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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

[Docket No. 05-16]

Lyle E. Craker, Ph.D.; Order Regarding Respondent's Request Under 5 U.S.C. 556(e) to Respond to Officially Noticed Evidence and Motion for Reconsideration

I. Summary

Lyle E. Craker, Ph.D. (Respondent) has requested that the administrative hearing be reopened so that he may call additional witnesses in view of certain documents of which I took official notice in the January 7, 2009, Final Order (74 FR 2101). He has further requested that I take official notice of certain documents, also in response to the documents of which I took official notice in the Final Order. Respondent's request is hereby granted in part, and denied in part, as explained below.

II. Background

By Final Order dated January 7, 2009, I denied Respondent's application to become registered as a bulk manufacturer of marijuana. The Final Order was served on Respondent on January 8, 2009, and published in the Federal Register on January 14, 2009 (74 FR 2101). As stated in the Final Order, it was to become effective February 13, 2009.

By letter to me dated January 21, 2009, Respondent, through his counsel, noted that, in several places in the Final Order, I indicated I was taking official notice of certain documents that were not submitted during the administrative hearing. With respect to such documents, the Final Order states: "To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the

order." Thus, Respondent had until January 23, 2009, to file a motion for reconsideration of the facts of which I took official notice. In her January 21, 2009, letter, counsel for Respondent requested an extension of this filing deadline until January 30, 2009. I granted this request for an extension by letter dated January 22, 2009.

On January 30, 2009, Respondent submitted to me a document entitled "Request for Opportunity Under 5 U.S.C. § 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration." In this document, Respondent provided a preliminary response to those documents of which I took official notice. However, Respondent asked for additional time to supplement his preliminary response, given the length of the Final Order as well as that of the documents of which I took official notice. I granted this request, allowing Respondent until March 11, 2009, to supplement his response and motion. I further instructed that counsel for the Government would have to submit its response no later than 15 days after being served with Respondent's submission.

On March 11, 2009, Respondent submitted "Respondent's Supplemental Brief in Support of Request Under 5 U.S.C. § 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration" (hereafter, "Respondent's Supplemental Brief"). In this document, Respondent provided the legal and factual bases for his motion for reconsideration of the Final Order. Also in the document, Respondent requested that the administrative hearing be reopened so that he may call additional witnesses in view of certain documents of which I took official notice in the final order. The Government submitted its response on April 13, 2009. In view of these submissions, and to clarify Respondent's request, I issued an interim order on May 18, 2009, directing Respondent to submit a list of all witnesses he would call if his request to reopen the administrative

hearing were granted and to provide a summary of the proposed testimony for each witness. This interim order further instructed Respondent to indicate precisely which documents he sought to introduce for purposes of his motion for reconsideration and, for each document, whether he wanted me to take official notice of it, or whether he wished to introduce it through witnesses if his request to reopen the hearing were granted.

On June 5, 2009, Respondent submitted his "Witness List and Document List in Support of Motion for Reconsideration" (hereafter "Respondent's Witness List and Document List"). Having considered all of the foregoing submissions, I address and rule on each of Respondent's proposed witnesses and documents in the order he presented them.

III. General Considerations

The taking of official notice of certain facts in administrative proceedings has been described by one court as follows: "Official notice is the proper method for agency decisionmakers to apply knowledge not included in the record. It is the administrative law counterpart of judicial notice. Both doctrines allow adjudicators to take notice of commonly acknowledged facts, but official notice is broader than judicial notice insofar as it also allows an administrative agency to take notice of technical or scientific facts that are within the agency's area of expertise." Sykes v. Apfel, 228 F.3d 259, 272 (3d Cir. 2000). Consistent with this doctrine, I took official notice of several facts in the Final Order. Respondent now seeks to call witnesses in response to certain of those facts.

As indicated in the Final Order (74 FR at 2108 n.24), the Administrative Procedure Act (APA) provides: "When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an

opportunity to show the contrary." 5 U.S.C. § 556(e). The DEA regulations contain a similar provision: "Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded opportunity to controvert such fact." 21 CFR 1316.59(e).

Under the APA provision, for a party to be entitled to "show the contrary" with respect to the taking of official notice of a fact, that fact must be a "material" one on which the Final Order "rests". Similarly, under the DEA regulation, for a party to be entitled "to controvert such fact," the fact must be "material." I.e., under both the APA and the DEA regulation, for a party to be entitled to refute a fact of which official notice is taken, the fact must be "significant or essential to the issue or matter at hand." See Black's Law Dictionary 670 (9th ed. 2009) (definition of "material fact").

Accordingly, with respect to those facts of which I took official notice that are material to the adjudication, Respondent is entitled, upon timely request, to "an opportunity to show the contrary". Respondent's request is timely. The materiality of the facts in question is assessed individually below. But even assuming, arguendo, the materiality of each of the facts in question of which I took official notice, it is notable that Respondent does not actually indicate that he wants to "show the contrary" with respect to most of them. That is, Respondent does not seem to dispute the correctness of facts of which I took official notice. Rather, Respondent seems to want to put forth arguments regarding the weight to be given such facts and/or the conclusions I drew in relation to such facts. While Respondent is entitled under 5 U.S.C. 556(e) and 21 CFR 1301.59(e) to an opportunity to make such arguments, as explained below, these provisions do not entitle him to reopen the hearing to call witnesses for the purposes he describes.

