LEGAL DEPARTMENT
DRUG LAW
REFORM PROJECT

June 5, 2009

By Facsimile Transmission

Ms. Michele M. Leonhart
Deputy Administrator
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Dear Mr. Crowley and Ms. Leonhart:

Attached please find a copy of Respondent Professor Lyle Craker's Respondent's Witness List and Document List in Support of Motion for Reconsideration. Per your previous transmittal instructions, I am faxing it to the attention of Mr. James I. Crowley at 202-307-4540 before 5:00 pm on June 5, 2009.

Because I have no contact information for anyone in your office, I request that someone in your office call me at 831-471-9000 ext. 14 when the document is received, so that we will know filing is complete. Thank you for this courtesy.

Sincerely.

Allen Hopper
American Civil Liberties Union
Counsel for Respondent

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 **Respondent's Witness List and Document List in Support of Motion for Reconsideration**

Pursuant to the Deputy Administrator's May 19, 2009 Order, Respondent Dr. Lyle E. Craker submits this witness list and document list in support of his March 11, 2009 Request Under 5 U.S.C. § 556(e) to Respond to Officially Noticed Evidence and Motion for Reconsideration.

1. WITNESS LIST

The following is a list of witnesses Respondent would call to testify at a reopened hearing, along with a brief description of their testimony and estimated time for examination.

A. Jeremy Sare, formerly of the Drugs Strategy Directorate, Home Office, Government of the United Kingdom.

Mr. Sare's testimony will rebut the new evidence relied upon by the Deputy Administrator, and the conclusions drawn from that evidence, concerning the International Narcotics Control Board ("INCB") 2005 Annual Report and the Single Convention Treaty. Mr. Sare will testify that: As head of Drug Legislation in the Home Office until he left that office in 2006, Mr. Sare had legislative responsibilities regarding the prescribing of cannabis-based medicine, and consequently was very familiar with the licensing arrangements for Sativex, a cannabis-based medical product produced by GW Pharmaceuticals ("GWP"), for prescribed use. In the INCB 2005 annual report, as well as subsequent annual reports, the Board noted that the Government of the United Kingdom had established a national cannabis agency. At the time of the writing of the INCB 2005 Annual Report, dated March 1, 2006, GWP—a privately-funded, non-governmental bulk manufacturer of cannabis—was fully licensed by the Home Office of the United Kingdom. The government approved pilot studies of Sativex by GWP in 2001 under the U.K.'s Misuse of Drugs Act ("MDA"). The MDA leans heavily on the Single Convention Treaty and successive U.K. Governments have endeavored, in all cases, to abide by international law. Mr. Sare has dealt

with the INCB, and is aware of no objection from the Board on this matter. Based on the experience of the U.K. Government with GWP and Sativex, licensing Professor Craker to produce marijuana for U.S. government-approved medical and scientific research would not violate the Convention.

Anticipated time for direct testimony: 30 minutes.

B. Peter Barton Hutt, former Chief Counsel for the Food and Drug Administration.

Mr. Hutt's testimony will 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 the Deputy Director drew from this new evidence about the proper interpretation of the Single Convention. Mr. Hutt will testify that: He formerly served as Chief Counsel at the FDA, and is currently an adjunct professor at Harvard Law School and a leading scholar in the field of food and drug law. The term "medicinal opium" used in Article 23(2)(e) of the Single Convention is not obsolete. Opium 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." The Orange Book lists only drugs that were approved by the FDA after certain requirements to prove safety and efficacy were put into place. The Orange Book does not purport to, nor does it, list legal drugs such as medicinal opium that were approved before these FDA requirements were put into place. The 1938 Food Drug & Cosmetic Act included a grandfather clause allowing drugs marketed before 1938 to continue to be marketed after 1938 without a New Drug Application ("NDA"). Similarly, the 1962 Amendments to the Food Drug & Cosmetic Act included another grandfather clause allowing drugs marketed before 1962 to continue to be marketed after 1962 without an NDA. 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"). Several thousand drugs that were in fact on the market at the time nonetheless were not included in the DESI and therefore do not appear in the Orange Book. Thus, the fact that no medicinal opium products are listed in the Orange Book does not mean that there are no currently legal medicinal opium products available in the U.S., nor that the term "medicinal opium" as used in the Single Convention is obsolete. Based upon the text of the Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the specific policies adopted by the INCB to monitor compliance with the treaty, Respondent's proposal to cultivate marijuana at the University of Massachusetts for medical research purposes would not contravene any provision of the treaty. To the contrary, based on Mr. Hutt's experience, granting Respondent's application would have the salutary purposes of facilitating the privately-funded investigation of marijuana and of adding to the international body of scientific knowledge concerning the medical usefulness of marijuana. This is especially true given that no privately-funded sponsor will invest the

resources necessary to take marijuana through the FDA approval process while NIDA holds a monopoly on the supply of marijuana that can be used for medical research.

