

(Slip Opinion)

Questions Related to the Potential Rescheduling of Marijuana

The approach that the Drug Enforcement Administration currently uses to determine whether a drug has a “currently accepted medical use in treatment in the United States” under the Controlled Substances Act is impermissibly narrow. An alternative, two-part inquiry proposed by the Department of Health and Human Services is sufficient to establish that a drug has a “currently accepted medical use” even if the drug would not satisfy DEA’s current approach.

Under 21 U.S.C. § 811(b), a recommendation by HHS that a drug has or lacks a “currently acceptable medical use” does not bind DEA. In contrast, the scientific and medical determinations that underlie HHS’s “currently acceptable medical use” recommendation are binding on DEA, but only until the initiation of formal rulemaking proceedings to schedule a drug. Once DEA initiates a formal rulemaking, HHS’s determinations no longer bind DEA, but DEA must continue to accord HHS’s scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS’s findings at any point in the process.

Neither the Single Convention on Narcotic Drugs nor the CSA requires marijuana to be placed into Schedule I or II of the CSA. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific restrictions that follow from a drug’s placement on a particular schedule. As a result, DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA’s regulatory authorities.

April 11, 2024

MEMORANDUM OPINION FOR THE ATTORNEY GENERAL

The Controlled Substances Act (“CSA”)¹ imposes a unified framework for controlling drugs and other substances that are found to pose a risk of abuse.² In doing so, it seeks to balance several, often competing, interests. These interests include ensuring the availability of drugs that “have a

¹ In 1970, Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, the provisions of which are codified at Chapter 13 of Title 21 of the U.S. Code. The Act comprised several titles, including Title II, which it called the Controlled Substances Act, and Title III, which it called the Controlled Substances Import and Export Act. For ease of reference, we refer to the entire 1970 law as the CSA.

² The CSA applies to both drugs and “other substance[s]” that have been controlled. *See* 21 U.S.C. § 802(6). For ease of reference, we use the term “drug” to refer to both.

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useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people”; preventing the “illegal importation, manufacture, distribution, and possession and improper use of controlled substances [that] have a substantial and detrimental effect on the health and general welfare of the American people”; and ensuring that the United States complies with “international conventions designed to establish effective control over international and domestic traffic in controlled substances.” 21 U.S.C. § 801(1), (2), (7).

The CSA balances these purposes by placing each drug warranting control into one of five “schedules,” with drugs in Schedule I subject to the strictest regulatory and criminal provisions, and drugs in Schedule V subject to the least strict. *See generally* 21 U.S.C. §§ 821–832, 841–865, 951–971. The CSA further authorizes the Attorney General to add, transfer, and remove drugs from the schedules using formal rulemaking procedures, *see id.* §§ 811, 812, and otherwise grants the Attorney General broad authority to take regulatory action consistent with the Act, *see, e.g., id.* §§ 821, 871(b). The Attorney General has in turn generally delegated these functions to the Administrator of the Drug Enforcement Administration (“DEA”). 28 C.F.R. § 0.100(b).

Marijuana has been a Schedule I drug since Congress enacted the CSA. *See* 21 U.S.C. § 812(c). To reschedule marijuana from Schedule I, DEA would need to determine, among other things, that the drug has a “currently accepted medical use in treatment in the United States” (“CAMU”). *Id.* § 812(b). Since 1992, however, DEA has determined that a drug has a CAMU only if either the Food and Drug Administration (“FDA”) has approved the drug for marketing in interstate commerce under the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, or the drug meets a five-part test that tracks the “core standards developed under the FDCA.” 57 Fed. Reg. 10,499, 10,503–04, 10,506 (Mar. 26, 1992). And because FDA has not approved marijuana and DEA has determined that marijuana does not meet its five-part test, DEA has repeatedly rejected petitions to move marijuana to a less restrictive schedule.

On October 6, 2022, President Biden asked the Secretary of Health and Human Services (“Secretary”) and the Attorney General to initiate an “administrative process to review expeditiously how marijuana is scheduled under federal law.” *Statement from President Biden on Marijuana Reform* (Oct. 6, 2022), <https://www.whitehouse.gov/briefing-room/>

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statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform. The CSA requires the Secretary to provide certain recommendations before the initiation of proceedings to schedule or reschedule a drug, and the statute provides that the Secretary’s recommendations “shall be binding” as to certain “scientific and medical matters.” 21 U.S.C. § 811(b).

Consistent with this requirement, in 2023, the Department of Health and Human Services (“HHS”) recommended that DEA reschedule marijuana to Schedule III. *See* Letter for Anne Milgram, Administrator, DEA, from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS (Aug. 29, 2023). HHS concluded that, regardless of whether a drug was approved by FDA or satisfied DEA’s five-part test, the drug could have a CAMU if it satisfied a new, two-part inquiry. Part 1 of that inquiry asks whether licensed health care providers have “widespread current experience with medical use” of the drug “in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” Memorandum for the Commissioner, FDA, from the Assistant Secretary for Health, HHS, *Re: Part 1 Analysis* at 1 (July 17, 2023) (“HHS Part 1 Analysis Memo”). If so, Part 2 of the inquiry asks whether there is “some credible scientific support for at least one of the medical uses.” *Id.* at 2.

Against this backdrop, you have asked us three questions:³

- (1) If a drug satisfies the two-part inquiry employed by HHS, does that establish a currently accepted medical use under the statute even if the drug has not been approved by FDA and even if the drug does not satisfy DEA’s five-part test?
- (2) To what extent do the “scientific and medical matters” referenced in 21 U.S.C. § 811(b), which are binding upon the Attorney General,

³ This opinion memorializes advice we provided you on February 16, 2024. To aid our analysis, we solicited and received written views from HHS and DEA on all three questions and from the State Department on the third question. *See* Memorandum for the Office of Legal Counsel from DEA (Jan. 30, 2024) (“DEA Response”); Memorandum for Gillian E. Metzger, Deputy Assistant Attorney General, Office of Legal Counsel, from Samuel R. Bagenstos, General Counsel, HHS, *Re: OLC’s Request for Views on Issues Related to the Scheduling of Marijuana Under the Controlled Substances Act* (Jan. 29, 2024) (“HHS Response”); Single Convention Requirements for Cannabis and Scheduling Under the Controlled Substances Act (Feb. 12, 2024) (“State Response”).

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include the Secretary’s evaluation of a drug’s currently accepted medical use or any scientific and medical considerations involved in that evaluation?

(3) Does the CSA, including the requirement that the Attorney General control drugs “under the schedule he deems most appropriate to carry out” the United States’ “obligations under international treaties, conventions, or protocols in effect on October 27, 1970,” *id.* § 811(d)(1), require DEA to place marijuana in either Schedule I or Schedule II to comply with the Single Convention on Narcotic Drugs, Mar. 30, 1961, 18 U.S.T. 1407 (“Single Convention”)?

As explained in more detail below, we conclude, first, that DEA’s current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by FDA and would not satisfy DEA’s five-part test.

Second, we conclude that HHS’s overall CAMU recommendation is not binding on DEA. We also conclude that the scientific and medical determinations that underlie HHS’s CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS’s determinations no longer bind DEA, but DEA must continue to accord HHS’s scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS’s findings at any point in the process.

Third, we conclude that neither the Single Convention nor the CSA requires DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific controls that follow from a drug’s placement on a particular schedule. As a result, we conclude that DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA’s regulatory authorities.

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I.

A.

Sections 811 and 812 of the CSA set forth the procedures and standards the Attorney General (and thus DEA) must follow to add a drug to a schedule, transfer a drug between schedules, or remove a drug from the schedules of control. Section 811(a) authorizes the Attorney General to add or transfer a drug to, or remove a drug from, a schedule by issuing a rule “made on the record after opportunity for a hearing” pursuant to the formal rulemaking procedures of the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 553(c), 556, 557. In promulgating such rules, the Attorney General is required to make particular findings, based on substantial evidence, that correspond to the schedule in which the drug is to be placed. 21 U.S.C. §§ 811(a)(1)(A)–(B), 812(b); *see also id.* § 811(b); 5 U.S.C. § 556(d).