The phrase "an opportunity to show the contrary" within the context of 5 U.S.C. 556(e) has been interpreted to mean that a party against whom an officially noticed fact is offered is entitled to "parry its effect." E.g., Union Electric Company v. F.E.R.C., 890 F.2d 1193, 1201 (D.C. 1989) (citing Ohio Bell Telephone Co. v. Public Util. Comm'n of Ohio, 301 U.S. 292, 302 (1937); see also Sykes, 228 F.3d at 272. Thus, as indicated, Respondent is entitled to argue, with respect to the facts of which I took official notice, that the inferences made in the Final Order in consideration of such facts were mistaken. (Indeed, Respondent has done just that in "Respondent's Supplemental Brief".) However, the taking of official notice does not automatically entitle a party to reopen the administrative hearing to call witnesses to rebut the facts of which the agency took official notice. The provisions of the APA and the DEA regulations governing official notice do not provide for such an automatic right. As a general rule, a party requesting to reopen the administrative hearing to call witnesses to testify regarding matters of which the agency took official notice should "make a good showing that it can contest the evidence." See Union Elec. Co., 890 F.2d at 1203 (citing Market Street Railway Co. v. Railroad Comm'n of California, 324 U.S. 548, 562 (1945)). Thus, if Respondent's reason for seeking to call a particular witness (if the hearing were reopened) is not to contest the evidence of which official notice was taken but instead to argue about the inferences drawn from such evidence, this is not an appropriate justification for calling the witness. It bears repeating here that Respondent is being afforded a full opportunity to submit argument regarding such inferences.

Another important consideration is whether, with respect to the witnesses that Respondent seeks to call if the hearing were reopened, the matters about which they would

testify have already been litigated. Respondent was put on notice of the issues at the onset of the proceedings when he was served with the order to show cause. In addition, the documents that all parties are required to submit prior to a DEA administrative hearing served to confirm for Respondent the issues in the case. Respondent had an essentially unfettered opportunity to call the witnesses of his choosing at the administrative hearing (either on direct examination or, if needed, on rebuttal). Thus, if the taking of official notice of a particular fact in the Final Order did not introduce a new issue, but instead provided an additional layer of evidence on top of numerous other layers of evidence that were already in the record, this further diminishes the justification for reopening the hearing to call a witness. The taking of official notice does not open the door to a rehearing in which a party gets to call yet one more witness to try to better explain a point that the party already tried to explain through its witnesses and documents previously presented at the earlier hearing.

With these general considerations in mind, each of Respondent's proposed witnesses and their proposed testimony are evaluated individually below.

IV. Respondent's Proposed Witnesses If the Hearing Is Reopened

1. Jeremy Sare

Respondent states that Mr. Sare is a former "head of Drug Legislation in the Home Office" of the Government of the United Kingdom. If the administrative hearing were reopened, Respondent proposes to call Mr. Sare to testify that granting Respondent's application to become registered as a bulk manufacturer of marijuana would not violate the Single Convention on Narcotic Drugs, 1961 (Single Convention). Respondent states that Mr. Sare would base this assertion on his familiarity with the circumstances under which a

British company, GW Pharmaceuticals, became licensed by the United Kingdom to produce a proposed medical product made from derivatives of the cannabis plant. Respondent's asserted justification for being allowed to reopen the proceedings for this witness to testify on this topic is that, in the Final Order, I took official notice of a portion of the 2005 International Narcotics Control Board (INCB) Annual Report, which, as Respondent states, "reiterates that signatories must have a national cannabis agency even if they only allow marijuana cultivation for research." Respondent's Supplemental Brief at 20 (referring to Final Order, 74 FR at 2115 and n.55).

Assuming, arguendo, that the quotation in the Final Order from the 2005 INCB report constitutes a material fact on which the Final Order rests,[1] Respondent is not seeking to show that this "fact" is in error. Indeed, Respondent neither contests the accuracy of the INCB quotation nor asserts that the quotation mischaracterizes the treaty requirement. Nor could Respondent reasonably do so as it is beyond dispute that the text of articles 23 and 28 of the Single Convention does indeed require that a national cannabis agency be established in countries where the cannabis plant is cultivated licitly for the production of cannabis, even if the cannabis produced is used for research purposes only. Thus, Respondent is not seeking to "show the contrary" with respect to this particular fact; rather, Respondent is seeking to use the taking of official notice of this fact as a springboard for relitigating the related legal issues that were thoroughly addressed by both parties in the proceedings leading up to the Final Order. As explained above, this would not be a proper utilization of 5 U.S.C. 556(e) and 21 CFR 1301.59(e).

[1] The taking of official notice of this quotation from the 2005 INCB could be deemed cumulative as it merely reiterated what the text of the treaty states, which was already discussed at length on the previous page of the Final Order (74 FR at 2214) through direct citation to the text of the treaty and the official commentary. Thus, one might fairly conclude that this "fact" is not a "material fact" on which the agency decision "rests" and, therefore, that Respondent is not entitled to any opportunity to rebut this fact.

Moreover, Respondent was on notice, starting at the moment he received the order to show cause, that one of the central issues in this adjudication was whether his proposed registration would be consistent with the Single Convention. In this context, among the matters taken up during the administrative hearing and addressed in the Final Order was that GW Pharmaceuticals was growing marijuana in the United Kingdom and whether that fact had any bearing on the treaty considerations in this case. See 74 FR at 2105, 2114, 2115, 2116, 2123. One of the exhibits Respondent introduced during the hearing was a document (RX 26) purporting to set forth the United Kingdom's explanation of how it carried out its obligation under the Single Convention to establish a national cannabis agency. 74 FR at 2115 n.53. Thus, Respondent had ample opportunity to call witnesses, directly or on rebuttal, to provide the type of testimony he now seeks to introduce through Mr. Sare.

Furthermore, Mr. Sare's proffered testimony, even if fully credited, would not affect the conclusions made in the Final Order since, as explained therein, the Controlled Substances Act does not call upon the Attorney General to consider how other nations interpret the Single Convention as a basis for the Attorney General's determination of what are the United States' obligations under the treaty. 74 FR at 2115. As further explained in the Final Order, what the United Kingdom might, in its opinion, deem to be appropriate control measures to meet its obligations under the Single Convention given the circumstances involving cannabis in Britain might be distinct from what the United States finds, in its opinion, to be the appropriate control measures to fit the circumstances involving cannabis in the United States. Id.