In Mr. Hutt's experience, the fact that the Single Convention does not foreclose a Government from permitting a private company to produce cannabis for medicinal purposes is best illustrated by the case of GW Pharmaceuticals ("GWP"). GWP is a British corporation that currently produces its own cannabis plants at a secure facility, processes those plants, and then ships cannabis extracts to its own affiliated medical cannabis research projects. Just as the Respondent's proposed project would be supervised by the DEA and the FDA, GWP cultivates its cannabis crop with the support and regulation of the United Kingdom's Home Office and the Department of Trade and Industry. Although the INCB reports frequently single out nations that are engaging in practices that violate their Single Convention obligations, none of the INCB's Reports makes any reference to GWP as an instance of international noncompliance. The operation of GWP demonstrates that it is possible under international law for a nongovernmental organization to cultivate medical cannabis in a manner that is easy for its government to regulate and that complies with international treaty obligations. The INCB has noted that scientific research on the efficacy of medical use of cannabis or cannabis extracts has been initiated or is planned in several countries, including Canada, Germany, the Netherlands, Switzerland, the United Kingdom and the United States in order to assess the efficacy of cannabis in treating AIDS wasting, glaucoma, multiple sclerosis and pain and in alleviating the side effects of cancer chemotherapy. Rather than criticizing this research, the Board has stated that it welcomes sound scientific research into the possible therapeutic properties and medical uses of cannabis or cannabis extracts.

Anticipated time for direct testimony: 60 minutes.

C. Professor Frederick Scherer, John F. Kennedy School of Government, Harvard University.

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) to support her conclusion that adequate competition exists within the current system of growing and distributing research marijuana in the United States. Professor Scherer is the former chief economist at the Federal Trade Commission and currently emeritus faculty at Harvard. A considerable part of his professional career has been devoted to studying the relationships between market structure and technological progress, and one of his 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. Professor Scherer would testify that, in his professional opinion as an economist, inadequate competition exists when a monopolist refuses to sell, at any price, to certain buyers. For legitimate research

to which NIDA has refused to supply research marijuana, the supply is constrained to zero. When there is a market demand for a commodity and there is no supply, any reputable economist would agree that the true price is the so-called shadow price, also called the implicit price, that is, the price consistent with finite demand but zero supply. Under the circumstances here, the shadow price is infinity for certain demand functions, i.e., those derived from Cobb-Douglas utility functions, or in other special cases, the price just above the price at which the demander's demand is choked off to a quantity of zero. In either case, such a shadow price is higher, usually much higher, than the price at which a monopoly would maximize its profits. And the monopoly price is higher than a competitive price. Thus, when a monopoly supplier denies supplies to legitimate demanders, there is a very significant impairment of competition. Scholars of all ideological shades who accept the basic premises favoring a market economy agree that refusal to supply by an entity with monopoly power is at least as undesirable as supplying at a monopoly price. In declaring under 21 U.S.C. § 823(a) that controlled substances should be supplied under "adequate competitive conditions" for lawful purposes, the U.S. Congress was following a four-century legal tradition, dating back to the Elizabethan era, of restricting government monopoly grants to patents and copyrights.

Anticipated time for direct testimony: 60 minutes.

D. Dr. John Halpern, Professor of Psychiatry, Harvard University Medical School.

Dr. Halpern will testify to rebut new evidence relied upon by the Deputy Administrator (a letter dated April 19, 1995 from 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 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. Dr. Halpern will testify that: He studies controlled substances at Harvard Medical School, but has not undertaken certain types of research because of the wide-spread chilling effect of NIDA's bias against certain types of marijuana research. Certain types of studies will never get provided with research material because of NIDA's institutional process and biases. 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.

Anticipated time for direct testimony: 30 minutes.

E. Dr. Anand K. Parekh, U.S. Department of Health and Human Services.

Respondent would attempt to present the testimony of Dr. Parekh, of the Office of Public Health and Science of HHS. Counsel for respondent has no way to compel the testimony of Dr. Parekh, and anticipates that Dr. Parekh will testify only if the Presiding Officer will issue a subpoena to compel his attendance, pursuant to 21 C.F.R. 1316.52(d). 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." Leonhart Order 29 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.