Section 812(b) lists the findings the Attorney General must make to place a drug in a particular schedule, with the findings varying by schedule. For example, the Attorney General may place a drug in Schedule I only if the Attorney General finds that the drug “has a high potential for abuse,” 21 U.S.C. § 812(b)(1)(A); “has no currently accepted medical use in treatment in the United States,” *id.* § 812(b)(1)(B); and “[t]here is a lack of accepted safety for use” of the drug “under medical supervision,” *id.* § 812(b)(1)(C). To place drugs in other schedules, the Attorney General must similarly make three findings, except that drugs on the other schedules must have a CAMU (or, in the case of Schedule II drugs, a CAMU with “severe restrictions”). *Id.* § 812(b)(2)(B), (b)(3)(B), (b)(4)(B), (b)(5)(B). Drugs are to be placed in less restrictive schedules as their potential for abuse and likelihood of leading to physiological or physical dependence declines. *Id.* § 812(b)(2)–(5). In the course of making these findings, section 811(c) requires the Attorney General to consider eight medical, scientific, and law-enforcement factors regarding the drug:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.

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- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Id. § 811(c).

Although section 811 provides that the Attorney General will issue the final rule to schedule a drug, *see id.* § 811(a), the CSA also assigns a significant role in scheduling decisions to the Secretary. Section 811(b) requires the Attorney General, before initiating a rulemaking proceeding to schedule or reschedule a drug, to request both a scientific and medical evaluation of the drug from the Secretary and the Secretary’s recommendation as to the schedule, if any, in which the drug should be placed. The Secretary’s recommendations “shall be binding on the Attorney General as to such scientific and medical matters” and the Attorney General is prohibited from controlling a drug if the Secretary recommends that it not be controlled. *Id.* § 811(b). After receiving the views of the Secretary, the Attorney General must initiate rulemaking proceedings if there is sufficient evidence to do so. *See id.*

The legislative history of section 811(b) indicates that its purpose was to place scientific and medical judgments in the hands of the Secretary. The report of the House Committee on Interstate and Foreign Commerce explains that “[c]onsiderable controversy arose” during the drafting process over the scheduling provisions of the bill, in particular “with respect to the proper role of the Attorney General and the Secretary of Health, Education, and Welfare [(‘HEW’)]⁴ in making determinations concerning which drugs should be controlled.” H.R. Rep. No. 91-1444, at 22 (1970).

⁴ In 1979, Congress created the Department of Education and changed the name of the Department of Health, Education, and Welfare to the Department of Health and Human Services. Department of Education Organization Act, Pub. L. No. 96-88, §§ 201, 509, 93 Stat. 668, 671, 695 (1979).

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This controversy appears to have stemmed from the fact that the version of the CSA that passed the Senate vested full decisionmaking authority regarding scheduling in the Attorney General alone and required only that the Attorney General obtain the “advice” of the Secretary in connection with scheduling decisions. S. 3246, 91st Cong. § 201(a) (1970); *see* 116 Cong. Rec. 1671, 1672 (1970). During the House’s consideration of the bill, Members of Congress, HEW officials, and scientific and medical professionals raised concerns over the dominant role the Senate bill assigned to the Attorney General, arguing that scheduling decisions largely require scientific and medical expertise and that HEW, not the Department of Justice, had this expertise. *See, e.g., Drug Abuse Control Amendments—1970: Hearings Before the Subcomm. on Pub. Health & Welfare of the H. Comm. on Interstate & Foreign Commerce*, 91st Cong. 102–04, 194–95, 199, 550, 557, 580–81 (1970) (“House Hearing”).

Reflecting these concerns, the House version of the bill, H.R. 18583, 91st Cong. (1970), made several changes to what is now 21 U.S.C. § 811(b) that expanded the role of the Secretary and eventually became law. The requirement that the Attorney General obtain “advice” was changed to an obligation to obtain “recommendations” that bound the Attorney General with respect to scientific and medical matters. H.R. 18583, § 201(b). The House bill also added a requirement that the Secretary give a recommendation regarding the schedule in which the drug should be placed and provided that the Attorney General could not control a drug that the Secretary recommended not be controlled. *Id.*

B.

As noted above, Congress classified marijuana as a Schedule I drug when it enacted the CSA in 1970. *See* 21 U.S.C. § 812(c). Shortly thereafter, several organizations petitioned to move marijuana from Schedule I to Schedule V. *See* 37 Fed. Reg. 18,097 (Sept. 7, 1972). The petition was denied three times, but each time on review the United States Court of Appeals for the District of Columbia Circuit remanded for further analysis. *See Nat’l Org. for the Reform of Marijuana Laws v. Ingersoll*, 497 F.2d 654, 661 (D.C. Cir. 1974); *Nat’l Org. for the Reform of Marijuana Laws v. DEA*, 559 F.2d 735, 757 (D.C. Cir. 1977) (“*NORML II*”); *Nat’l Org. for the Reform of Marijuana Laws v. DEA*, No. 79-1660, 1980 U.S. App. LEXIS 13099, at *1 (D.C. Cir. Oct. 16, 1980) (per curiam).

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After the third remand, DEA denied the rescheduling petition once more, concluding that marijuana did not have a CAMU. *See* 54 Fed. Reg. 53,767, 53,767, 53,783–84 (Dec. 29, 1989). In reaching that conclusion, DEA relied on an eight-part test for determining whether a drug had a CAMU that included the following three factors: whether the drug was generally available; whether its use was generally recognized in various medical reference works; and whether its use was recognized by “a substantial segment of the medical practitioners in the United States.” *Id.* at 53,783. As before, the petitioners sought review and the D.C. Circuit remanded the case to DEA, concluding that these three factors were arbitrary and capricious because they would be “logically impossible” for drugs in Schedule I to satisfy. *All. for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 937, 940 (D.C. Cir. 1991) (“*ACT I*”). But the court held that DEA’s interpretation of the statutory phrase “currently accepted medical use” was “in the main acceptable,” and rejected petitioners’ principal argument that DEA’s interpretation unreasonably relied upon “the absence of demonstrated scientific evidence that the drug is medically useful and safe.” *Id.* at 937, 939. In particular, the court noted that the petitioners had presented only “anecdotal evidence” that “a number of physicians believe marijuana is medically useful.” *Id.* at 939.

On remand a fourth time, DEA again denied the petition, again finding that marijuana did not have a CAMU. 57 Fed. Reg. at 10,499. DEA stated that a drug would have a CAMU if it had been approved by FDA under its “New Drug Application” process or if the drug met the criteria to be recognized by FDA as “Generally Recognized As Safe and Effective.” *Id.* at 10,503 (citing 21 U.S.C. §§ 321(p), 355). In addition, DEA concluded that a drug would have a CAMU if it satisfied a new, five-part test (a revised version of DEA’s previous eight-part test that the D.C. Circuit considered in *ACT I*). *Id.* at 10,504. Under DEA’s new test, a drug has a CAMU if the following elements are satisfied:

- (1) the drug’s chemistry is known and reproducible;
- (2) there are adequate safety studies;
- (3) there are adequate and well-controlled studies proving efficacy;
- (4) the drug is accepted by qualified experts; and
- (5) scientific evidence about the drug is widely available.

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Id. at 10,503–06. All five parts were based on the “core FDCA standards for acceptance of drugs for medical use,” and four were expressly derived from the FDCA or FDA regulations setting forth requirements that a drug must meet before receiving FDA approval. *Id.* at 10,504–05 (citing 21 U.S.C. §§ 321(p), (w), 355(d); and 21 C.F.R. §§ 314.103(c)(3), 314.50(d)(1), 314.125(b), 314.126). DEA concluded that marijuana did not meet any of these criteria and accordingly denied the request to remove marijuana from Schedule I. *Id.* at 10,507–08.

This time the D.C. Circuit upheld DEA’s decision. *See All. for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1133 (D.C. Cir. 1994) (“*ACT I*”). It rejected the petitioners’ “central claim” that DEA’s order rested on an “unreasonable interpretation of the statute.” *Id.* The court noted that it had already concluded in *ACT I* that DEA’s interpretation of the CSA was generally reasonable, and it refused to reconsider that determination. *Id.* at 1134. It further reasoned that none of the criteria in DEA’s new five-part test were “impossible for a Schedule I drug to meet” and that DEA had “corrected the flaws [the court] identified in” *ACT I*. *Id.* at 1135.