Accordingly, Respondent's request to call Mr. Sare if the administrative hearing is reopened is denied.[2]

2. Peter Barton Hutt

Respondent identifies Mr. Hutt as a "former Chief Counsel for the Food and Drug Administration". Respondent seeks to call Mr. Hutt to "rebut the new evidence relied upon by the Deputy Administrator concerning the FDA Orange Book, whether there are legal medicinal opium products currently available in the U.S., whether the term 'medicinal opium' used in Article 23(2)(e) of the Single Convention is obsolete, and the conclusions that the Deputy Administrator drew from this new evidence about the proper interpretation of the Single Convention." Respondent's Witness List and Document List at 2.

Respondent identifies only one document of which I took official notice as his predicate for calling Mr. Hutt: the FDA Orange Book. The only reference to the Orange Book in the Final order was the following statement, which appeared in a footnote: "There 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." 74 FR at 2116 n.58. Respondent does not dispute the accuracy of the preceding statement. Thus, Respondent does not actually seek to "show the contrary" with respect to this fact of which I took official notice. Rather, Respondent asserts that "The Orange Book does not purport to, nor does it, list legal drugs such as medicinal opium that were approved before these

[2] On a related note, in Respondent's Supplemental Brief, he asserted that if counsel for the Government had introduced at the hearing the portion of the 2005 INCB report of which I took official notice, Respondent "would have responded by introducing the INCB 2001 Annual Report as well as others." Respondent's Supplemental Brief at 20. Respondent appears now to have abandoned this position as his Document List submitted on June 5, 2009, does not list any of the INCB reports among his proposed documents.

FDA requirements[3] were put into place." Respondent's Witness List and Document List at 2. Respondent further asserts that "[o]pium tincture and paregoric are approved, legally marketed and available medicines even though they are not among the medicines listed in the FDA's 'Orange Book.'" Id.[4] Respondent's reason for making these assertions is to support his contention that I erroneously stated in the Final Order that the term "medicinal opium" is now obsolete. See 74 FR at 2116.

For a variety of reasons, Respondent has failed to demonstrate that the footnoted reference to the Orange Book justifies reopening the hearing to call Mr. Hutt as a witness. First, my conclusion in the Final Order that the term "medicinal opium" is now obsolete was based on the text of the Single Convention, the Official Commentary thereto, and various pharmacopœas. Id.[5] The short, footnoted reference to the Orange Book merely provided a fact that was consistent with my then-already-explained conclusion in the text of the Final Order regarding the obsolete nature of the term "medicinal opium." It is clear from reading the Final Order in its entirety that this single reference to the Orange Book

[3] Respondent's reference to "these FDA requirements" in the above sentence refers to the 1938 Federal Food Drug and Cosmetic Act (FFDCA), which required manufacturers to prove to the FDA their new drugs were safe before the drugs could be marketed, and the 1962 amendments to the FFDCA, which added the requirement that manufacturers prove to the FDA the effectiveness of their drug products before marketing them.

[4] Respondent also asserts: "In the late 1960s – as a result of the 1962 Amendments – the FDA conducted a comprehensive review of the effectiveness and safety of all drugs on the market: the Drug Efficacy Study Implementation ('DESI')." Respondent's Witness List and Document List at 2.

[5] In this context, regarding the pharmacopœas, the Final Order states:

> In a footnote, the Commentary further explains that "[t]he fifth edition of the Pharmacopœa Helvetica (1949) . . . defines 'medicinal opium' as opium powder reduced to a content of 9.2 to 10.2 per cent of anhydrous morphine by the addition of lactose. This pharmacopœa calls 'medicinal opium' also 'powdered opium.'" Commentary at 22 n.8. The Commentary then notes that "[t]he term 'medicinal opium' ha[d] been abandoned in" in favor of the terms "powdered opium" and "standardized powered opium" in several pharmacopœas which were been published in the late 1960s. Id. (citing British Pharmacopœa 686 (1968), and Pharmacopœa Internationalis 403 (2d ed. 1967)). Of further note, the term is not used at all in more recent pharmacopœas. See, e.g., The United States Pharmacopeia 2008, at 2860-61 (31st Rev. 2007); British Pharmacopoeia 2008, at 1599-1601 (2007).

(which appeared only in one of 125 footnotes in the Final Order) did not alter this, or any other, legal conclusion in the document. In other words, had the footnote containing the reference to the Final Order been deleted, every other word of the Final Order would have remained the same. Thus, it would be inaccurate to characterize the taking of official notice of the Orange Book as a material fact on which the Final Order rests. For this reason, Respondent is not entitled under the APA to "show the contrary" with respect to the taking of official notice of the Orange Book.

Second, even assuming, arguendo, that the footnoted reference to the Orange Book was material, as indicated above, Respondent does not dispute the accuracy of the fact of which I took official notice – 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." This further weakens his contention that he should be permitted under 5 U.S.C. 556(e) to call witnesses in response to the taking of official notice of this fact.

Third, the conclusion in the Final Order about which Respondent complains (which bears only a rather attenuated connection to the footnoted reference to the Orange Book) – that the term "medicinal opium" is now obsolete – was not determinative of outcome of the Final Order. This was explained in the following portion of the Final Order:

> Finally, even if all the foregoing considerations were ignored and DEA were to treat the marijuana that Respondent seeks to grow as akin to "medicinal opium" for purposes of the Single Convention, Respondent's proposed activity would still be inconsistent with the Convention for the following reason. As the Commentary explains: "Opium-producing countries may thus authorize private manufacture of, and private international and domestic wholesale trade in, medicinal opium and opium preparations. The opium other than medicinal opium needed for such

> manufacture must however be procured from the national opium agency." Commentary at 284 (emphasis added). Thus, under the Convention, even if "medicinal cannabis" may be privately traded, the treaty requires that the raw material needed to produce the "medicinal cannabis" (i.e., the marijuana plant material) must be obtained from the national cannabis agency. This again reflects the central theme of cannabis control under the Single Convention – that the 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.