Anticipated time for direct testimony: 15 minutes.

2. DOCUMENT LIST

The following is a list of documents, by exhibit letter, attached to Respondent's March 11, 2009 briefing with a brief description of how Respondent intends to use them.

A. News report.

Respondent 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.

B. Presidential memorandum.

Respondent 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.

C. Russo letter.

Respondent would ask the Deputy Administrator to take official notice of this letter.

D. Chemic letters.

Respondent would ask the Deputy Administrator to take official notice of these letters.

E. Scherer testimony.

Respondent is prepared to call Professor Scherer as a witness and, if permitted to do so, does not need official notice taken of his proposed testimony.

F, G, and H. Documents regarding medical opium.

Respondent is prepared to present live testimony addressing the points for which these documents were proffered, and, if permitted to do so, does not need official notice taken of these documents.

Finally, Respondent requests that the Deputy Administrator take official notice of one additional document, an article published in October 2000 in the Fordham Urban Law Journal, entitled, "Rethinking Our Drug Policy." The citation for the article is 28 Fordham Urb. L.J. 9 (2000), and it is available on Westlaw (28 FDMULJ 9). The relevant pages from the article are attached hereto as an exhibit, and labeled Exhibit I (for ease of reference, given Respondent's previous submission of eight exhibits labeled A through H). Pursuant to the notice previously provided at page 9 of Respondent's January 30, 2009 Request for Opportunity Under 5 U.S.C. § 556(e) To Respond to New Officially Noticed Evidence and Motion for Reconsideration, this article is proffered as 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 new evidence officially noticed by and relied upon by the Deputy Administrator— a letter dated April 19, 1995 from NIDA to Dr. Donald Abrams—and the Deputy Administrator's conclusion that despite the evidence located on the same website and linked to the same pages on which this new officially noticed evidence was located, Respondent's evidence was 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.*

DATED: June 5, 2009

Respectfully Submitted,

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EXHIBIT I

IS OUR DRUG POLICY EFFECTIVE? ARE THERE ALTERNATIVES?

Proceedings of A Conference Sponsored by
The Association of the Bar of the City of New York,
the New York Academy of Medicine, and
the New York Academy of Sciences

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I absolutely oppose the legalization of drugs. I think it is the only *non*-solution. I have yet to hear anybody who feels we should legalize drugs to describe their system so that more harm is not done. Despite all you hear, look at the facts. Look at every country that has ever legalized drugs or permitted additional drug use, and you will see there are additional addicts and additional problems.

Secondly, what if we legalize drugs? Suppose you have a twelve year-old child? Do I get to sell it to him? Do you think Johnson & Johnson wants to compete with the Colombian cartels in selling crack cocaine in the projects down the street? I do not think so.

Obviously feel free to call me a zealot. I am. I think we have alternatives. I believe in treatment, I believe in drug courts, I believe in alternate sentencing, but you cannot do away with law enforcement and you certainly cannot legalize drugs.

Thank you.

DR. HAINES: Our next speaker is a scientist who works on cannabis and migraine headaches, among other things. He is a neurologist in Missoula, Montana. He is the author of *The Handbook of Psychotropic Herbs*[284] and the editor of the *Journal of Cannabis Therapeutics*.[285] Dr. Ethan Russo.

DR. RUSSO: I guarantee this will be different. Fasten your seat belts. It is going to be a rapid ride. I was asked to speak about the effect of the government on Schedule I drug research. Schedule I drugs, for those of you who do not know, are defined as being dangerous or addictive or having no rational medical usage.[286]

I want to tell you that I have not smoked marijuana in many years and I did not begin this work with the idea of becoming an advocate, but the government turned me into one. Additionally, not far from here in Brooklyn, some seventy-five years ago, my grandfather, who was a mild-mannered Macedonian Jew, brewed beer in his basement during Prohibition. So, I come by this naturally.

[Slide] What we have here is a demonstration of ergot, the rye fungus *Claviceps purpurea*.[287] You will see that a synthetic LSD-25

284. ETHAN RUSSO, HANDBOOK OF PYCHOTROPIC HERBS: A SCIENTIFIC ANALYSIS OF HERBAL REMEDIES FOR PSYCHIATRIC CONDITIONS, WITH CASE STUDIES (2000)

285. First issue is forthcoming in 2001.

286. 21 U.S.C. § 812(b) (1999).

