Scottsdale Research Institute
5436 E Tapekim Rd, Cave Creek AZ 85331 USA
Phone: +1 (480) 326-6023

April 29, 2020

Dear Senator or Member of Congress:

Today, the Department of Justice's ("DOJ") Office of Legal Counsel ("OLC") released, in unredacted form, a copy of its previously undisclosed June 6, 2018 memorandum on "Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs" at https://www.justice.gov/olc/opinions, as part of a settlement in *Scottsdale Research Institute v. Department of Justice*, No. 20-cv-605 (D. Ariz.). This 25-page memo, which is attached along with a chronology of key events, explains, in detail, how and why DOJ concluded back in June 6, 2018 that "DEA must change its current practices and the policy it announced in 2016 to comply with the Single Convention."

Over the past two years, across ten letters and numerous congressional hearings, members have repeatedly asked DOJ and the Drug Enforcement Administration ("DEA"):

- "What is the current status of the twenty-six marijuana manufacturer applications?"
- "What steps have both DEA and DOJ taken to review the twenty-six marijuana manufacturer applications currently pending?"
- "Please share DOJ's analysis of the Single Convention and if the opinion of the Justice Department is the same or similar to that of DEA's."
- "If there are legal barriers to licensing multiple schedule I marijuana manufacturers under the Single Convention, please identify them."

We believe this previously undisclosed memo and our chronology provide answers to these important questions. We summarize the key takeaways below.

In August 2016, DEA announced it would approve new cultivators of marijuana for research. But soon after, in 2017, DOJ blocked DEA from proceeding. DOJ then embarked on a "policy review process" culminating in the June 6, 2018 OLC memo. The memo concludes that that DEA had to change its current practices and the policy it announced in 2016 to comply with the Single Convention. But rather than deny any of the applications—which would have required the agency state the reasons for the denial, subjecting those reasons to public scrutiny and judicial review—the pending applications remained and still remain in administrative purgatory.

Sensing a deep irregularity in the administrative process, Scottsdale Research Institute ("SRI") filed a mandamus petition in the D.C. Circuit in June 2019, requesting judicial intervention. We hoped DEA would explain to the court what it had not explained to Congress. Instead, two days before the August 28, 2019 response deadline, DEA processed the pending applications but stated it needed even more time before it could make decisions to promulgate new rules. Two days later, in its court filing, DEA did not defend or explain its delay, but only argued the action was moot.

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In January 2020, DEA again had a chance to explain in a hearing entitled "Cannabis Policies for the New Decade" before the House Subcommittee on Health of the Committee on Energy and Commerce. DEA's Senior Policy Advisor shared Congress's frustration with the delays and agreed that the program needed to move forward. But he could not share details of the "deliberative" process that was causing the delays.

On March 20, 2020, in the middle of a pandemic, DEA announced the proposed new rules and set a May 22, 2020 deadline for public comments. The Notice of Proposed Rulemaking explains that these rules "would amend DEA regulations only to the extent necessary to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana." Because DEA believed it lacked discretion to deviate from DOJ's new view of the CSA and U.S. treaty obligations, it did not consider alternative proposals before proposing the new rules.

But the OLC memo—which explained how DEA and DOJ applied the law, caused the delay, and required DEA to amend its regulations—remained secret, undermining SRI's and the public's ability to understand, much less comment intelligently on, DEA's proposed rules. As a result, we filed another lawsuit in the District of Arizona under the Freedom of Information Act on March 25, 2020. As part of our settlement, OLC agreed to publish the June 6, 2018 memorandum—something it should have done long ago.

* * *

SRI is a non-commercial Arizona limited liability company and clinical trials site whose mission is to conduct high quality, controlled scientific studies to ascertain the general medical safety and efficacy of plant products, including marijuana, to treat pain and PTSD as well as for potential substitution of opioid dependence. It wants to be in the lab, not the courtroom. Unfortunately, because of ongoing violations of its rights under the Due Process Clause and the Administrative Procedure Act stemming from the highly irregular administrative process just described, SRI has twice had to turn to litigation.

In the United States, doing robust clinical research with marijuana should not be so difficult. Scores of Americans rely on medical marijuana to treat a variety of symptoms, including our nation's veterans and terminally ill. Not surprisingly, this issue has solid bipartisan support. It also has support among federal agencies including FDA, NIH, and DEA itself.