74 FR at 2117. In other words, even if I were persuaded by Respondent's post-Final-Order submissions to alter my conclusion that the term "medicinal opium" is now obsolete, the conclusion in the above-quoted paragraph would remain unaltered.

For the foregoing reasons, Respondent has failed to provide a sufficient justification to call Mr. Hutt as a witness if the hearing were reopened.

Nonetheless, in view of Respondent's post-Final Order submissions related to this issue, I will revise the Final Order as follows. Upon the conclusion of these post-Final Order proceedings concerning Respondent's motion for reconsideration, I will issue an order that will clarify certain statements in the Final Order relating to concept of "medicinal cannabis" within the meaning of the Single Convention on Narcotic Drugs, 1961 (Single Convention). Specifically, it will be made clear that it is at least theoretically possible for a cannabis derivative to be developed in the future that would constitute "medicinal cannabis" within the meaning of the treaty. For example, if the FDA were to approve for marketing a drug product containing material extracted from marijuana, such product could constitute "medicinal cannabis" within the meaning of the treaty. This upcoming modification to the Final Order renders inconsequential, for purposes of this adjudication, the issue whether the term "medicinal opium" is obsolete. This is yet

another reason to deny Respondent's request to call Mr. Hutt, as his proffered testimony relating to "medicinal opium" would serve no useful purpose.[6]

3. Frederick Scherer

Respondent describes Professor Scherer as "the former chief economist at the Federal Trade Commission and currently emeritus faculty at Harvard." Respondent's description of Professor Scherer's proposed testimony begins with the statement that "Professor Scherer will testify to rebut new evidence relied upon by the Deputy Administrator (a 2004 letter from Assistant Attorney General William Moschella to Congressman Souder) . . . ." However, it is evident from the remainder of the description of the proposed testimony that Respondent is not actually seeking to do so. Rather, Respondent's description of the proposed testimony indicates that he seeks to call Professor Scherer to relitigate the issue of whether there is adequate competition within the meaning of 21 U.S.C. 823(a)(1).

The "fact" of which I took official notice – that which Respondent asserts provides a predicate for reopening the hearing to call Professor Scherer as a witness – was a letter issued by the Department of Justice in 2004. This letter was referenced in the Final Order

[6] If the issue of "medicinal opium" were not moot, and assuming further that it were relevant to the outcome of this proceeding whether there are any drugs containing opium that are currently marketed lawfully in the United States under the FDCA as "grandfathered" drugs, I would have instructed the parties, as part of their submissions in connection with Respondent's motion for reconsideration, to address the following documents written by the FDA: FDA aims to remove unapproved drugs from market, Pharmacy Today, Aug. 2008, http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm119899.pdf ("FDA believes that very few drugs are on the market that are actually entitled to grandfather status because the drugs currently on the market likely differ from the previous versions in some respect, such as formulation, dosage or strength, dosage form, route of administration, indications, labeling, or intended patient population. If a firm claims that its product is grandfathered, it is that firm's burden to prove that assertion."); Marketed Unapproved Drugs — Compliance Policy Guide (Sec. 440.100), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf (same).

in a footnote contained in a lengthy (six pages of condensed Federal Register text) discussion of 21 U.S.C. 823(a)(1), which included a detailed examination of the statutory text, legislative history, treaty considerations, regulatory provisions, and prior DEA statements. In the portion of this six-page discussion that focused on the pertinent DEA regulation, an explanation was provided as to the meaning of the regulatory text. In a footnote to that portion of the discussion, the following statement appeared: "In 2004, the Department of Justice provided Congress with an explanation of subsection 1301.33(b) that is consistent with the explanation provided in the text above." 74 FR at 2130-2131 n.111. This statement was followed by a citation to the Department of Justice letter (citing the page on which the letter appeared in the Government Printing Office publication of the record of a Congressional hearing). Thus, the letter was not cited as the basis for the determination in the Final Order as to the meaning of the relevant regulatory provision. Rather, the letter was cited merely for the proposition that the Department of Justice had previously provided Congress with an interpretation of the regulation that was consistent with that which appeared in the Final Order. It is thus clear that, even if this footnoted reference to the 2004 letter had been omitted from the Final Order, the remainder of the Final Order would be identical. The footnoted reference to the letter might therefore be described as cumulative, and it certainly does not constitute a "material fact" on which the "agency decision rests." For this reason, Respondent is not entitled under 5 U.S.C. § 556(e) and 21 CFR 1316.59(e) to an opportunity "to show the contrary."

Further, as indicated above, Respondent does not really seek "to show the contrary" with respect to the letter. That is, Respondent does not dispute the purpose for which the letter was cited (to show that the Department of Justice had previously provided Congress

with an interpretation of the regulation that was consistent with that which appeared in the Final Order). Instead, Respondent is attempting to use the fact that the letter touches on a particular subject (competition within the meaning of 21 U.S.C. 823(a)(1)) as a premise for reopening the hearing to bring in yet another witness to testify on this subject. This is not an appropriate use of 5 U.S.C. § 556(e) and 21 CFR 1316.59(e). If it were, then essentially every instance of an agency taking official notice of a fact would provide an automatic right to reopening the administrative hearing to call more witnesses to testify about matters already litigated during the administrative hearing. There is no precedent for construing 5 U.S.C. § 556(e) and 21 CFR 1316.59(e) in such an overly expansive manner. Doing so would also promote the inefficient use of administrative resources.