287. RICHARD E. SCHULTES & ALBERT HOFMANN, THE BOTANY AND CHEMISTRY OF HALLUCINOGENS 36 (1980). The slide shows *Claviceps purpurea*, ergot rye fungus and its chemicals—LSD vs. ergonovine; methysergide has a methoxy-side chain instead of ethyl. It becomes a question of dose.

was derived from it. Of course, it is a Schedule I drug, but it had a legitimate medical usage in psycholytic therapy[288] before it was made illegal.

[Slide] This drug, ergonovine, is used against migraine, but in a high enough dosage, it is also a psychedelic.[289] Similarly, methysergide, though not a scheduled drug, has a similar effect. If we give six milligrams of methysergide to someone who is not used to it, that person will "trip."[290] It is a very artificial distinction to say pharmacologically that methysergide and ergonovine are medically useful and do not require Schedule I status, while LSD remains mired as a pariah despite its biochemical similarity.[291]

[Slide] This is peyote, *Lophophora williamsii*, the source of mescaline.[292] If a person is Native American and a member of the Native American Church, they are permitted to use this as a sacrament, and experience the type of visions displayed in these yarn paintings from the Huichol Indians of Mexico. We find the same alkaloids from peyote in the following plant, *Trichocereus pachanoi*, from South America.[293] This plant has just as much mescaline in it as peyote does, but, because it is a very popular rootstock for cactus growing, it is tolerated. Both cacti are used in indigenous medicine, not only for visions, but also for treating headaches and for other legitimate uses.[294] In fact, a tincture of peyote was used in the United States in the nineteenth century to treat migraines and for a variety of other ills.[295]

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288. Psycholytic therapy is a kind of therapy performed while the patient is under the influence of psychedelics.

289. J. Bigwood et al., *Entheogenic Effects of Ergonovine*, 11 J. PSYCHEDELIC DRUGS 147 (1979).

290. JONATHAN OTT, PHARMACOTHEON: ENTHEOGENIC DRUGS, THEIR PLANT SOURCES AND HISTORY 129, 145 (1996); H.A. Abramson & A. Rolo, *Comparison of LSD with Methysergide and Psilocybin on Test Subjects*, THE USE OF LSD IN PSYCHOTHERAPY AND ALCOHOLISM, 53 (H.A. Abramson ed., 1967).

291. ALBERT HOFFMAN, LSD: MY PROBLEM CHILD (1980).

292. EDWARD F. ANDERSON, PEYOTE: THE DIVINE CACTUS (1996). The slide shows *Peyote, Lophophora williamsii*, in flower. Indigenous Americans used it to treat headache during the nineteenth century.

293. W. J. Turner & J. J. Heyman, *The Presence of Mescaline in Opuntia cylindrica*, 25 J. ORGANIC CHEM. 2250 (1960).

294. Richard E. Schultes, *The Aboriginal Therapeutic Uses of Lophophora williamsii*, 12 CACTUS & SUCCULENT J. 177 (1940); D. Joralemon, *The Role of Hallucinogenic Drugs and Sensory Stimuli in Peruvian Ritual Healing*, 8 CULT. MED. PSYCHIATRY 399 (1984); Marlene Dobkin de Rios, *Trichocereus pachanoi: A Mescaline Cactus used in Folk Healing in Northern Peru (San Pedro)*, 22 ECON. BOTANY 191 (1968).

295. D. W. Prentiss & F. P. Morgan, *Therapeutic Uses of Mescal Buttons (Anhalonium lewinii)*, 12 THERAPEUTIC GAZETTE 4 (1896); D. A. Richardson, *A Re-*

[Slide] This is *Psilocybe azurescens*, the most potent source of psilocybin.[296] The mushroom, as compared to peyote, which is Schedule I, is not illegal, but if you try to use it for psychedelic purposes, you will be arrested. Psilocybe mushrooms reportedly have been used sublingually, under the tongue, to treat headaches, and orally to treat obsessive-compulsive disorder.[297]

[Slide] From South America there are many examples of entheogens or psychedelic plants that are used in indigenous medicine.[298] Here, César is pounding the *ayahuasca* vine, *Banisteriopsis caapi*,[299] combining it with *Psychotria viridis*[300] leaves that provide dimethyltryptamine ("DMT"), another Schedule I chemical.

[Slide] Here we see *Psychotria* leaves from a different species. When these are instilled in the eyes, they treat headache. This is the most effective treatment I have ever had for migraine, and I saw it work for many other people as well, with no side effects.[301]

[Slide] This is another plant, *Fittonia albivenis*. It is used by one Amazonian group, the Kofán, to treat headache,[302] but among the Machiguenga with whom I worked, it was combined with the *Banisteriopsis* vine to be used as an entheogen.[303] Perhaps it has DMT in it as well, because that substance is found in many plants.