That Congress can fix these issues with legislation goes without saying. But what fewer recognize is that this Administration can cut through the regulatory red-tape right now. Under 21 U.S.C. § 822(d)—which the OLC memo does not address—"The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety." The Attorney General has delegated his authority under this subsection to DEA.

The Supreme Court has cited § 822(d) as hard evidence that despite Congress's general findings about Schedule I substances, it may sometimes be "consistent with the public health and

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safety" to exempt certain people from its requirements under § 822(d).[1] And in fact, DEA has waived registration requirements under § 822(d) before.[2] As recently as February 2020, DEA invoked § 822(d) to propose a regulation that would waive the requirement of a separate registration for narcotic treatment programs to dispense narcotic drugs at locations remote from, but within the same state as, the narcotic treatment program's registered location.[3]

Notably, unlike 21 U.S.C. § 823(a), the statutory text of § 822(d) does *not* mention international treaty obligations. So, waivers under § 822(d) should not be subject to the constraints of the Single Convention.[4] The only condition under § 822(d) is that waivers be "consistent with the public health and safety." Plainly, given the undisputed urgency of the need for this research, waiving certain registration requirements to allow already-licensed Schedule I researchers obtain marijuana from real world or alternative sources would be "consistent with the public health and safety."

DEA could, for example, exempt licensed Schedule I marijuana researchers from having to obtain a separate registration to manufacture marijuana, provided those researchers agree not to distribute any marijuana they manufacture. Alternatively, it could permit licensed Schedule I marijuana researchers to obtain marijuana from state-legal dispensaries. The executive's authority to grant waivers under § 822(d) is broad.

Boiled down, the fact that a secret re-interpretation of an international treaty from 1961 has blocked the advancement of marijuana science in this country for the past three years is absurd. Allowing American scientists to cultivate or acquire marijuana grown in this country under strict

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1 *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 432–33 (2006) ("The fact that the Act itself contemplates that exempting certain people from its requirements would be 'consistent with the public health and safety' indicates that congressional findings with respect to Schedule I substances should not carry the determinative weight, for RFRA purposes, that the Government would ascribe to them."); *see also O Centro Espirita Beneficiente Uniao Do Vegetal v. Ashcroft*, 389 F.3d 973, 1022 (10th Cir. 2004) (McConnell, J. concurring); *United States v. Lafley*, 656 F.3d 936, 941 (9th Cir. 2011) ("the Act explicitly provides for exceptions").

2 *See, e.g.*, 60 Fed. Reg. 55,348 (Oct. 31, 1995) (invoking § 822(d) to waive the registration requirement for retail distributors of regulated pseudoephedrine products79 Fed. Reg. 70,087 (Nov. 25, 2014) (waiving registration requirements for persons administering DaTscanTM, which contains a controlled substance, providing those persons follow the applicable Nuclear Regulatory Commission or Agreement State regulations and requirements when handling DaTscanTM).

3 85 Fed. Reg. 11,008 (Feb. 26, 2020).

4 Non self-executing treaties like the Single Convention are international commitments, not binding federal law. *Medellin v. Texas*, 552 U.S. 491, 504 (2008); *see also United States v. Feld*, 514 F. Supp. 283, 288 (E.D.N.Y. 1981) ("The Single Convention is not self-executing, but works through the constitutional and legal systems of its signatory nations."). DEA's authority to register manufacturers under 21 U.S.C. § 823(a) implicates international treaties obligations because the statutory text requires registration be "consistent with … United States obligations under international treaties." 21 U.S.C. § 822(d), however, makes no mention of obligations under international treaties, and therefore should not subject to international treaty obligations.

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DEA regulation and supervision is pro-science, pro-veteran, and pro-law enforcement. It puts America First and promotes public health and safety.

We appreciate your time, attention, and consideration of this important public health matter. Please let us know if you have any questions. We are eager to assist in moving the ball forward on improving access to marijuana for scientific research and provide other insights on how the Controlled Substances Act could be amended to fix these and other issues.

Sincerely,

Sue Sisley, MD
President/Principal Investigator, SRI
ssisleymd@gmail.com

Matthew C. Zorn

Shane Pennington

Attorneys for Scottsdale Research Institute
mzorn@yettercoleman.com
spennington@yettercoleman.com