Further, Respondent had abundant opportunities during the regular administrative proceedings to call Professor Scherer (or other similar witnesses) for the very purpose he now seeks to call him. From the moment he received the order to show cause, and continuing throughout all phases of the administrative proceeding, it was obvious that the issue of competition within the meaning 21 U.S.C. 823(a)(1) was one of the central issues in the case. Keenly aware of this, both Respondent and the Government put on their own experts to testify regarding this subject during the hearing. Neither 5 U.S.C. § 556(e) nor 21 CFR 1316.59(e) can be used as a means to reopen the hearing to supplement or improve on the performances of witnesses called during the hearing. Moreover, to suggest that the single reference (in footnote 111 of the Final Order) to the 2004 Department of Justice letter provides a justification to reopen the hearing to call a replacement expert witness to make a better presentation on an issue that has already been thoroughly litigated by both sides is without merit.

In sum, Respondent may present argument as the weight to be given the 2004 Department of Justice letter of which official notice was taken, but the taking of official notice of this letter does not open the door to reconvening the hearing to call another expert to testify regarding a core issue that has already been extensively litigated.

4. John Halpern

Respondent identifies Dr. Halpern as a professor of psychiatry at Harvard University Medical School. Respondent states: "Dr. Halpern will testify to rebut new evidence relied upon by the Deputy Administrator (a letter dated April 19, 1995 from [the National Institute on Drug Abuse (NIDA)] to Dr. Donald Abrams) and the conclusions the Deputy Administrator drew from that evidence, including the conclusion that NIDA's denial of Dr. Abrams' research protocols was based solely upon issues of design, scientific merit and rationale, and that that [sic] the current supply of marijuana is sufficient because there is no evidence that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines."

Thus, Respondent's asserted predicate for reopening the hearing to call Dr. Halpern is my taking official notice of a 1995 letter from NIDA to Dr. Abrams – a letter in which NIDA stated its bases for denying at that time Dr. Abrams' request that the National Institutes of Health (NIH) supply him with marijuana for his proposed research. The following excerpt from the Final Order provides the context in which this arose:

> **HHS's Denials of Researcher's Requests for NIDA Marijuana**
>
> Respondent's first claim is based on three incidents over a decade-long time period in which he alleges that researchers were improperly denied access to NIDA's marijuana. The first incident, which occurred in 1995, involved an application submitted by Donald Abrams, M.D., who sought marijuana from NIDA to study its effects on persons with HIV-related wasting syndrome. RX 15, at 1. NIDA rejected Dr. Abrams's

> application "based upon issues of design, scientific merit and rationale."[7] Dr. Abrams subsequently submitted a revised research protocol that NIDA found to be scientifically meritorious and for which NIDA supplied marijuana in 1997.[8] See GX 21, at 1. NIDA also supplied Dr. Abrams with marijuana for subsequent studies. Id.; Tr. 689. In any event, for purposes of determining the relevance of the 1995 incident in which Dr. Abrams' original protocol was rejected by NIDA, it is notable that this occurred before HHS adopted its new guidelines for the provision of marijuana for research purposes. As Dr. Gust testified, in 1995, HHS's practice was to provide marijuana only to researchers who obtained NIH funding – a practice that was abandoned by HHS in 1999 when the agency adopted its new procedures for facilitating marijuana research (allowing privately funded researchers to also obtain marijuana). Tr. 1749.

74 FR at 2107-2108.

As the foregoing excerpt from the Final Order indicates, the 1995 NIDA letter of which I took official notice (that which Respondent now cites as a basis for reopening the hearing to call Dr. Halpern) was the letter that gave rise to a letter that Respondent himself

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[7] [Footnote 24 in the Final Order]: That the above-quoted grounds were the bases upon which NIDA denied Dr. Abrams' original application is implicit from the letter that Dr. Abrams submitted to NIDA in response to the denial (RX 15). These bases are explicitly stated in NIDA's April 19, 1995, letter to Dr. Abrams, which appears on MAPS' Web site (at www.maps.org/mmj/leshner.html) and of which I take official notice. This letter from NIDA stated, among other things, the following:

> Our decision here is based upon issues of design, scientific merit and rationale. We believe that your study will not adequately answer the question posed.
>
> Although the study propose[d] seeks to make a dose-effect comparison of smoked marijuana to delta-9-tetrahydrocannabinol (THC), there is no real dosing control. The marijuana is to be taken home and there is no requirement and way to ensure that the subjects smoke all available materials on any fixed schedule. Additionally, that they are given a two-week supply of marijuana at one time further confounds the study design. Thus, we believe the dose-effect component is confounded since the study cannot correlate variability in weight gain with dosage.
>
> We also believe the study lacks adequate sample size to make any inferences regarding the dose-effect relationship. . . . Another confounding variable not adequately controlled for in your proposed study is diet. Neither the total daily caloric intake nor the percentages of the composition of the foodstuffs is assessed.
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> ****

[8] [Footnote 25 in the Final Order]: Following the 1996 passage of proposition 215, NIDA contacted Dr. Abrams and asked him if he would redesign his study to determine whether marijuana usage by persons who were HIV-positive (but who did not have AIDS-wasting syndrome) increased viral load as well as the interaction of marijuana with protease inhibitors. Tr. 523-24. Dr. Abrams agreed to do so and NIDA provided him with a $1 million grant to fund the study.

introduced at the hearing. In order words, Respondent's own exhibit (RX 15) was written in response to – and directly referenced – the 1995 NIDA letter of which I took official notice. While Dr. Abrams did not agree with NIDA's conclusions about the lack of scientific merit of his research proposal, both Respondent's own exhibit (RX 15) and the preceding NIDA letter of which I took official notice indicate that NIDA was denying the Dr. Abrams' application for marijuana based on issues of design, scientific merit, and rationale.