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port on the Action of Anhalonium lewinii (Mescal Button), 64 N.Y. MED. J. 194 (1896).

296. PAUL STAMETS, PSILOCYBIN MUSHROOMS OF THE WORLD: AN IDENTIFICATION GUIDE (1996).

297. F. A. Moreno & P. L. Delgado, *Hallucinogen-induced Relief of Obsessions and Compulsions*, 154 AM. J. PSYCHIATRY 1037 (1997).

298. *See generally* OTT, *supra* note 290; RICHARD E. SCHULTES ET AL., VINE OF THE SOUL: MEDICINE MEN, THEIR PLANTS AND RITUALS IN THE COLOMBIAN AMAZONIA (1992).

299. *See generally* Ethan B. Russo, *Plants of the Machiguenga*, *at* http://www.montana.com/manu.

300. Banisteriopsis caapi is a source of beta-carboline alkaloids, which are MAO-inhibitors, while Psychotria virdis provides DMT, an otherwise orally inactive hallucinogen.

301. Ethan B. Russo et al., *Schedule I Research Protocol: An Investigation of Psychedelic Plants and Compounds for Activity in Serotonin Receptor Assays for Headache Treatment and Prophylaxis*, 7 BULL. OF THE MULTIDISCIPLINARY ASS'N FOR PSYCHEDELIC STUDIES 4 (1997).

302. W. T. Vickers & T. Plowman, *Useful Plants of the Siona and Secoya Indians of Eastern Ecuador*, 15 FIELDIANA 1 (1984); Ethan B. Russo, *Headache Treatments by Native Peoples of the Ecuadorian Amazon: A Preliminary Cross-Disciplinary Assessment*, 36 J. ETHNOPHARMACOLOGY 193 (1992).

303. ETHAN B. RUSSO, AN OCELOT FOR A PILLOW: RESEARCHING HEADACHES, HALLUCINOGENS AND HUNTING MAGIC AMONG THE MACHIGUENGA OF MANU (1996).

[Slide] This is *Balansia* fungus on *Cyperus* roots that also provide ergot alkaloids,[304] and someday, we may find LSD in such a plant association.

[Slide] In the lab in 1996 we assayed some of my headache plants for serotonin receptor activity, and we saw that about 80% of the native plants yielded significant results. We see the top one here. *Phalaris*, a grass that may grow in your lawn at home, is a very potent DMT source,[305] and thereby, you may be contravening drug law yourself. DMT is also found in our brains in trace amounts and may have a natural role in our neurophysiology.[306]

About this time, I chose to look at other substances for their effects on headache.[307] I was able to get a Schedule I drug license from the Drug Enforcement Administration. Three weeks later, I ordered many Schedule I substances, such as mescaline and LSD, with which to do biochemical studies. In contrast, it took a full year of wrangling with the National Institute on Drug Abuse ("NIDA") to get a baggie of marijuana, which was 2.92% THC—very low. Additionally, the material was already three years old, but they told me that they had stored it well. It is interesting, because NIDA says that it can grow cannabis with up to 5% THC content, but their machines can't roll the cannabis because it's too sticky. Well, I would like to say, "Give me the 5%, I still remember how to do it."[308]

In 1986, the Controlled Substance Analogue Enforcement Act was passed.[309] The Act basically said that if you make anything in the lab that looks like a Schedule I product, it may be illegal. This creates problems because Cerenex, a drug company, made the drug sumatriptan for treating migraine. However, sumatriptan is really just DMT with a methane sulfonamide side chain in the five position.[310] Why isn't that an analogue?

I also had a friend make this crystalline powder for me. This compound is not in Schedule I, but it closely resembles some substances that are so categorized. I don't want to tell you its name

304. T. C. Plowman et al., *Significance of the Fungus Balansia cyperi Infecting Medicinal Species of Cyperus (Cyperaceae) from Amazonia*, 44 ECON. BOTANY 452 (1990).

305. JONATHAN OTT, AYAHUASCA ANALOGUES; PANGAEAN ENTHEOGENS (1994).

306. Steven A. Baker et al., *N-Dimethyltryptamine: An Endogenous Hallucinogen*, 22 INTL. REV. OF NEUROBIOLOGY 83 (1981).

