drug, results in FDA-approved research being stymied. Respondent established that whether or not NIDA or the PHS review committee agrees that proposed research ought to take place, the fact that some FDA-approved research has been blocked is enough to render the current supply inadequate. This is particularly true with regard to the specific research Respondent wishes to facilitate: research targeted at taking marijuana through the FDA approval process. Respondent established, and the Deputy Administrator does not meaningfully dispute, that no pharmaceutical company, including MAPS, can possibly use NIDA marijuana under the

current NIDA-PHS review system to gain FDA approval and provide for patient use of whole-plant smoked or vaporized marijuana as a prescription medicine. Whether DEA or NIDA or PHS agrees that taking marijuana through the FDA approval process and making it available to patients through prescription is a worthwhile or attainable goal does not determine whether the current supply of marijuana is adequate under the statute. In effect, the Leonhart Order maintains that the current supply is adequate because the research DEA supports is able to occur even though other FDA-approved research DEA and NIDA oppose is effectively blocked by the current NIDA monopoly. Put another way, the Deputy Administrator evaluated the adequacy of supply in terms of whether DEA's own political, policy and research goals are being met, without regard for the effect on other studies, even studies approved by FDA, that DEA opposes or considers foolhardy.

Regarding the letter dated April 19, 1995 from NIDA to Dr. Donald Abrams ("Leshner Letter"), the Deputy Administrator officially noticed the letter as evidence of the bases upon which NIDA denied Dr. Abrams' original application for marijuana. *See* Leonhart Order 23 n. 24. Respondent requests an opportunity to obtain and present the following rebuttal evidence:

i. Testimony, affidavit and/or documentary evidence from Dr. Abrams and the author of the Leshner Letter, Alan Leshner. Such testimony would concern the reasons NIDA denied Dr. Abrams' original application, but then later approved Dr. Abrams' subsequent application, 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.

ii. Testimony, affidavit and/or documentary evidence from Dr. Rick Doblin to rebut the purported reasons provided in the Leshner letter.

iii. Respondent furthermore requests that the Deputy Administrator officially notice Dr. Doblin's substantive critique of the reasons provided in the Leshner Letter for NIDA's denying Dr. Abrams' original request for marijuana. *See* http://www.maps.org/mmj/ricklesh.html.

iv. Testimony, affidavit and/or documentary evidence from Dr. Ethan Russo concerning NIDA's 1999 denial of his application for marijuana to undertake FDA-approved research to study the use of marijuana to treat migraine headaches. *See* Leonhart Order 25-26. Such evidence is relevant to rebut both the Leshner Letter and the Deputy Administrator's conclusion that despite the evidence located on the same website and linked to the same pages on which officially noticed evidence was located, the evidence is insufficient to show that Dr. Russo's request for NIDA marijuana was denied after the May 21, 1999 implementation of HHS's new procedures for making marijuana available to researchers. *Id.* In fact, as Dr. Russo can confirm, NIDA notified him on December 6, 1999, that his application was denied, and he subsequently received a letter formally denying his request on February 1, 2000.

v. Respondent furthermore requests that the Deputy Administrator officially notice the February 1, 2000 letter from NIDA to Dr. Russo denying his request for marijuana for his FDA-approved migraine headache research, and indicating the denial was based upon a special review committee's recommendation after convening to consider his application in November, 1999. The letter appears on the MAPS website at http://www.maps.org/mmj/russo1199/02010001.html.

2. Proffer of additional evidence Respondent will present to respond to the Deputy Administrator's official notice of reports concerning testing of a device known as the Volcano Vaporizer.

The Deputy Administrator officially noticed two reports from Chemic Laboratories concerning testing of a device known as the Volcano Vaporizer. *See* Leonhart Order 26-27 n. 30; *id.* at 29 n. 32. In this same context, the Deputy Administrator also officially noticed a 2003 MAPS newsletter concerning studies of the Volcano Vaporizer. *See id.* at 26-27 n. 30. The Deputy Administrator infers from, among other evidence, 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 the agency action either within HHS or in the courts . . . . Respondent produced no evidence showing that Chemic has pursued any such remedies." Leonhart Order 29 n. 33. Evidence adduced by Respondent at the hearing established that Chemic submitted a protocol to NIDA in June 2003, seeking to purchase 10 grams of marijuana from NIDA for vaporizer research. On July 21, 2004, MAPS filed a lawsuit

against HHS and NIDA in the Court of Appeals for the D.C. Circuit alleging 'unreasonable delay" under the APA. This lawsuit was dismissed without prejudice. NIDA finally rejected Chemic's protocol on July 27, 2005, more than two years after the protocol was submitted. Chemic's reply to that rejection was submitted on September 9, 2005. Further developments since the February 12, 2007 ALJ recommendation and since the time the officially noticed documents were created, further highlight the inadequacy of NIDA's monopoly in providing marijuana for research purposes. Respondent requests an opportunity to obtain and present the following rebuttal evidence:

i Testimony, affidavit and/or documentary evidence from, among others, Joseph St. Laurent or others employed by Chemic Labs, and/or Dr. Rick Doblin concerning, among other topics, the following: Chemic's September 9, 2005 reply to NIDA's July 27, 2005 critique of its June 2003 protocol submission; Chemic's submission of a new protocol to NIDA on January 16, 2008; NIDA's June 18, 2008 rejection letter of Chemic's revised protocol, with critiques that contradicted previous critiques NIDA had lodged in earlier reviews; and subsequent correspondence between Chemic and NIDA in which NIDA indicated that it would not consider Chemic's responses until Chemic conducted a "method validation study" (at a cost Chemic estimates to be approximately $50,000), a step never before mentioned by NIDA throughout the five-and-a-half-year process.

ii Respondent furthermore requests that the Deputy Administrator officially notice the following documents available on the MAPS website: January 16, 2008 Chemic protocol submitted to NIDA/HHS, http://www.maps.org/mmj/vaporizor_protocol/2696A.MAPS.volcanofinal1-16-08.NIDAmaterial.pdf; November 5, 2008 Chemic letter to NIDA/HHS, http://www.maps.org/mmj/response_to_nida.pdf; and January 23, 2009 letter from NIDA/HHS to Chemic labs, http://www.maps.org/mmj/chemiclab_letter_1.23.09.pdf.

3. Proffer of additional evidence Respondent will present to respond to the Deputy Administrator's official notice of the 2005 INCB Annual Report.

To rebut Respondent's arguments that the example of GW Pharmaceuticals in the United Kingdom demonstrates that private research such as Respondent's is consistent with a proper interpretation of the Single Convention, the Deputy Administrator officially noticed the 2005

International Narcotics Control Board ("INCB") Annual Report. *See* Leonhart Order 53 n. 56. The Deputy Administrator quoted selectively from the Report: "In its 2005 Annual Report, the INCB reiterated: 'Articles 23 and 28 of the [Single] Convention provide for a national cannabis agency to be established in countries where the cannabis plant is cultivated licitly for the production of cannabis, even if the cannabis produced is for research purposes only.'" *Id.* at 52-53. Respondent requests an opportunity to obtain and present the following rebuttal evidence:

i Testimony, affidavit and/or documentary evidence from British Government officials and/or employees of GW Pharmaceuticals, and/or Dr. Rick Doblin and/or INCB officials to further establish that: the sentence immediately following the sentence quoted by the Deputy Administrator from the INCB 2005 Annual Report continues, "The Board notes that since the last report of the Board was published, the Government of the United Kingdom has established a national cannabis agency"; at the time of the writing of the INCB 2005 Annual Report, dated March 1, 2006, GW Pharmaceuticals—a privately-funded, non-governmental bulk manufacturer of cannabis—was fully licensed by the Home Office of the United Kingdom; that the fact that the INCB would note that the Government of the United Kingdom had indeed established a national cannabis agency, without mentioning or objecting to the licensing of GW Pharmaceuticals, demonstrates that privately-funded production of cannabis can be conducted in a manner consistent with all the provisions of the Single Convention; and that Respondent is not seeking, as DEA repeatedly claims, to be licensed outside of the requirements of the Single Convention, but rather is seeking to be licensed within the control of the relevant national U.S. government agency and in furtherance of the goals of the INCB.

ii Respondent furthermore requests that the Deputy Administrator officially notice the 2001 INCB Annual Report, which notes that research on the efficacy of the medical use of cannabis or cannabis extracts was at that time taking place in England, an implicit reference to GW Pharmaceuticals, *see* INCB 2001 Annual Report at 25, ¶ 158, thus indicating that the United Kingdom and the INCB interpret the Single Convention as allowing a private production facility such as GW Pharmaceuticals—and such as Respondent's proposed project—so long as it is licensed, controlled and regulated by the relevant government agency.

iii Respondent furthermore requests that the Deputy Administrator officially notice the 2006 and 2007 INCB Annual Reports, which contain no criticism of the United Kingdom for licensing GW and thus provide further indication that the Single Convention does not preclude the relevant national agency from licensing a private production facility under appropriate controls and regulation.

4. Proffer of additional evidence Respondent will present to respond to the Deputy Administrator's official notice of the 2008 Edition of FDA's "Orange Book."