Since *ACT II*, DEA has denied several petitions that sought rescheduling of marijuana after applying its five-part test and concluding that marijuana did not have a CAMU. *See, e.g.*, 66 Fed. Reg. 20,038, 20,038 (Apr. 18, 2001); 76 Fed. Reg. 40,552, 40,552 (July 8, 2011); 81 Fed. Reg. 53,688, 53,688 (Aug. 12, 2016); 81 Fed. Reg. 53,767, 53,767 (Aug. 12, 2016). Efforts to challenge these denials in court have proven unsuccessful. *See Ams. for Safe Access v. DEA*, 706 F.3d 438, 450 (D.C. Cir. 2013); *Krumm v. DEA*, 739 F. App’x 655 (D.C. Cir. 2018). In recent years, however, several jurists have raised serious concerns about DEA’s conclusion that marijuana does not have a CAMU. *See United States v. Green*, 222 F. Supp. 3d 267, 275 (W.D.N.Y. 2016); *United States v. Amalfi*, 47 F.4th 114, 125 (2d Cir. 2022); *Sisley v. DEA*, 11 F.4th 1029, 1036 (9th Cir. 2021) (Watford, J., concurring).

C.

Since 1996, 38 States, the District of Columbia, and four federal territories have legalized the use of medical marijuana. *See* HHS Part 1 Analysis Memo at 4. These laws typically allow the cultivation, sale, and use of marijuana by patients (or their caregivers) whose health care practitioners have recommended that they use marijuana to treat certain, specified

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conditions. *See, e.g.*, Ohio Rev. Code §§ 3796.01(A)(6)(a)–(v), 3796.08(A); N.Y. Cannabis Law §§ 3(18), 30, 31; N.M. Stat. §§ 26-2B-3(F)(1)–(23), 26-2B-3(N), 26-2B-4(A). Conditions can be added to, or removed from, the list of illnesses that may be treated with marijuana, often by (or at the recommendation of) a state’s public health authorities or special boards convened to consider such matters. *See, e.g.*, Conn. Gen. Stat. § 21a-408l(a), (c); 410 Ill. Comp. Stat. §§ 130/10(h)(2), 130/45; Or. Admin. Rule 333-008-0090. In each fiscal year since 2015, Congress has also adopted an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *E.g.*, Consolidated Appropriations Act, 2024, Pub. L. No. 118-42, § 531, 138 Stat. 25; Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 531, 136 Stat. 4459, 4561 (2022); *see* Cong. Rsch. Serv., R44782, *The Evolution of Marijuana as a Controlled Substance and the Federal-State Policy Gap* at 26 & n.159 (updated Apr. 7, 2022) (collecting laws).

On October 6, 2022, as noted above, President Biden asked the Secretary and the Attorney General to review how marijuana is scheduled under federal law. As part of its analysis in response to this request, HHS considered whether DEA’s test for determining if a drug has a CAMU was consistent with the text of the CSA. HHS Response at 5–6. HHS agreed that if a drug met the requirements for FDA approval or DEA’s five-part test, the drug would have a CAMU. *Id.* at 8. But it concluded that it would be inconsistent with the text and purpose of the CSA for those standards to be the “sole basis for determining whether a substance has a [CAMU].” *Id.* at 7.

HHS’s analysis instead relied on an additional, two-part inquiry for considering whether a drug has a CAMU. Part 1 of HHS’s inquiry focuses on the extent and nature of medical use. It asks whether there is “widespread current experience with medical use of the substance in the United States by licensed health care practitioners . . . operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” HHS Part 1 Analysis Memo at 1. HHS further identifies several factors to consider in undertaking this analysis, none being dispositive on its own—specifically, (1) “[w]hether a substantial number of licensed health care practitioners

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have gained clinical experience with at least one specific medical use of the substance under existing and implemented state-authorized programs,” *id.* at 3; (2) “[w]hether a substantial number of entities that regulate the practice of medicine recognize at least one specific medical use of the substance,” *id.*; and (3) “[w]hether licensed health care practitioners’ clinical experience with the medical use of the substance is of sufficient extent and duration to help evaluate potential clinical uses and longer term toxicities and potential harms of the substance when used under medical supervision,” *id.* at 5.

Part 2 of HHS’s test focuses on the scientific basis for any identified medical use. It asks whether there is “some credible scientific support for at least one medical use of the substance for which Part 1 is met.” *Id.* at 2. According to HHS, although again not dispositive, factors that count in favor of the conclusion that some credible scientific support exists include (1) whether “favorable clinical studies of the medical use” of the drug, although not FDA approval-level studies, “have been published in peer-reviewed journals” and (2) whether “[q]ualified expert organizations (e.g., academic or professional societies, government agencies) have opined in favor of the medical use or provided guidance to practitioners on the medical use.” Ctr. for Drug Evaluation & Rsch., FDA, *Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act* at 4 (Aug. 28, 2023) (“HHS Part 2 Analysis Memo”). By contrast, factors weighing against the conclusion that such credible scientific support exists include (1) whether “data or information indicates that medical use of the substance poses unacceptably high safety risks for the likely patient population, e.g., due to toxicity concerns”; (2) whether “clinical studies with negative efficacy findings for the medical use have been published in peer reviewed journals”; and (3) whether “qualified expert organizations (e.g., academic or professional societies, government agencies) have recommended against the medical use of the substance.” *Id.* at 4–5.

Applying this two-part inquiry, HHS concluded that marijuana has a CAMU. *Id.* It found that Part 1 of its inquiry was satisfied because more than 30,000 licensed health care practitioners across 43 jurisdictions are authorized to recommend the use of marijuana for more than six million registered patients for at least 15 medical conditions. HHS Part 1 Analysis Memo at 1. HHS also found that Part 2 of its inquiry was satisfied. *See*

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HHS Part 2 Analysis Memo at 7. Although noting that no professional medical organization currently recommends use of marijuana (and that one recommends against its use), HHS concluded after reviewing several studies that there was some credible scientific support that marijuana could be used to effectively treat pain, anorexia, and nausea and vomiting and that using medical marijuana to treat these conditions did not pose “unacceptably high safety risks.” *Id.* at 7. Consistent with this conclusion, and in light of other findings it made, HHS recommended to DEA that marijuana be placed in Schedule III of the CSA.

II.

As discussed above, DEA currently concludes that a drug has a CAMU only if FDA has approved the drug under the FDCA or the drug meets DEA’s five-part test. 57 Fed. Reg. at 10,505–06. HHS agrees with DEA that FDA approval and DEA’s five-part test are sufficient to establish that a drug has a CAMU, *see* HHS Response at 8, and we also agree. To receive FDA approval, a drug must satisfy “rigorous testing and safety reviews” showing that the drug is “both safe and effective.” *Sadoz Inc. v. Becerra*, 57 F.4th 272, 282 (D.C. Cir. 2023). And the entire purpose of FDA’s rigorous approval process is to identify drugs that can be safely and effectively used to treat medical conditions. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133–34 (2000). It would thus make no sense to keep a drug that has met—or could meet—FDA’s standards on Schedule I, which would prevent the drug from being used to treat medical conditions. *See* 21 U.S.C. §§ 829, 841–43.

HHS argues, however, that DEA’s approach to CAMU is impermissibly narrow and that HHS’s two-part inquiry is a permissible way to establish that a drug has a CAMU. You have asked whether, if a drug satisfies the two-part inquiry employed by HHS, that establishes that the drug has a CAMU regardless of whether the drug has been approved by FDA or satisfies DEA’s five-part test. For the reasons that follow, we agree with HHS and conclude that limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA’s five-part test is an impermissibly narrow interpretation of section 812(b) and that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU.

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Section 812(b) requires the Attorney General (and thus DEA), in making scheduling decisions under the CSA, to determine whether a drug has a “currently accepted medical use in treatment in the United States.” It is hard to square DEA’s exclusive reliance on FDA approval and its five-part test with this language.

To begin, DEA’s approach conflicts with the text of section 812(b) by ignoring a wide range of activity that is plainly relevant to whether a drug meets the statutory standard. At the time the CSA was adopted (and as is still true today) the word “accepted” meant “widely used or found” or “generally approved.” *Accepted*, Webster’s Third New International Dictionary 11 (1971); *see also Accepted*, The American Heritage Dictionary of the English Language 8 (1970) (“Generally approved, believed, or recognized.”); *Accepted*, Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/accepted> (last visited Apr. 2, 2024) (defining “accepted” to mean “regarded favorably” or “generally approved or used”). And the focus on “medical use” suggests that the relevant inquiry is whether the medical community has accepted that a drug has a “use in treatment.” 21 U.S.C. § 812(b)(1)(B).