307. Russo et al., *supra* note 301, at 4.

308. Dr. Russo held up a faux marijuana cigarette.

309. Pub. L. No. 99-570 (1986).

310. Russo et al., *supra* note 301, at 5.

because I hope to patent it for treating migraine. It may be illegal under this loose and arbitrary law. This kind of abuse caused my friend Alexander Shulgin, to make this comment on the Analogues Act, "The Law of the Land—The drug component is but a small chunk of this, but it is still one of the most complex and self-serving bodies of legal aggression that exists anywhere in the world."[311]

Due to all this, I decided that I would look at another natural product that had been used for millennia in treating headaches, and this was cannabis.[312] In 1996, we did the biochemical studies. In 1997, I applied to the Food and Drug Administration ("FDA") for what is called an IND, Investigational New Drug. The FDA said, "we really can't look at this because you can get cannabis only from the National Institute on Drug Abuse ("NIDA"), and to do that you will need to get funded by the National Institute of Health ("NIH")." Alternatively, if I had wanted to study the therapeutic properties of arsenic, I could just go straight to the FDA with the IND, without going through the National Institute of Health. Here, however, the FDA refused to review my application. I therefore applied to NIH. The NIH panel of some thirty people, none of whom were neurologists or headache specialists, said, "Oh no, you can't do this. We won't fund it."

The next year I did the same thing. This time, the FDA said, "No, we can't comment on your IND because you don't have a legal source of marijuana." They asked me to withdraw my study application again and I refused. At that point the FDA was breaking its own federal law by failing to comment within the required thirty days. I applied to NIH once more in 1998 and was again turned down.

In 1999, I went straight to the ombudsman, who was very distressed that the FDA had not been following its own policy. He guaranteed a different outcome. I therefore reapplied, and after other changes, I got an IND approval from the FDA. However, in June of last year, the Public Health Service ("PHS") developed new guidelines requiring a "NIDA review." We underwent the NIDA review, and they concluded that we couldn't do our study. The study called for forty patients with up to twenty exposures to cannabis and other substances. Instead, NIDA wanted me to do a study with a few patients who used cannabis only once. Essentially

311. ALEXANDER SHULGIN & ANN SHULGIN, TIHKAL: THE CONTINUATION 592 (1997).

312. ETHAN B. RUSSO, CANNABIS IN MIGRAINE TREATMENT (1999), *at* http://www.maps.org/mmj/mjrusso.html. Study is ongoing.

they were rewriting the study. This is unprecedented and would not happen with any other substance.

I am now in the process of finding out whether I need to import cannabis extract from the United Kingdom, because NIDA still does not want to provide it.

[Slide] Here we have marijuana, Exhibit A, a natural source of multitudinous cannabinoids, terpenes, and flavonoids, many of which actually have therapeutic properties. This is Sumerian data from 2000 B.C.E. about therapeutic use of cannabis.[313] [Slide] We also have Chinese evidence to support this data.[314] [Slide] This is Sir William Russell Reynolds, who gave cannabis to Queen Victoria for her dysmenorrhea, menstrual cramps.[315] [Slide] Hobart Hare said that cannabis was just as strong a painkiller as an opiate extract, which was proven years later.[316] [Slide] In 1915, Sir William Osler said that cannabis was the best remedy for migraine.[317] [Slide] Morris Fishbein said in 1942, a year after cannabis was removed from the *National Formulary* and *U.S. Pharmacopoeia*, that it was still the best treatment for menstrual migraine.[318] I have extensively investigated the biochemical basis that cannabis is useful in migraine.[319] As Hobart Hare said, "THC was as or more effective than codeine as a painkiller."[320]

I can tell you that, based on an anecdotal survey of my patients, as well as testimonies of others, up to 80% of patients with mi-

313. *E.g.*, R. CAMPBELL THOMPSON, THE ASSYRIAN HERBAL (1924); R. CAMPBELL THOMPSON, A DICTIONARY OF ASSYRIAN BOTANY (1949).

314. *E.g.*, H. L. Li, *An Archaeological and Historical Account of Cannabis in China*, 28 ECON. BOT. 437 (1974); Silvestre de Sacy, *Des Preparations Enivrantes Faites avec le Chanvre*, 4 BULL. DES SCIENCES MEDICALES 204 (1809).

315. *E.g.*, John R. Reynolds, *On Some of the Therapeutical Uses of Indian Hemp*, 2 ARCH. OF MEDICINE 154 (1868); John R. Reynolds, *Therapeutical Uses and Toxic Effects of Cannabis Indica*, 1 LANCET 637 (1890).

316. Hobart A. Hare, *Clinical and physiological notes on the action of Cannabis Indica*, 2 THERAPEUTIC GAZETTE 225 (1887).