The Deputy Administrator officially noticed the 2008 Edition of FDA's "Orange Book" in her analysis of the Single Convention. *See* Leonhart Order 54 n. 58. The Deputy Administrator notes that the Orange Book "lists each drug product currently approved for marketing . . . based on a determination by the FDA that the drug is safe and effective"; the Order then observes that the book contains "no listing of any opium-containing product," *id.*

Respondent requests that the Deputy Administrator officially notice the following documents clearly establishing that, in fact, opium tincture—containing opium—is a currently produced, marketed and prescribed medication: http://www.fda.gov/cder/drug/MedErrors/opiumTincture_paregoric.pdf, http://www.drugs.com/ppa/opium-tincture-paregoric.html, and http://www.medicinenet.com/tincture_of_opium-oral_liquid/article.htm.

5. Proffer of additional evidence Respondent will present to respond to the Deputy Administrator's official notice of the 2004 letter from Assistant Attorney General William Moschella to Congressman Souder.

The Deputy Administrator cites to and quotes from a 2004 letter from Assistant Attorney General William Moschella to Congressman Souder ("Moschella Letter"). *See* Leonhart Order 108 n. 111. As noted, though the Deputy Administrator does not explicitly state that she took official notice of this letter, it is certainly not part of the administrative record and Respondent cannot locate it from the citation provided by the Deputy Administrator. Respondent has therefore never read the Moschella letter and cannot possibly be deemed to have been given an adequate opportunity to respond to it. Respondent therefore requests that he be provided with a copy of the Moschella Letter and an adequate opportunity to present rebuttal evidence. Based

solely on the text purportedly quoted from the letter in the Leonhart Order, Respondent requests the opportunity to obtain and present the following:

i Testimony, affidavit and/or documentary evidence from, among others, Professor Frederic M. Scherer and/or Dr. Rick Doblin concerning the point raised in the quoted passage of Moschella Letter, that "one example of inadequate competition among the existing manufacturers of the particular controlled substance that the applicant seeks to produce" is lack of competition concerning price—"substantial overcharging by the existing manufacturers due to an insufficient number of competing manufacturers of that controlled substance." Respondent's rebuttal evidence would establish that according to the predominate economic theories in the United States today, another more economically significant and socially harmful example of inadequate competition is a monopoly that refuses to sell, at all, to some buyers, making the effective price to such buyers "infinite," and therefore any reasonable interpretation of 21 U.S.C. § 823(a)(1) and 21 C.F.R. 130133(b) must recognize that a system that permits a monopoly-holding supplier to refuse to provide marijuana, at any price, to legitimate researchers cannot be deemed to satisfy the statutory and regulatory requirement of "adequate supply." Specifically, among other evidence, Respondent requests the opportunity to present testimony from Professor Frederic M. Scherer as proffered in his written statement available on the MAPS website at http://www.maps.org/mmj/january_30_2009_statement_of_frederic_scherer.pdf.

ii Professor Frederic M. Scherer's testimony and/or other documentary evidence will also address the important relationship between adequate competition and promoting technical advances. A considerable part of Professor Scherer's professional career has been devoted to studying the relationships between market structure and technological progress. One of his most important findings has been that innovation, quality, and diversity of product characteristics satisfying consumers' demands are more likely to be achieved when there are multiple producers than when there is only one, i.e., a monopoly.

iii Respondent furthermore requests that the Deputy Administrator officially notice the written statement of Professor Frederic M. Scherer, available on the MAPS website at http://www.maps.org/mmj/january_30_2009_statement_of_frederic_scherer.pdf

CONCLUSION

In sum, what Respondent Professor Craker seeks here is nothing more than a basic component of due process: an adequate opportunity to respond to new evidence. Professor

Craker has sketched some of the responses he would marshal; given adequate time, he would be able to flesh these out and potentially develop others.

Finally, given the eleventh-hour nature of the Leonhart Order—issued less than two weeks before the change in Presidential Administration and after nearly eight years of repeated delay—DEA should act in the spirit of the January 20, 2009 memorandum from the President's Chief of Staff to the heads of all executive departments and agencies. Although that directive does not cover adjudications by its terms, its instruction that agencies should consider "extending for 60 days the effective date of regulations that have been published in the Federal Register but have not yet taken effect . . . for the purpose of questions of law and policy," Memo. of R. Emanuel to Heads of Exec. Agencies and Dep'ts., Jan. 20, 2009, *available at* http://ombwatch.org/regs/midnightregfreezememo.pdf, expresses a sensible principle no less applicable in this instant context: on the eve of a presidential transition, agencies should act with caution in finalizing and implementing important policy decisions that may conflict with the goals of the new administration.

This caution is especially appropriate where, as here, an agency decision that "contains a far more extensive analysis of [a statutory provision] than [the agency] has previously published," *see* Leonhart Order 94, has relied extensively on voluminous extra-record evidence without providing the adversely-affected party adequate opportunity to respond.

For all these reasons, the agency should withdraw or modify the Leonhart Order, grant Respondent 60 days to develop his response to the extra-record evidence upon which that Order relied, and order a further hearing to reconsider its decision.

DATED: January 30, 2009

Respectfully Submitted,

Allen Hopper (by JMC)

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