Any examination of whether the medical community “accept[s]” that a drug has a “use in treatment,” *id.*, naturally requires an examination of what licensed health care practitioners are actually doing. Practitioners treat patients, after all, and their treatment decisions and clinical experience with a drug (where such experience exists) provide important evidence in determining whether a medical use is accepted. Moreover, an understanding of what the medical community accepts would also naturally require consideration of the views of the principal regulators of the medical profession: state entities that license and police healthcare practitioners. As the Supreme Court has noted, the CSA “presume[s] and rel[ies] upon a functioning medical profession regulated under the States’ police powers.” *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

But neither FDA approval nor DEA’s five-part test examines whether health care practitioners are actually using a drug to treat a condition or whether the entities regulating those practitioners allow the drug to be so used. Instead, FDA approval and DEA’s five-part test rely exclusively on certain scientific evidence and the views of some experts and FDA. Simp-

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ly put, ignoring widespread clinical experience with a drug that is sanctioned by state medical licensing regulators when evaluating whether a drug has a CAMU is at odds with the plain meaning of section 812(b).⁵

Limiting the CAMU analysis to whether a drug has been approved by FDA or meets DEA’s five-part test also conflicts with the text of section 812(b) by erroneously equating identification of an “accepted” medical use under the CSA with the “approval,” or potential approvability, of the drug under the FDCA. Under the CSA, a substance can only be placed on Schedule I if it lacks *both* a “currently accepted medical use in treatment in the United States” *and* an “accepted safety for use . . . under medical supervision.” 21 U.S.C. § 812(b)(1)(B), (C). By contrast, “the FDCA does not even mention the term ‘medical use,’” *Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987), and under the FDCA approval can be denied *either* because the drug is unsafe *or* because it is ineffective, *see* 21 U.S.C. § 355(d)(2), (5). FDA may also deny approval for several other reasons that have nothing to do with medical use, including that the application did not contain the necessary patent information, *see id.* § 355(d)(6), or that the methods used to manufacture, process, and pack the drug “are inadequate to preserve its identity, strength, quality, and purity,” *id.* § 355(d)(3).

Moreover, other CSA provisions confirm that a drug having a CAMU is distinct from it being approved (or approvable) by FDA. Among other things, the CSA elsewhere repeatedly refers to, and in some places explicitly relies on, the FDCA. As an example, 21 U.S.C. § 829 prohibits the dispensing of “prescription drug[s] as determined under the [FDCA]” that are controlled under Schedules II through IV without a prescription from a practitioner, subject to certain exceptions. *See also, e.g., id.* §§ 811(g)(1), 825(e). Congress’s decision to explicitly invoke the FDCA’s standards with respect to some parts of the CSA, but not with respect to whether a drug has a CAMU, strongly suggests that it did not mean to equate CAMU with the standards necessary for FDA approval.

⁵ The First Circuit’s decision in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), is not to the contrary. *Grinspoon* rejected the argument that Congress meant to privilege the views of “certain members of the medical community” in determining if a drug has a CAMU. *Id.* at 892. The court did not consider, however, the broader understanding of the relevant inquiry that we offer here—i.e., whether the medical community as a whole, including practitioners and regulators (among others), has “accepted” that a drug has a “medical use in treatment.” 21 U.S.C. § 812(b)(1)(B).

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Amendments to the CSA reinforce this conclusion. Congress added the “emergency scheduling” provision to the CSA in 1984. Pub. L. No. 98-473, § 508, 98 Stat. 1837, 2071–72 (1984) (codified as amended at 21 U.S.C. § 811(h)). That provision allows the Attorney General to place certain substances in Schedule I on a temporary basis without following the normal scheduling criteria if “necessary to avoid an imminent hazard to the public safety.” 21 U.S.C. § 811(h). But this authority does not apply where an “exemption or approval is in effect for the [drug] under section 505” of the FDCA—i.e., where FDA allows the drug to be marketed in interstate commerce. *See id.*; *see also* Controlled Substances Analogue Enforcement Act of 1986, Pub. L. No. 99-570, tit. I, subtit. E, 100 Stat. 3207, 3207-13 to -14 (codified as amended at 21 U.S.C. § 801(32)) (exempting drugs that have been approved by FDA from the definition of controlled substance analogue). As the First Circuit has observed, these provisions demonstrate that “absolute reliance on the absence of FDA approval” outside of these limited contexts “would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA.” *Grinspoon*, 828 F.2d at 890.

We recognize that our conclusion that DEA cannot rely exclusively on FDA approval or its five-part test in determining whether a drug has a CAMU is in some tension with the D.C. Circuit’s decisions in *ACT I* and *ACT II*. The record in those cases, however, was materially different from the one contemplated by HHS’s two-part inquiry: the petitioners in *ACT I* and *ACT II* had shown that, at most, a “number of physicians believe[d] that marijuana is medically useful”—evidence that the court twice said was “anecdotal.” *ACT I*, 930 F.2d at 939; *see also id.* (describing petitioner’s evidence as “largely anecdotal”). Indeed, although the court noted that it “ha[d] no grounds” on the record before it “to dispute [DEA’s] premise that without much more complete scientific data American physicians will not ‘accept’ marijuana,” it further observed that DEA’s conclusion would be “more vulnerable” if “virtually all doctors in the United States were vociferous in their espousal of marijuana for medical treatment—notwithstanding scientific uncertainties.” *Id.*; *see also ACT II*, 15 F.3d at 1134–35 (holding that DEA’s interpretation of “currently accepted medical use” was reasonable on law of the case grounds).

In other words, neither *ACT I* nor *ACT II* assessed DEA’s approach in the circumstance envisioned by HHS’s two-part inquiry—where there is

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“widespread current experience with medical use of” a Schedule I drug in the United States by licensed health care practitioners “operating in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine.” HHS Part 1 Analysis Memo at 1. To the contrary, the D.C. Circuit suggested that such circumstances might never occur, as one of its reasons for rejecting DEA’s original eight-part test was that it “appear[ed] impossible” for a Schedule I drug to meet the requirement that there be “[r]ecognition and use of the [drug] by a substantial segment of the medical practitioners in the United States.” *ACT I*, 930 F.2d at 938, 940. Yet with respect to at least one drug—marijuana—subsequent events have shown that a drug can be in Schedule I but still be recommended for medical use by a large number of medical practitioners in the United States. And for the reasons we have explained, when these circumstances exist, the plain text of section 812 mandates that they be taken into account when determining whether a drug has a CAMU.

B.

Having explained why DEA’s construction of the phrase “currently accepted medical use in treatment in the United States” is impermissibly narrow, we turn to why HHS’s two-part inquiry is sufficient to determine whether a drug has a CAMU.

1.

Part II.A explained that, to determine if a drug has a CAMU, section 812(b) requires an analysis of whether, at the present time, the medical community widely understands that a drug has a “use in treatment in the United States.” Although there is no single right answer as to *how* specifically DEA should make this determination, the text of the CSA establishes certain basic parameters to guide the inquiry.

As an initial matter, the definitions discussed above indicate that “accepted” means that something is “*widely* used or found” or “*generally* approved.” *Accepted*, Webster’s Third New International Dictionary 11 (emphasis added). It therefore follows from the word’s plain meaning that “anecdotal evidence” that a “number of physicians believe that [a drug] is medically useful” is not enough to show that the medical community has

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accepted that a drug has a use in treatment in the United States. *ACT I*, 930 F.2d at 939. At the same time, however, “accepted” does not require universal consensus. Rather, it is sufficient if there is a widespread understanding in the medical community that a drug has a use in treatment.

Relatedly, nothing in the text of the CSA suggests that establishing that a drug has a CAMU requires the medical community to believe that the drug is the best way to treat a condition. So long as there is widespread understanding in the medical community that a drug is a permissible and reasonable way to treat a condition, it has a CAMU. That reflects a basic reality about the medical profession: that “in medicine there is often a range of reasonable treatments[.]” *Young v. United States*, 942 F.3d 349, 352 (7th Cir. 2019).