In view of the foregoing facts, Respondent's proposal to reopen the hearing to call Dr. Halpern to, in Respondent's words, "rebut . . . the conclusion that NIDA's denial of Dr. Abrams' research protocols was based solely upon issues of design, scientific merit and rationale . . ." is unsound for several reasons. First, in proposing to call Dr. Halpern for this purpose, Respondent is essentially arguing that NIDA's own official, written explanation provided to Dr. Abrams for denying his request for marijuana (written in 1995, when the determination was made by NIDA) is not the best evidence of NIDA's actual bases for denying the request. Respondent is asking that I reject that written explanation provided by NIDA itself in favor of the explanation that would be provided by Dr. Halpern, if the hearing were reopened so he may testify. What makes this request particularly untenable is that, based on Respondent's own submissions, Dr. Halpern appears to have had no involvement whatsoever in Dr. Abrams' request for marijuana.

Second, Respondent – having decided before the 2005 hearing that part of his strategy would be to call into question NIDA's 1995 denial of marijuana to Dr. Abrams – has already put forth into evidence Dr. Abrams' own written response to NIDA's denial letter. This suggests that Respondent (through his counsel) had in his possession – prior to

the hearing – NIDA's 1995 letter of which I took official notice. That the NIDA letter appeared on MAPS' own website eliminates any possible doubt as to that fact.[9] Armed with this knowledge going into the hearing, Respondent chose the strategy of introducing Dr. Abrams' response letter (RX 15) as the "evidence" of NIDA's reasons for denying Dr. Abrams' request for marijuana. In addition, Respondent's counsel cross-examined – on this very issue – the witness who represented NIDA at the hearing, Steven Gust, Ph.D. Tr. 1743, 1747-1749. All of this confirms that Respondent proceeded throughout the hearing with the view that the NIDA-Dr. Abrams issue was crucial to the adjudication. There is therefore no basis to conclude that Respondent – by virtue of my taking of official notice of the NIDA letter posted on the MAPS website – now needs yet another opportunity to call a witness to testify as to the "real reason" that NIDA denied Dr. Abrams' application in 1995.

Third, Respondent, through his proffered testimony of Dr. Halpern, does not even attempt to assert that Dr. Halpern has any personal knowledge of NIDA's process for reviewing applications by researchers for marijuana, much less that he has any personal knowledge of the facts relating the 1995 NIDA decision regarding Dr. Abrams. Respondent admits through his proffered testimony of Dr. Halpern that Dr. Halpern has never himself applied to NIDA for marijuana. Respondent therefore appears to be asking that the hearing be reopened so that Dr. Abrams may put forth conjecture as to why NIDA had denied applications for marijuana in the past. Or perhaps Respondent is suggesting that Dr. Halpern should be permitted to testify as to rumors that he has heard over the years

[9] MAPS' active role in funding Respondent's application and assisting him throughout the various phases of the application process is detailed in the Final Order. See 74 FR at 2126.

from unnamed colleagues about NIDA's "bias" against marijuana researchers.[10] In either case, Respondent has not proffered any testimony by Dr. Halpern concerning the NIDA-Dr. Abrams issue that would be properly admitted in this proceeding – particularly at this stage. See 21 CFR 1316.59(a) ("The presiding officer shall admit only evidence that is competent, relevant, material, and not unduly repetitious.").

Fourth, as was stressed repeatedly in the Final Order, the Department of Health and Human Services (HHS, of which NIDA is a part), established new procedures in 1999 to make it easier for researchers to obtain marijuana. E.g., 74 FR at 2015, 2108, 2111, 2112, 2119, & 2120. For this reason, the Final Order stated that the 1995 denial by NIDA of Dr. Abrams' request for marijuana was "irrelevant" to this proceeding, as it "occurred before HHS adopted its new procedures in 1999 for making marijuana more widely available to researchers." 74 FR at 2119. This alone makes it difficult to characterize NIDA's 1995 letter to Dr. Abrams (explaining reasons for its denying his request for marijuana) as a "material fact" on which the "agency decision rests."

Respondent also seeks to use the taking of official notice of this 1995 NIDA letter as a basis for calling Dr. Halpern to testify regarding matters unrelated to the 1995 denial by NIDA of Dr. Abrams' application. Although Respondent's submissions are somewhat vague in this regard, he appears to want to have Dr. Halpern testify about alleged NIDA "bias" in connection with marijuana research proposals submitted after 1999. As this would be going beyond the scope of the 1995 NIDA letter (or any inferences drawn from

[10] There is no basis in the record to conclude that NIDA was motivated by "bias" or any other improper motive in rejecting Dr. Abrams' original protocol in 1995. No evidence has been put forth in this proceeding that would lead a reasonable fact finder to reject NIDA's written explanation, issued in 1995, that it denied Dr. Abrams' application "based upon issues of design, scientific merit, and rationale." See 74 FR at 2108. Moreover, as stated in the Final Order, the record indicates that "Dr. Abrams subsequently submitted a revised research protocol that NIDA found to be scientifically meritorious and for which NIDA supplied marijuana in 1997." Id.

the letter), Respondent is not entitled under 5 U.S.C. 556(e) and 21 CFR 1301.59(e) to reopen the hearing to call a witness for this purpose.

Respondent further states that "Dr. Halpern will also rebut the Deputy Administrator's conclusions regarding the obsolescence of the term 'medicinal opium.' Specifically, Dr. Halpern will testify to currently recognized uses for opium as medicine." For the variety of reasons discussed above in connection with Mr. Hutt's proposed testimony on this subject, this aspect of the proffered testimony provides no justification for calling Dr. Halpern.

