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Re: Legal Opinion re U.S. Drug Enforcement Agency's New Proposed Interim Rule

Regarding Hemp and Hemp Products, RIN 1117-AB53/ Docket No. DEA-500

Regarding the DEA's most recent proposed Rule, the DEA provides the following Executive Summary:

> **Executive Summary**
> The Agriculture Improvement Act of 2018, Public Law 115-334 (the AIA), was signed into law on December 20, 2018. It provided a new statutory definition of "hemp" and amended the definition of marihuana under 21 U.S.C. 802(16) and the listing of tetrahydrocannabinols under 21 U.S.C. 812(c). The AIA thereby amends the regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents in the Controlled Substances Act (CSA).
>
> This rulemaking makes four conforming changes to DEA's existing regulations:
>
> It modifies 21 CFR 1308.11(d)(31) by adding language stating that the definition of "Tetrahydrocannabinols" does not include "any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639 o."
> It removes from control in schedule V under 21 CFR 1308.15(f) a "drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-

3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols."

It also removes the import and export controls described in 21 CFR 1312.30(b) over those same substances.

It modifies 21 CFR 1308.11(d)(58) by stating that the definition of "Marihuana Extract" is limited to extracts "containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis." This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations.

Accordingly, there are no additional costs resulting from these regulatory changes. However, as discussed below, the changes reflected in this interim final rule are expected to result in annual cost savings for affected entities.

However, of more concern is the DEA's proposed to changes to its rules implementing the Controlled Substances Act:

Changes to the Definition of Tetrahydrocannabinols The AIA [Agriculture Improvement Act of 2018] also modified the listing for tetrahydrocannabinols under 21 U.S.C. 812(c) by stating that the term tetrahydrocannabinols does not include tetrahydrocannabinols in hemp. Specifically, 21 U.S.C. 812(c) Schedule I now lists as schedule I controlled substances: "Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639o of Title 7)." Therefore, the AIA limits the control of tetrahydrocannabinols (for Controlled Substance Code Number 7370). For tetrahydrocannabinols that are naturally occurring constituents of the plant material, Cannabis sativa L., any material that contains 0.3% or less of D9-THC by dry weight is not controlled, unless specifically controlled elsewhere under the CSA. Conversely, for tetrahydrocannabinols that are naturally occurring constituents of Cannabis sativa L., any such material that contains greater than 0.3% of D9-THC by dry weight remains a controlled substance in schedule I. **The AIA does not impact the control status of synthetically derived tetrahydrocannabinols (for Controlled Substance Code Number 7370) because the statutory definition of "hemp" is limited to materials that are derived from the plant Cannabis sativa L. For synthetically derived tetrahydrocannabinols, the concentration of D9-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances**. This rulemaking is modifying 21 CFR

> 1308.11(d)(31) to reflect this statutory change. By this rulemaking, 21 CFR 1308.11(d)(31) is being modified via the addition of subsection (ii), which reads: "Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o." [Bold added for emphasis.]

The above proposed DEA interpretative rule is direct at odds with AIA's definition of "hemp," which defines "hemp" as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. § § 1639o, subdiv. (1).

Congress thus not only exempted hemp plants, whether living or not, from the federal Controlled Substances Act, but also ***all derivatives, extracts…*** made from "hemp" a cannabis plant having less than 0.3% delta-9 THC dry weight per volume. A "derivative" or an "extract" is man-made or synthetic process to make something out of hemp, based on the common understanding and standard dictionary definitions of what constitutes a "derivative" or an "extract." See, for example, Webster's on-line dictionary at https://www.merriam-webster.com/dictionary/derivative, defining "derivative" to mean "…**4 chemistry** a: a chemical substance related structurally to another substance and theoretically derivable from it b: a substance that can be made from another substance: Petroleum is a derivative of coal tar. Soybean derivatives."

Similarly, Webster's defines "extracts" as, "2a: to withdraw (something, such as a juice or a constituent element) by physical or chemical process b: to treat with a solvent so as to remove a soluble substance." https://www.merriam-webster.com/dictionary/extracts.