Moreover, the medical community is not a monolith: It contains individuals and entities with a range of expertise and experiences, including licensed health care practitioners who specialize in certain areas of medicine, generalists with broader expertise, researchers, and regulators. In assessing the views of the medical community, section 812(b)(1)(B)’s emphasis on a “medical use in treatment” indicates that the views of all these constituencies are not equally important in every case. Instead, to determine whether the medical community understands using a particular drug to be within the range of reasonable treatment options, it is the views and practices of the health care practitioners who actually treat a given condition, as well as the regulators charged with enforcing applicable norms of practice, that are often especially relevant.

Finally, we believe a CAMU test must include consideration of the scientific evidence that supports the relevant medical use. This follows from section 811(c)’s requirement that the Attorney General “shall consider” eight factors in making the CAMU determination and other findings under section 812(b), some number of which inherently require consideration of scientific evidence. Although it is unclear exactly how the eight factors listed in section 811(c) correlate to the findings required by section 812(b), it is plain that at least two of those factors—the “scientific evidence of [the drug’s] pharmacological effect, if known” and the “state of current scientific knowledge regarding the drug,” 21 U.S.C. § 811(c)(2), (3)—bear on whether a drug has a currently accepted medical use, and that those factors necessarily require evaluation of scientific evidence. In addition, the requirement to consider “[w]hat, if any, risk there is to the

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public health” and the drug’s “psychic or physiological dependence liability,” *id.* § 811(c)(6), (7), further suggests that an assessment of the available science is an integral part of a CAMU determination. Reviewing the available scientific evidence as part of the CAMU analysis is also consistent with the common-sense intuition that there is an inherent connection between whether the medical community has “accepted” a drug for “use in treatment,” *id.* § 812(b)(1)(B), and the scientific evidence supporting that conclusion. We generally would not expect the medical community to understand that it is reasonable to use a drug to treat a condition unless (as HHS suggests) there is at least some scientific evidence in support of that conclusion—evidence demonstrating, for example, that the drug was effective in treating the condition or does not create unacceptably high safety risks. HHS Part 2 Analysis Memo at 4–5.

2.

We conclude that HHS’s two-part inquiry falls within the basic parameters the CSA provides for establishing that a drug has a CAMU.

Part 1 of HHS’s test requires an assessment of whether health care practitioners are recommending that patients use a drug to treat a medical condition and whether they are doing so in accordance with guidelines issued by entities that regulate the practice of medicine. This approach is consistent with our view that determining whether a drug has a CAMU requires assessing whether there is a widespread understanding in the medical community that using the drug to treat a condition falls within the range of reasonable treatment options. In particular, the actual recommendations of practitioners made under applicable regulatory guidelines constitute strong evidence of whether the medical community understands a drug to be a reasonable treatment option.

The three non-dispositive factors HHS includes in its Part 1 analysis further demonstrate why its test is sufficient. Two of HHS’s factors look, respectively, at whether a “substantial number of licensed health care practitioners” have gained clinical experience with a drug under a state-authorized program and whether a “substantial number” of entities that regulate the practice of medicine have authorized the use of a drug for medical purposes. *See* HHS Part 1 Analysis Memo at 3. In our view, these inquiries provide good evidence of whether there is widespread agreement within the medical community that using the drug would be a reasonable

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treatment option. Similarly, it is more likely that the medical community would widely understand that a drug represents a reasonable treatment option if HHS's third factor is present—i.e., that practitioners' clinical experience with the drug is of a "sufficient extent and duration" to help evaluate whether there are "potential clinical uses," "longer-term toxicities," and "potential harms." *Id.* at 5.

Moreover, Part 2 of HHS's test adequately takes the available scientific evidence into account by asking whether there is some credible scientific support for a least one of the medical uses for which the Part 1 test is met and then providing guidance as to what counts as "credible" scientific support. *See* HHS Part 2 Analysis Memo at 4 (identifying "favorable clinical studies" published in peer-reviewed journals as cutting in favor of the conclusion that the drug has a CAMU); *id.* (identifying data or information that "indicate[s] that medical use of the [drug] is associated with unacceptably high safety risks for the likely patient population" because of "toxicity concerns" as cutting against the conclusion that the drug has a CAMU). Neither section 811(c) nor section 812(b) requires a particular threshold of scientific support to conclude that a drug has a CAMU, and we believe that Part 2's requirement of some credible scientific support is sufficient in a context where health care practitioners have extensive experience with a drug and medical regulators have sanctioned the drug's use. Such clinical experience and regulatory sanction provide alternative sources of information about a drug, thereby making it reasonable not to require the high level of scientific support that might be demanded before a new and untried drug is determined to have a CAMU.

DEA's main concern with HHS's two-part inquiry is that it places too much emphasis on state regulatory decisions. Specifically, DEA suggests that HHS's emphasis on states is "misplaced" because, in DEA's view, the processes states follow for enacting legislation "are generally less rigorous than the requirements placed on federal agencies when they act pursuant to the APA." DEA Response at 11. But there is nothing in the text of the CSA that would warrant categorically discounting state practice in this fashion, particularly since doing so would be inconsistent with both the role of states as the central regulators of medical practice, *see Oregon*, 546 U.S. at 270, 274–75, and the fact that they are afforded "great leeway" in adopting measures to "protect public health and safety," *Mackey v. Montrym*, 443 U.S. 1, 17 (1979). Indeed, Congress has already

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recognized the importance of states' views on whether marijuana in particular may be used to treat medical conditions by annually adopting an appropriations rider that prohibits the Department of Justice from using funds to prevent certain states, territories, and the District of Columbia from implementing their own laws with respect to medical marijuana. *See supra* Part I.C.

In addition, states do often look to scientific and medical judgment in regulating medical marijuana. States typically only allow medical practitioners to recommend medical marijuana to treat specific conditions. *See, e.g.*, Ohio Rev. Code § 3796.01(A)(6)(a)–(v); N.Y. Cannabis Law § 3(18). In some states, practitioners may only recommend the use of medical marijuana after determining that the patient suffers from one of those conditions and that the “potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use.” *E.g.*, Conn. Gen. Stat. § 21a-408c(a); *see also* Fla. Stat. § 381.986(4). Several states have also established processes through which experts can recommend additions to, or removals from, the list of conditions that marijuana may be used to treat, *see, e.g.*, Conn. Gen. Stat. § 21a-408l(a), (c)(1), (d); Or. Admin. Rule 333-008-0090(3)(e), (4)(a)—indeed, HHS has informed us that 17 jurisdictions have added conditions that may be treated with marijuana using such processes, *see* HHS Part 1 Analysis Memo at 4. In short, it is simply not the case that state practice concerning medical marijuana is completely divorced from scientific and medical assessment.

III.

As discussed above, the CSA authorizes the Attorney General to place drugs in particular schedules if, after a formal rulemaking, the Attorney General makes certain findings. A particularly important finding is whether a drug has a CAMU, as the Attorney General may only keep or place a drug in Schedule I if it lacks a CAMU. Before initiating a rulemaking proceeding to schedule or reschedule a drug, however, the Attorney General is required to request recommendations from the Secretary that must include whether the drug has a CAMU. *See* 21 U.S.C. § 811(b). The CSA further makes these recommendations binding “as to” certain “scientific and medical matters.” *Id.*

Since HHS has recommended that marijuana has a CAMU, you have asked about the extent to which the “scientific and medical matters” that

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are binding on the Attorney General, and thus DEA, include HHS's CAMU recommendation or any scientific and medical determinations underlying that recommendation. For the reasons that follow, we conclude, first, that HHS's overall CAMU recommendation is not binding on DEA. Second, we conclude that the scientific and medical determinations that underlie HHS's CAMU recommendation are binding, but only until the initiation of formal rulemaking proceedings. Once DEA initiates formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to accord HHS's scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process.

A.

We first explain why HHS's overall CAMU recommendation does not bind DEA, starting with the two CSA provisions that govern the CAMU determination. Section 811(a) authorizes the Attorney General to schedule or reschedule a drug if the Attorney General makes certain findings "on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the APA]." Section 812(b) then lays out the relevant findings the Attorney General must make to schedule a drug, including whether the drug has a CAMU.