5. Anand K. Parekh

Respondent identifies Dr. Parekh as "of the Office of Public Health and Science of HHS."[11] Respondent states the following regarding this proposed witness:

> Respondent would seek Dr. Parekh's testimony to rebut the Deputy Administrator's reliance upon new evidence for her assertion that "If Chemic [Laboratories] 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." [74 FR at 2109 n.33.] Dr. Parekh could testify about Chemic's extensive and continued efforts to challenge HHS's denial of its request for marijuana, including the contents of the November 5, 2008, letter he received from Joseph St. Laurent of Chemic, providing detailed responses to HHS critiques of Chemic's proposed study, discussed by Respondent in his March 11, 2009 brief.

Respondent's Witness List and Document List at 5.

Respondent does not identify the "new evidence" to which he refers in the first sentence of the foregoing statement. It is therefore unclear what, if any, fact of which I took official notice he is relying on as his predicate for requesting to call Dr. Parekh to

[11] The HHS website states: "Anand K. Parekh, MD, MPH is the Acting Deputy Assistant Secretary for Health (Science & Medicine) in the Office of Public Health & Science at the Department of Health and Human Services." www.hhs.gov/about/bios/asstsechealth.html.

testify. The statement in the Final Order that Respondent quotes above (that Chemic had remedies available to challenge HHS's denial of its request for marijuana) appears, as Respondent indicates, in footnote 33 of the Final Order. However, it is clear that this footnoted statement was not premised on any fact of which of I took official notice. Rather, the statement, by its plain terms, is premised on the lack of certain evidence in the record (that "Respondent produced no evidence showing that Chemic has pursued any such remedies.") Thus, with regard to his proposal to reopen the hearing to call Dr. Parekh, Respondent has not met what might be considered the first prong of 5 U.S.C. 556(e) and 21 CFR 1301.59(e) – that the witness would be called for the purpose of rebutting a fact of which official notice was taken. Accordingly, 5 U.S.C. 556(e) and 21 CFR 1301.59(e) cannot be deemed a basis for allowing Dr. Parekh to testify for Respondent's stated purpose.

Nonetheless, Respondent should be able to achieve the purpose for which he seeks to call Dr. Parekh. As indicated above, Respondent states in his summary of Dr. Parekh's proposed testimony that the subject of this proposed testimony would be "Chemic's extensive and continued efforts to challenge HHS's denial of its request for marijuana, including the contents of the November 5, 2008, letter he received from Joseph St. Laurent of Chemic, providing detailed responses to HHS critiques of Chemic's proposed study." As explained below, assuming certain conditions are met, I will grant Respondent's request to take official notice of the November 5, 2008, letter from Chemic to HHS, along with any other pertinent correspondence between Chemic and HHS.

V. Respondent's Proposed Additional Documents

1. News Report

The item marked Exhibit A attached to Respondent's Witness List and Document List is a news account. Respondent states that he "submitted this exhibit to his briefing for the purpose of alerting the Deputy Administrator to the new policy direction of the Administration, not as evidence." As Respondent has not requested that I take official notice of this document, there is no occasion to decide whether it would be appropriate to do so.

2. Presidential memorandum

The item marked Exhibit B attached to Respondent's Witness List and Document List is a Presidential memorandum. As with his Exhibit A, Respondent states that he "submitted this exhibit to his briefing for the purpose of alerting the Deputy Administrator to the new policy direction of the Administration, not as evidence." As with Exhibit A, because Respondent has not requested that I take official notice of this document, there is no occasion to decide whether it would be appropriate to do so.

3. Russo letter

The item marked Exhibit C attached to Respondent's Witness List and Document List is a February 1, 2000, letter from HHS to Ethan Russo, M.D.[12] More specifically, the letter was from the U.S. Public Health Service (PHS, a component of HHS). The letter provided the PHS's assessment of the scientific merit of what was then Dr. Russo's proposed research and request for marijuana. The letter also advised Dr. Russo of the changes to his protocol that he needed to make for PHS to reconsider his request. Based

[12] As Respondent indicates, the letter is available on the MAPS website at www.maps.org/mmj/russo1199/02010001.html.

on Respondent's Supplemental Brief, it appears that Respondent's request that I take official notice of this letter relates to the following portion of the Final Order:

> Dr. Ethan Russo . . . sought funding from NIDA to study the use of marijuana to treat migraine headaches beginning around 1996. Tr. 527-28. The precise dates of the events related to Dr. Russo are somewhat unclear as Respondent presented these events through the testimony of Mr. Doblin. (Dr. Russo did not testify.) Id. Based on Mr. Doblin's testimony, it appears that during 1996-97, NIDA twice rejected Dr. Russo's protocol for reasons which are not clearly established by the record. Id. at 527, 691-92. However, according to Mr. Doblin, Dr. Russo conceded that, on both of these two occasions when NIDA rejected his protocol, NIDA's bases for doing so did include "some valid critiques." Tr. 692. Mr. Doblin testified that Dr. Russo subsequently attempted for a third time to obtain marijuana from NIDA, but on this third occasion he decided not to seek government funding but to seek private funding to purchase the marijuana from NIDA. Id. at 692. According to Mr. Doblin, this third protocol submitted by Dr. Russo was approved by both the FDA and Dr. Russo's institutional review board, but NIDA again refused to supply marijuana. Id. at 692-93. When asked when this last denial by NIDA occurred, Mr. Doblin testified: "I think it was 1999." Id. at 693.
>
> As noted above, NIH announced on May 21, 1999, HHS's new procedures for making marijuana available to researchers. Bearing in mind that Respondent had the burden of proving any proposition of fact that he asserted in the hearing, 21 CFR 1301.44(a), nothing in Mr. Doblin's testimony, or any other evidence presented by Respondent, established that HHS denied Dr. Russo's request for marijuana under the new procedures implemented by the agency in 1999. Indeed, Respondent produced no evidence showing that HHS has denied marijuana to any clinical researcher with an FDA-approved protocol subsequent to the adoption of the 1999 guidelines.