317. WILLIAM OSLER & T. MCCRAE, THE PRINCIPLES AND PRACTICE OF MEDICINE 1089 (1915).

318. Morris Fishbein, *Migraine Associated with Menstruation*, 237 JAMA 326 (1942).

319. Ethan B. Russo, *Cannabis for Migraine Treatment: The Once and Future Prescription? An Historical and Scientific Review*, 76 PAIN 3 (1998); Ethan B. Russo, *Hemp for Headache: An In-depth Historical and Scientific Review of Cannabis in Migraine Treatment*, 1 J. CANNABIS THERAPEUTICS (forthcoming 2001); Ethan B. Russo, *Migraine: Indications for Cannabis and THC*, CANNABIS AND CANNABINOIDS: PHARMACOLOGY, TOXICOLOGY AND THERAPEUTIC POTENTIAL (Franjo Grotenhermen & Ethan B. Russo eds., forthcoming 2001).

320. R. Noyes et al., *The Analgesic Properties of Delta-9-tetrahydrocannabinol and Codeine*, 18 CLINICAL PHARMACOLOGY THERAPY 84 (1975).

graine may benefit from the use of cannabis. In migraine, oral dosing is impractical because of vomiting, but smoking may provide a rapid, easily titrated method of drug delivery. In terms of smoke, by-products such as tar may be reduced or avoided by using vaporizers, sublingual tinctures, or future delivery systems. The government is not presently investigating any of these methods.

Migraine affects 23.6 million Americans,[321] but (because it predominantly affects females) migraine studies do not receive significant government funding.[322] On several measures of health and adjustment, however, migraine sufferers see themselves as worse off than people with high blood pressure, osteoarthritis, or, shockingly, a disease as severe and chronic as diabetes.[323] The bottom line is that migraine costs our economy approximately $9.2 billion a year.[324] I therefore raise the question: "Cannabis or cabernet? Shouldn't this be a personal choice?"

I believe that on the issue of medical cannabis, the government has already lost the battle in the hearts and minds of the people. The seeds of change have been sown. This may seem like fantasy, but people in wheelchairs have been arrested.[325] Our society has a greater desire to preserve the purity of its ideology than to show concern for the public health. Unfortunately, our Founding Fathers would have been felons for their agricultural pursuits.[326]

Thank you.

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321. W. F. Stewart et al., *Prevalence of Migraine Headache in the United States. Relation to Age, Income, Race, and Other Sociodemographic Factors*, 267 JAMA 64 (1992); *accord* M. S. Linet et al., *An Epidemiologic Study of Headache among Adolescents and Young Adults,* 261 JAMA 2211 (1989).

322. *See generally*, *Focus on Women's Health: New Directions in Women's Health Research*, THE GLOBE & MAIL, Sept. 25, 2000, at W11 (stating that "[i]t is true that less that 5% of medical research funding is directed to women"). *Contra* OFFICE OF RESEARCH ON WOMEN'S HEALTH AND NIH SUPPORT FOR RESEARCH ON WOMEN'S HEALTH ISSUES, REPORT OF THE ADVISORY COMMITTEE ON RESEARCH ON WOMEN'S HEALTH 56-65 (1997-98) (stating that, during 1997 and 1998, "78% of the budget was spent on research that was not gender-specific" and providing accompanying budget tables and statistics).

323. *E.g.*, G. D. Solomon et al., *Quality of Life and Well-being of Headache Patients: Measurement by the Medical Outcomes Study Instrument*, 33 HEADACHE 351 (1993); *accord* J. T. Osterhaus et al., *Measuring the Functional Status and Well-being of Patients with Migraine Headache*, 34 HEADACHE 337 (1994).

324. R. B. Lipton & W. F. Stewart, *Migraine in the United States: A Review of Epidemiology and Health Care Use*, 43 NEUROLOGY S6 (1993).

325. JACK HERER, THE EMPEROR WEARS NO CLOTHES 252 (1998); MIKKI NORRIS ET AL., *Shattered Lives: Portraits From America's Drug War*, CREATIVE XPRESSIONS (1998).

326. CHRIS CONRAD, HEMP: LIFELINE TO THE FUTURE 304 (1994); *accord* THOMAS JEFFERSON, FARM JOURNAL, Mar. 16 (1791); *accord* GEORGE WASHINGTON, THE DIARIES OF GEORGE WASHINGTON (John C. Fitzpatrick ed., 1925).

stant in that small window. In fact, not long ago in Germany I had one demonstrated to me.