Taken together, these two provisions commit exclusively to the Attorney General the ultimate responsibility for making the findings required to schedule a drug, including a CAMU finding, and neither mentions the Secretary at all. Instead, the role of the Secretary is addressed in a separate provision of the CSA, section 811(b), which reads as follows:

The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The

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recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

This provision makes clear that the Secretary plays a crucial role in the scheduling process. It expressly directs the Attorney General to obtain a scheduling recommendation from the Secretary before initiating the scheduling process and to treat as binding certain “scientific or medical matters.” *Id.*⁶ But section 811(b) does not so much as mention the Secretary’s

⁶ In two recent rulemakings, DEA has stated that HHS’s scientific and medical recommendations only bind DEA with respect to factors (1), (4), and (5) of section 811(c). See 86 Fed. Reg. 29,506, 29,507–08 (June 2, 2021); 86 Fed. Reg. 27,803, 27,805 (May 24, 2021). This view appears to be based on a contrast in section 811(b)’s text: it directs the Secretary to “consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of [section 811(c)],” and “any scientific or medical considerations involved in paragraphs (1), (4), and (5) of [section 811(c)],” with the Secretary’s recommendations being “binding . . . as to such scientific and medical matters.” But section 811(b) highlights the “scientific and medical considerations” in factors (1), (4), and (5) not because HHS should consider the science and medicine underlying only those factors, but rather because those factors all relate to a drug’s abuse potential, the analysis of which Congress understood as resting primarily on law enforcement considerations. See H.R. Rep. No. 91-1444, at 33–36; House Hearing at 718. By comparison, there is no need to direct HHS to consider the “scientific or medical considerations” involved with factors (2), (3), (6), (7), and (8) since those factors involve inquiries that are predominantly, if not entirely, scientific and medical in nature. We thus think it plain that HHS’s recommendations with respect to “scientific and medical matters” are binding for all eight factors listed in section 811(c). See H.R. Rep. 91-1444, at 33; see also *id.* at 22–23 (“[A]ll scientific and

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CAMU recommendation. Instead, section 811(b) expressly identifies a different circumstance in which the Secretary’s recommendation concerning an ultimate scheduling determination is dispositive: when the Secretary recommends against controlling a drug. This fact—that section 811(b) identifies a separate scheduling recommendation as binding—makes its silence on the Secretary’s CAMU recommendation all the more conspicuous.

Moreover, we do not believe the Secretary’s authority to bind the Attorney General with respect to “scientific and medical matters” encompasses a CAMU determination, because such a determination involves judgments that are neither wholly scientific nor wholly medical. For example, as the discussion in Part II indicates, assessing whether a drug has a CAMU may involve, in part, determining whether the extent of medical use present is sufficient to qualify as “accepted” within the medical community. 21 U.S.C. § 812(b)(1)(B). This inquiry is more akin to the application of a legal standard to a set of facts than a judgment necessarily requiring medical or scientific expertise, as it could turn (at least in part) on reasoning or facts that are neither scientific nor medical in nature, such as determining how many states have authorized use of a drug in treating a medical condition. *Cf., e.g., United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) (conclusions that are the “product of reasoning processes familiar to the average person in everyday life” do not require specialized expertise); *accord United States v. Vega*, 813 F.3d 386, 394–95 (1st Cir. 2016) (conclusions based on “logic and pattern recognition” do not require specialized expertise). Because a CAMU determination can include elements that fall outside the substantive scope of HHS’s authority to bind DEA, HHS’s overall determination that a substance has (or lacks) a CAMU cannot be binding.

B.

We next explain why the scientific and medical determinations underlying HHS’s overall CAMU recommendations bind DEA, although only until the initiation of formal rulemaking, and why DEA is nonetheless obligated to accord the findings significant deference thereafter.

medical determinations [will be] made by the Secretary of Health, Education, and Welfare[.]” (emphasis added)).

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As a threshold matter, the text and legislative history of section 811(b) demonstrate that the “scientific and medical matters” binding on the Attorney General include the scientific and medical determinations that underlie the Secretary’s CAMU recommendation. *See* H.R. Rep. No. 91-1444, at 33; HHS Response at 10; DEA Response at 16. For example, whether some credible scientific support exists for a particular widespread clinical use, *see supra* Part I.C, is undoubtedly relevant to a CAMU finding—and undoubtedly a “scientific and medical matter.”

The more difficult question, however, is whether HHS’s scientific and medical determinations remain binding throughout the scheduling process—a question on which DEA and HHS hold sharply different views. DEA argues that it “is only bound by HHS’s evaluation as to scientific and medical matters . . . at the beginning of the [scheduling] process,” but “[o]nce rulemaking has begun, DEA can—and must—consider material submitted during the administrative process in reaching a final scheduling determination.” DEA Response at 13; *see also* 76 Fed. Reg. 77,330, 77,334–36 (Dec. 12, 2011) (adopting this position). HHS takes the opposite view, arguing that its scientific and medical recommendations bind DEA throughout the scheduling process, including the formal rulemaking. *See* HHS Response at 10–11.

The CSA is unquestionably hard to parse on this issue. It does not expressly address for what portion of the administrative proceedings HHS’s determinations are binding, nor does it specify how, if at all, such determinations must be considered during the formal rulemaking proceedings. Moreover, what clues the statute does offer point in two opposing directions: On the one hand, the statute requires the Attorney General alone to make the ultimate findings required for scheduling after an on-the-record formal rulemaking, which implies that the Attorney General must consider contrary scientific or medical evidence submitted during that process. *See* 21 U.S.C. § 811(a). On the other hand, the statute makes the Secretary’s scientific and medical determinations “binding” on the Attorney General without expressly limiting the binding nature of those determinations to any particular stage of the scheduling process. *See id.* § 811(b).

Although a close question, we think Congress’s decision to make scheduling decisions subject to a formal rulemaking process ultimately provides the answer. Fundamentally, the proposition that HHS’s determinations bind DEA for the entirety of the scheduling process cannot be

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squared with the nature of the formal rulemaking that section 811(a) requires. Nothing in the CSA limits outside participants to submitting only nonscientific and nonmedical evidence at a rulemaking hearing. Given the possibility that parties may submit contrary scientific or medical evidence, construing section 811(b) to preclude DEA from considering such evidence would be inconsistent with the APA's requirement that rules issued via formal rulemaking be based "on consideration of the whole record . . . and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d); see *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951) ("The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirement . . . [to] consider the whole record."). In short, DEA would not be making a decision based on the "whole record" and "in accordance with the reliable, probative, and substantial evidence," 5 U.S.C. § 556(d), if HHS's determinations barred DEA from considering contrary scientific or medical evidence. Two courts of appeals have suggested in dicta that they view the issue similarly. See *Grinspoon*, 828 F.2d at 890; *Reckitt & Colman, Ltd. v. Administrator, DEA*, 788 F.2d 22, 27 n.8 (D.C. Cir. 1986).

The fact that HHS's recommendations as to certain "scientific and medical matters" do not bind DEA for the entire scheduling process does not mean, however, that they are without effect. Rather, in order to give force to the statutory command that HHS's recommendations "bind[]" DEA, we believe HHS's scientific and medical determinations must be binding until the issuance of a notice of proposed rulemaking ("NPRM"). Up to this point, the formal rulemaking procedures required by section 811(a) are not yet in effect, see 21 C.F.R. §§ 1308.43(f), 1316.42(g), meaning there is no conflict between the statutory commands to consider contrary evidence in the record and accord binding effect to HHS's recommendations.

In addition, DEA may not simply cast aside HHS's scientific and medical recommendations once it initiates formal rulemaking proceedings by issuing an NPRM. The categorical use of the word "binding" in section 811(b) suggests that Congress intended HHS's scientific and medical views to at least be a very significant input in the scheduling process. And there would seem to be little reason to make the HHS's views binding at any stage in the process if DEA eventually could discard HHS's determi-

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nations and review scientific and medical matters *de novo*. Cf. *Reno v. Am.-Arab Anti-Discrimination Comm.*, 525 U.S. 471, 487 (1999) (statutes should be read in a manner that “makes sense of the statutory scheme as a whole”).

The legislative history of the CSA supports the view that HHS’s scientific and medical determinations should remain significant throughout the rulemaking process. The House report on the CSA states that Congress intended “all scientific and medical determinations” to be “made by the Secretary,” rather than the Attorney General, and nothing in the legislative history suggests that the Attorney General would be free to make *de novo* scientific and medical judgments once the formal rulemaking is underway. H.R. Rep. No. 91-1444, at 22–23. Indeed, the House report emphasized that section 811 was “not intended to authorize the Attorney General to undertake or support medical and scientific research” for the purpose of scheduling, as that research “is within the competence of [HHS].” *Id.* at 33. And considering this same legislative history, the Supreme Court noted in *Gonzales* that the CSA places “medical judgments” made under the Act in the “hands of the Secretary.” 546 U.S. at 265.