74 FR at 2108.

Regarding this portion of the Final Order, Respondent's Supplemental Brief states: "Had this argument [that HHS denials of requests for marijuana made prior to the implementation of the 1999 HHS guidelines are irrelevant to this adjudication] been raised at the hearing, or had DEA counsel questioned the date, [Respondent] could easily have demonstrated what is in fact true: that NIDA denied Dr. Russo's request under the 1999

Guidelines." Respondent's Supplemental Brief at 12. Thus, Respondent's request that I take official notice of the February 1, 2000, letter from HHS to Dr. Russo is not predicated on Respondent pointing to any fact of which I took official notice in the Final Order. Rather, Respondent is asking that I take official notice of this letter for the purpose of seeking to rebut a conclusion made in the Final Order regarding the weight and relevancy of certain evidence.[13] Although nothing in the APA or DEA regulations compels the granting of this type of request to take official notice, I will do so for the following reasons. The above-quoted portion of the Final Order expressly recognized the uncertainty in the record of the timing of NIDA's denial of Dr. Russo's application vis-à-vis the implementation by HHS of its then new 1999 guidelines, 74 FR at 2108, and the February 1, 2000, letter from HHS to Dr. Russo is relevant to this issue. In addition, the letter is reliable on its face, and taking official notice of it at this juncture will not result in any delay in the proceedings.

4. Chemic letter

Exhibit D attached to Respondent's Witness List and Document List is a November 5, 2008, letter from Chemic to HHS (addressed to Dr. Parekh, in his official capacity at PHS), to which are attached a series of questions and answers regarding Chemic's proposed research protocol. As explained above in the discussion of Dr. Parekh's proposed testimony, Respondent has not put forth any fact of which I took official notice

[13] As indicated, Respondent began the above-quoted statement by stating: "Had this argument [that NIDA rejections of requests made prior to the implementation of the 1999 HHS guidelines are irrelevant to this adjudication] been raised at the hearing, or had DEA counsel questioned the date, ..." Respondent thus appears to be suggesting here that a deciding agency official's conclusions about the weight and relevancy of evidence presented during an administrative hearing constitute "argument," and that the deciding official is precluded from making such conclusions unless they were submitted by counsel for one of the parties during the hearing so that the opposing party had the opportunity to respond during the hearing. Nothing in the APA, the DEA regulations, or any other provision of law so constrains a deciding agency official.

as a predicate for taking official notice of this Chemic letter.[14] Thus, 5 U.S.C. 556(e) and 21 CFR 1301.59(e) cannot be cited as a basis for doing so.

However, because (1) Chemic's application to HHS to receive marijuana for research appears to be an ongoing matter, (2) this application was a matter considered in the Final Order, and (3) Respondent has requested, for purposes of his motion for reconsideration, that I take official notice of certain correspondence between Chemic and HHS, I will issue the following order regarding this request. If Respondent submits all of the correspondence between Chemic and HHS (or any of its components) relating to this application that he has in his possession or can reasonably access (including, but not limited to, any such correspondence on the MAPS website, such as the January 23, 2009, letter from HHS to Chemic), I will take official notice of all such correspondence.

5. Scherer letter

Exhibit E attached to Respondent's Witness List and Document List is a statement issued by Professor Scherer, which Respondent offers as proposed testimony. As explained above, Respondent has failed to demonstrate that it would be legally appropriate under 5 U.S.C. § 556(e) and 21 CFR 1316.59(e) to reopen the hearing to allow Professor Scherer to provide additional live testimony regarding an issue that has already been extensively litigated. For the same reasons, Respondent has failed to provide justification to allow Professor Scherer to provide additional testimony through a written document. Respondent's request that I take official notice of this document is therefore denied.

[14] In the Final Order, official notice was taken of a report prepared by Chemic that appeared on the MAPS website (see 74 FR at 2109 and n.32). However, Respondent does not state that he is relying on the taking of official notice of this Chemic report as a predicate for seeking to have official notice taken of the November 8, 2008, letter from Chemic to HHS. Nor would there be a basis for doing so under 5 U.S.C. 556(e) and 21 CFR 1301.59(e).

6. Documents regarding opium products

Exhibits F, G, and H attached to Respondent's Witness List and Document List are three documents addressing drug products that contain opium. As explained above in addressing the proposed testimony of Mr. Hutt, Respondent has failed to demonstrate that it would be legally appropriate under 5 U.S.C. § 556(e) and 21 CFR 1316.59(e) to reopen the hearing to allow additional testimony regarding opium products. For the same reasons, I deny Respondent's request to take official notice of these three documents.

VI. Respondent's Request for Reconsideration

Respondent has already submitted extensive written explanation in support of his motion of reconsideration of the Final Order. However, in fairness to Respondent, I will grant him an additional opportunity to file a brief in support of his motion for reconsideration of the Final Order now that the matter of Respondent's request to reopen the hearing to call certain witnesses and to take official notice of certain documents has been resolved. Allowing Respondent this additional briefing opportunity is especially warranted given the complexities of this adjudication. Toward this end, the parties are instructed as follows:

On or before March 7, 2011, Respondent may file a brief in support of his motion for reconsideration of the Final Order. The brief may include arguments previously submitted as well as any additional arguments he wishes to present. Counsel for the Government may file a responsive brief no later than 30 days after receipt of Respondent's brief.

VII. Additional Note to the Counsel

The parties are reminded that while this matter remains pending before the agency, the APA prohibition on ex parte communications remains in effect. As stated in 5 U.S.C. 557(d)(1)(A), "[N]o interested person outside the agency shall make or knowingly cause to be made to any member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding." This prohibition includes, among other things, any attempts to communicate with officials in the Department of Justice or elsewhere in Government in a manner designed to influence the agency decision-making process or the outcome of the adjudication.

Dated: 12/2/10

Michele Leonhart

Michele M. Leonhart
Deputy Administrator