The marijuana material is put into the chamber. There is no question that the smoker gets the cannabinoids. Anybody who is familiar with it knows that he is inhaling cannabinoids. And then, when finished, if the smoker looks at the contents of the chamber, he observes that it has not been burned at all. In fact what was inhaled cannot be seen as smoke. You can't see it, you can't feel it; there is a little bit of a taste to it.

The National Academy of Sciences Institute of Medicine[375] made a big issue of the danger of smoking. They insisted that we cannot think of using whole marijuana because it has to be smoked. In my view, that was an exaggerated statement. It served the purpose of conveying what I think the Institute of Medicine wanted to convey: yes, marijuana is medicine, but we have got to take away the whole plant and make pharmaceutical products which will be acceptable as medicine.

DR. HAINES: The next question is for Dr. Russo. "Has any study been done on marijuana effectiveness as a treatment for depressive episodes of manic depression sufferers? Has the pharmaceutical industry blocked such studies, and why doesn't the NIMH pursue it?"

DR. RUSSO: Boy, the last one would be really tough. NIMH does not pursue such studies for the same reasons that they don't want any studies to go forward: everything is anecdotal if they do not approve research.

With respect to depression, we have 4000 years of information on the use of cannabis as treatment. For example, one of the Sumerians' indications for cannabis was *nissati*, their term for grief.[376] Apparently use of cannabis was quite helpful in its treatment. Also, Herodotus wrote about how the Scythians would howl with joy in their funerary rites for fallen comrades by putting cannabis flowering tops on hot stones.[377] There is a well-established tradition of using cannabis to treat depression, that has been extensively documented, specifically, by French researcher Jacques-Joseph Moreau, in 1845.[378] More recently, this topic has not been

375. The mission of the National Academy of Sciences, Institute of Medicine is to advance and disseminate scientific knowledge. For additional information, see http://www.iom.com.

376. R. CAMPBELL THOMPSON, A DICTIONARY OF ASSYRIAN BOTANY (1949).

377. HERODOTUS, THE HISTORIES 259 (Oxford University Press, 1998).

378. JACQUES-JOSEPH MOREAU DE TOURS, DU HACHISCH ET L'ALIENATION MENTALE: ETUDES PSYCHOLOGIQUES (1845).

more formally studied for the same reason that I cannot get my research done: the government is not approving such studies.

There is only one clinical study currently underway with cannabis, by Donald Abrams at the University of California at San Francisco. However, he only received approval to use cannabis to study the effects of protease inhibitors on HIV patients when the study was changed from an efficacy study to a safety study.[379] I think this is an important area that should be studied.

DR. GRINSPOON: Let me just add to that very briefly. Anybody interested in the particular question about the therapeutic utility of marijuana in bipolar disorders may be interested in looking at a paper I published in June 1998 in the *Journal of Psychoactive Drugs*.[380] Marijuana will be a very important drug in the future of mood stabilization, both depression and manic high.

DR. HAINES: The next question is to Terrence Farley. "A recent report conducted and issued by the Manhattan Institute, authored by conservative criminologist John J. DiIulio, studied prison commitments in New York, Arizona, and New Mexico.[381] The study determined that mandatory minimum sentencing for drug-only offenders is not cost-effective, when taking into account the cost of the crimes committed annually. These sentences do not increase public safety because they misdirect scarce resources toward individuals that pose minimal danger in comparison to violent offenders."

MR. FARLEY: Well again, I disagree with the conclusion that drug offenders and violent offenders constitute distinct categories. As far as the cost factor, I am not aware of what data DiIulio used in his study. However, other studies tell us that if someone is involved in criminal activity, it costs $413,000 a year. Further, thirteen crimes per year are committed, on average, by career criminals. Therefore, the yearly cost of criminal activity is greater than the cost of incarceration. Studies such as the Rand Study are the ones that have been out there, and have been accepted for

379. In an efficacy study, Abrams would look at whether the patients gained weight while on cannabis. Alternatively, as a safety study, Abrams would investigate whether cannabis produced any interference with other drugs being used to treat the patients.

380. Lester Grinspoon & J. Bakalar, *Use of Cannabis as a Mood Stabilizer in Bipolar Disorder: Anecdotal Evidence and the Need for Clinical Research*, 30 J. PSYCHOACTIVE DRUGS 171 (1998).

381. Anne Morrison Piehl et al., *Right-Sizing Justice: A Cost-Benefit Analysis of Imprisonment in Three States*, CIVIC REPORT NO. 8 (Sept. 1999), http://www.manhattan-institute.org/cr_08.pdf.

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