We therefore conclude that, to give proper effect to HHS’s scientific and medical determinations, DEA must continue to accord significant deference to those determinations even once formal rulemaking has commenced and may not undertake a *de novo* assessment of HHS’s findings at any point in the rulemaking process.

IV.

The Single Convention requires parties to impose controls on the cultivation, manufacture, and distribution of various drugs, including “cannabis.”⁷ Among other things, parties to the Convention generally must

⁷ The Convention defines “cannabis” as “the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.” Single Convention art. 1(1)(b). We understand the marijuana in use in the United States to fall within this definition, although the definition of cannabis under the Single Convention is slightly less inclusive than the CSA’s definition of “marihuana,” which includes all parts of the *Cannabis sativa* L. plant with certain exceptions, including mature stalks and sterilized seeds that are incapable of germination. *See* 21 U.S.C. § 802(16).

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require that manufacturers, distributors, importers, and exporters of cannabis secure a license, Single Convention arts. 29–31; impose quotas on the import and manufacture of cannabis, *id.* art. 21(1); generally prohibit the unauthorized possession of cannabis, *id.* art. 33; and adopt penal provisions making violations of the controls required by the Convention punishable offenses, *id.* art. 36.

Several provisions of the CSA—including sections 801(7), 811(d)(1), 812(b), 823(a), 953(a), and 958(a)—“reflect Congress’s intent to comply with the obligations imposed by the Single Convention.” *Control of Papaver bracteatum*, 1 Op. O.L.C. 93, 95 (1977). Of particular relevance here, section 811(d)(1) provides:

If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures described by subsections (a) and (b) of this section.

The Single Convention entered into force for the United States on June 24, 1967, and was thus “in effect on October 27, 1970.” *Id.* Both our Office and the D.C. Circuit have interpreted section 811(d)(1) to apply to any scheduling action by the Attorney General concerning a drug covered by the Single Convention, including actions to transfer a drug between schedules. Memorandum for John E. Ingersoll, Director, Bureau of Narcotics & Dangerous Drugs, from Mary C. Lawton, Deputy Assistant Attorney General, Office of Legal Counsel, *Re: Petition to Decontrol Marijuana; Interpretation of Section 201 of the Controlled Substances Act of 1970* at 9 (Aug. 21, 1972) (“Lawton Memo”); *NORML II*, 559 F.2d at 747.

Given this, your third question asks whether the CSA or the Single Convention requires marijuana to be placed in Schedule I or Schedule II. This question is one our Office has considered before: in 1972, we concluded that the Convention requires marijuana to be placed in Schedule I or II because placing marijuana in Schedules III, IV, or V would not enable the United States to satisfy its Convention obligations. *See* Lawton Memo at 12–13. In particular, we emphasized that the “quotas on manu-

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facture and importation of a substance required by the Convention could not be maintained under existing statutory authority were marijuana listed in Schedules III, IV, or V.” *Id.*; see also *NORML II*, 559 F.2d at 750–51 (agreeing with the Lawton Memo that Schedule I or II was necessary to meet the United States’ Single Convention obligations). In reaching this conclusion, however, we did not address an issue that both HHS and the State Department now ask us to consider: whether under the CSA the United States can comply with its Single Convention obligations by placing marijuana in Schedule III while “adopting such additional regulations as are necessary for treaty compliance.” HHS Response at 13; State Response at 5–7; see also *NORML II*, 559 F.2d at 752–53 (recognizing the possibility of a similar regulatory approach but taking no position on its availability).

We think this question is a close one. For the reasons that follow, however, we believe that the Single Convention does not require DEA to place marijuana in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific controls that follow from a drug’s placement on a particular schedule. And consistent with this conclusion, we believe DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional controls pursuant to the CSA’s regulatory authorities.

A.

To begin, nothing in the Single Convention requires the United States to comply with its international obligations by placing a drug in a statutory “schedule” that specifically authorizes all the necessary restrictions. To the contrary, the Single Convention states that parties will implement the Convention using both “laws and *regulations*.” Single Convention art. 18(1)(b) (emphasis added); see also *id.* art. 4 (referring to the use of “legislative and *administrative measures*” to carry out the Single Convention (emphasis added)). The Single Convention thus appears to explicitly contemplate a scenario in which DEA decides to implement the United States’ obligations through a combination of scheduling and regulatory actions.

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As a result, any limitation on satisfying the United States' Single Convention obligations by supplementing a scheduling decision with regulatory action would have to come from domestic law. Nothing in the CSA, however, states that a drug must be placed into Schedule I or II, or any other particular schedule, to comply with the Single Convention. Nor does the CSA expressly foreclose DEA from satisfying the United States' international obligations with a combination of scheduling and regulatory actions. Rather, section 811(d)(1) directs the Attorney General to “control[]” a drug “under the schedule [the Attorney General] *deems most appropriate*” (emphasis added)—language that signals a broad grant of discretion to the Attorney General (and thus DEA), *see Rex Chainbelt, Inc. v. Volpe*, 486 F.2d 757, 761 (7th Cir. 1973). To be sure, the very same language could be read to mean that DEA must select a schedule without resort to regulatory supplementation. *See* 21 U.S.C. § 802(5) (defining “control” as “to add a drug . . . to a *schedule*” (emphasis added)). But we are reluctant to adopt a restrictive reading of such broad discretionary language, particularly when doing so would preclude DEA from relying on regulatory supplementation to close even relatively minor gaps between a schedule and the United States' international obligations. Indeed, consistent with this reading, DEA has previously placed a drug with the psychoactive chemicals found in cannabis into Schedule V and then imposed additional controls through regulation to comply with the United States' international obligations. *See* 83 Fed. Reg. 48,950, 48,952 (Sept. 28, 2018).⁸

The CSA's varied, and potentially conflicting, purposes further show why it is appropriate to read section 811(d)(1)'s broad grant of authority in this way. Consider a hypothetical case in which the Single Convention imposes obligations that DEA determines would, absent regulatory action,

⁸ We have taken a similar interpretive approach to section 811(d)(1)'s language specifying that the Attorney General meet international obligations “without regard” to the findings and procedures otherwise required by sections 811(a) through (b) and 812(b). Rather than viewing this language as precluding the Attorney General from following ordinary scheduling practices when international obligations are involved, both our Office and the D.C. Circuit have understood it to allow the Attorney General to identify which schedules would satisfy the United States' international obligations with respect to a particular drug, and then—if more than one schedule would do so—select which schedule to use through the section 811(a) through (b) and 812(b) procedures. Lawton Memo at 10; *accord NORML II*, 559 F.2d at 747.

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require placement on Schedule I or Schedule II, but DEA has also determined that the same drug’s abuse potential, medical usefulness, and health effects warrant placing the drug in Schedule III. *See* 21 U.S.C. §§ 801(1), (2), 812(b)(3). In such a circumstance, reading section 811(d)(1) to allow for consideration of regulatory action allows DEA to conclude that Schedule III is the “most appropriate” schedule by pairing that choice with regulatory actions that ensure compliance with the Single Convention. This enables DEA to comply with the United States’ international obligations while furthering the CSA’s other purposes, thus fulfilling both sets of objectives.

The broad regulatory authority provided by the CSA further suggests that DEA need not rely on scheduling decisions alone to comply with the Single Convention. The CSA authorizes the Attorney General (and thus DEA) both to “promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances,” *id.* § 821, and to “promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions,” *id.* § 871(b). Courts recognize that broad, discretionary language such as this conveys “extensive” regulatory authority, *Volpe*, 486 F.2d at 761; *see also, e.g., Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1209 (D.C. Cir. 2020)—and, here, the language by its plain terms would seem to encompass regulatory actions that DEA may take to satisfy Single Convention obligations not met by a drug’s schedule alone.