So Congress expressly exempted hemp derivatives and hemp extracts from the federal Controlled Substances Act, as well as "hemp" itself. See 21 U.S.C. 802, subdiv. (16): "(A) Subject to subparagraph (B), the term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. **(B) The term "marihuana" does not include—(i) hemp, as defined in section 1639o of title 7**; or (ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." [Bold added for emphasis.]

Not only did Congress expressly exempt “hemp,” “hemp derivatives,” and hemp extracts from the definition of “marihuana [marijuana or cannabis]”-a controlled substance, Congress also expressly exempted the AIA’s definition of “hemp,” “hemp derivatives,” and “hemp extracts” from the Controlled Substances Act list of Schedule 1 drugs. See 21 U.S.C. 812, subdivision (C), subpart (17): “(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation: (17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946 [7 USCS § 1639o]).”

Since Congress defined “hemp” to *include* “hemp derivatives” and “hemp extracts,” as long as delta-8 tetrahydrocannabinol (delta-8 THC) is extracted or derived from hemp or is extracted or derived from extract or derivative of “hemp,” it cannot be criminalized under the federal Controlled Substances Act, until Congress either further amends the AIA of 2018 or amends the existing CSA.

The Supreme Court developed in *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984), the standard for determining whether courts should give deference to an agency's interpretation of a statute. As an initial matter, an agency’s interpretation should only be given deference “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” *Dr. Reedy's Lab., Inc. v. Thompson*, 302 F. Supp. 2d 340, 348 (D.N.J. 2003) (quoting *United States v. Mead*, 533 U.S. 218, 226-27, 150 L. Ed. 2d 292, 121 S. Ct. 2164 (2001); *Robert Wood Johnson Univ. Hosp. v. Thompson*, 297 F.3d 273, 281 (3d Cir. 2002)).

Courts must employ a two-step analysis under *Chevron*. First, if the statute speaks clearly “to the precise question at issue," the Court must give effect to the unambiguously expressed intent of Congress.” *Chevron*, 467 U.S. at 842-43. Second, where the statute is “silent or ambiguous with respect to the specific issue,” the Court must sustain the agency determination if it is based on a “permissible construction” of the statute. *Id.* at 843. A court does not need to reach this second step if, “employing traditional tools of statutory construction, [it] ascertains that Congress had an intention on the precise question at issue . . . .” *Id.* at 843 n.9.

"The primary and general rule of statutory construction is that the intent of the lawmaker is to be found in the language that he has used.” *United States v. Goldenberg*, 168 U.S. 95, 102-03, 42 L. Ed. 394, 18 S. Ct. 3 (1897). “When

the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." *Lamie v. United States Trustee*, 540 U.S. 526, 157 L. Ed. 2d 1024, 124 S. Ct. 1023, ____, 540 U.S. 526, 124 S. Ct. 1023, 1030, 157 L. Ed. 2d 1024 (2004).

When the language of a Congressional Act is clear and unambiguous, courts must give effect to Congress's intent regardless of the interpretation employed by the executive agency charged with enforcing the Congressional statute. See *America's Cmty. Bankers v. F.D.I.C.*, 339 U.S. App. D.C. 364, 200 F.3d 822, 834 (D.C. Cir. 2000) ("Under the *Chevron* standard, if Congress has directly spoken to the issue, and the intent of Congress is clear, then there is nothing for the agency to interpret, and the court must give effect to the unambiguous expression of Congress"; compare with *Hemp Indus. Ass'n v. Drug Enforcement Admin.*, 357 F.3d 1012, 1018 n.6 (9th Cir. 2004) (declining to address the appellants' Regulatory Flexibility Act, 5 U.S.C. § 611, arguments because the court concluded that the plain language of the statue controlled over the DEA's rule interpreting the Controlled Substances Act.

In sum, where Congress has directly spoken to an issue, the DEA cannot make a rule that directly conflicts with the will of Congress. Congress expressly *exempted* not only hemp plants themselves from the Controlled Substances Act, but also exempted all hemp derivatives and extracts, which normally would include products that can be derived from hemp, such as THCs, salts, etc. derived or extracted from hemp. The DEA's proposed "synthetically derived" versus "naturally occurring" distinction regarding THCs found in hemp is inconsistent with express language in Congress's AIA and in Congress's express exemptions from the CSA for hemp.

Sincerely,

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