Likewise, the CSA provides the Attorney General with a number of more specific regulatory authorities that DEA may use to enable compliance with particular Single Convention obligations, such as the CSA’s registration requirements. Subject to certain limited exceptions, section 822(a) requires “[e]very person who manufactures or distributes” or “dispenses” a drug to “obtain annually a registration issued by the Attorney General in accordance with rules and regulations promulgated by him,” and section 822(b) further specifies that “[p]ersons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . to the extent authorized by their registration.” These provisions give DEA the authority to impose a number of controls on a particular drug through registration. Other CSA

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provisions provide similar regulatory authority that could enable a drug on a schedule other than Schedule I or Schedule II to comply with the Single Convention. *See, e.g.*, 21 U.S.C. §§ 823(e), (f), 827(e), 952(b)(2), 953(e)(2), 958(c).

Finally, past practice also supports our conclusion. Specifically, in addition to the example recounted above of DEA imposing additional controls through regulation to comply with the United States' international obligations, *see* 83 Fed. Reg. at 48,952, we understand that DEA previously has relied on a combination of the Attorney General's registration power and general regulatory authority to promulgate extensive safety and security regulations that govern manufacturers and distributors of controlled substances. *See* 21 C.F.R. §§ 1301.71–.77. And our Office has previously read the Attorney General's authority to register manufacturers broadly to permit the imposition of certain controls that would enable compliance with the Single Convention. *See Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs*, 42 Op. O.L.C. ___, at *24 (June 6, 2018) (“*Licensing Marijuana Cultivation*”). These prior regulatory actions indicate that the broad and varied provisions discussed above provide authority that may be used to impose additional controls to satisfy the United States' international obligations.

We recognize that reading the CSA as allowing DEA to use regulatory authorities to close gaps in our compliance with international obligations could be viewed as in tension with certain aspects of the CSA's text and structure. As the Lawton Memo noted, several provisions of the CSA implementing controls required by the Single Convention draw a distinction between Schedules I and II, on the one hand, and Schedules III through V, on the other, in a manner that can be read to suggest that Congress understood the United States would comply with its Convention obligations by placing drugs into Schedules I or II. Lawton Memo at 12; *see, e.g.*, 21 U.S.C. §§ 823(a), (d), (e), 826(a), 842(b), 952(a), (b), 958(a), (c). Moreover, Congress designed the CSA to include five schedules, each with a distinct bundle of requirements and consequences, and allowing DEA to add or subtract controls would arguably have the practical effect of enabling DEA to create new schedules.

These arguments have some force, but they do not carry the day. Since the CSA's enactment, Congress has amended the Act in a manner that indicates the distinction between Schedules I and II and Schedules III

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through V may not be as sharp as the argument above suggests. *See infra* Part IV.B (describing how amendments that added sections 952(b)(2), 953(e)(2), and 827(e) enable the United States to meet certain Single Convention obligations while placing nonnarcotic drugs in Schedule III). In any event, right alongside the provisions that could *impliedly* suggest Schedules I and II will be used to comply with the United States’ Single Convention obligations are provisions that *expressly* grant the Attorney General (and thus DEA) both broad discretion to select the schedule “most appropriate” to satisfy the United States’ international obligations, *see* 21 U.S.C. § 811(d)(1), and broad regulatory authority, *see, e.g., id.* §§ 821, 871(b). And given the plain meaning of the CSA’s regulatory provisions, we do not believe that the CSA’s five-schedule structure can be reasonably understood to preclude DEA from taking at least some regulatory actions to comply with the United States’ international obligations. Indeed, it would be particularly strange to view DEA as so constrained in the context of treaty compliance, given section 811(d)(1)’s express grant of broad discretion to meet international obligations. We therefore believe that something more than such textual and structural inferences are needed to foreclose use of these broad and express statutory grants of regulatory authority to impose additional controls to meet the United States’ international obligations.

Thus, while we take no position on the full extent to which DEA may use the CSA’s broad regulatory authority to impose additional controls to meet international obligations, we do not read the CSA as precluding DEA from ever satisfying the United States’ Single Convention obligations by supplementing scheduling decisions with regulatory action. Rather, we believe that the CSA provides DEA with the discretion to decide, at least in some circumstances, that such a scheduling and regulatory approach is the most appropriate way to strike a balance between the CSA’s varied—and potentially conflicting—purposes of curtailing the improper use of drugs with abuse potential, complying with the United States’ international obligations, and ensuring that medically useful drugs remain available for legitimate purposes. *See* 21 U.S.C. § 801(1), (2), (7).

*Questions Related to the Potential Rescheduling of Marijuana***B.**

We next consider the specific question of whether DEA may comply with the United States' obligations under the Single Convention by supplementing a decision to place marijuana in Schedule III with regulatory action.

As a threshold matter, we understand that, if marijuana were placed on Schedule III, the gap that DEA would need to fill would be modest. To be sure, the Lawton Memo and the D.C. Circuit expressed concern that placing marijuana into Schedule III would create compliance concerns with respect to certain Single Convention requirements. In its submission to us, however, the State Department observed that, even if marijuana were listed in Schedule III, most of the United States' Single Convention obligations would continue to be met. *See* State Response at 4–7. The State Department's view reflects amendments to the CSA that postdate the Lawton Memo (from 1972) and the D.C. Circuit's consideration of the issue (in 1977) and that specifically authorize certain controls required by the Single Convention to be placed on drugs outside Schedules I and II. Given these amendments, many of the gaps previously identified in Single Convention compliance would no longer exist if marijuana were placed in Schedule III.

In particular, the Lawton Memo and D.C. Circuit both pointed to the manufacturing and import quotas required by Article 21 of the Single Convention as potential gaps, *see* Lawton Memo at 12–13, while the D.C. Circuit also identified the estimates and statistical reports required by Articles 19 and 20 and the import and export authorizations required by Article 31(4), *see NORML II*, 559 F.2d at 751 n.71. In 1978, however, Congress enacted 21 U.S.C. § 827(e), which specifically authorizes the Attorney General, among other things, to prescribe measures necessary to comply with the reporting requirements of Articles 19 and 20 of the Single Convention for drugs in any schedule, not just those in Schedules I and II. *See* Psychotropic Substances Act of 1978, Pub. L. No. 95-633, § 104, 92 Stat. 3768, 3772. In addition, in 1984 Congress amended the CSA provisions that implement the import and export permit requirements to specifically authorize the use of permits for a nonnarcotic Schedule III drug. *See* 21 U.S.C. §§ 952(b)(2), 953(e) (enacted by the Controlled Substances Penalties Amendments Act of 1984, Pub. L. No. 98-473,

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§§ 521–522, 98 Stat. 1837, 2075–76). If marijuana, a nonnarcotic drug, were placed in Schedule III, we believe these statutory provisions would ensure compliance with both the import quota obligation of Article 21 and the import and export authorization requirements of Article 31(4).

These subsequent enactments address most of the concerns the Lawton Memo and D.C. Circuit identified, with the exception of the manufacturing quota requirements of Article 21 of the Convention. But we believe this remaining gap is addressable using the CSA’s regulatory authorities. Several different authorities appear potentially applicable. A regulation imposing a manufacturing quota on a drug would fall easily within the broad language of section 821, as it would be “relat[ed] to the . . . control of the manufacture” of a drug. 21 U.S.C. § 821. DEA likewise could deem a regulation imposing a manufacturing quota as “necessary and appropriate for the efficient execution of” the CSA function of controlling drugs to meet the United States’ international obligations. *Id.* § 871(b); *see id.* § 811(d)(1). By their plain terms, the CSA’s registration authorities would also give DEA the authority to impose a manufacturing quota on a particular drug through regulation: no person can manufacture a drug (including marijuana) without a registration issued by DEA, *see id.* § 822(a), and in that registration DEA can limit the “extent” to which any person is “authorized to . . . manufacture” marijuana under their registration, *id.* § 822(b). Section 823(e) provides yet another potential source of authority for imposing a manufacturing quota on a Schedule III drug, as DEA could conclude under section 823(e) that registrations to manufacture marijuana would be “inconsistent with the public interest” unless a quota consistent with Article 21 of the Single Convention was implemented to maintain “effective controls against diversion.” *Id.* § 823(e); *see also Oregon*, 546 U.S. at 260 (identifying similar language in section 823(a) as providing regulatory authority).⁹

⁹ We note that section 823(a) provides that the Attorney General shall register manufacturers of Schedule I and Schedule II drugs upon determining that “such registration is consistent with the public interest and *with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.*” (Emphasis added.) In *Licensing Marijuana Cultivation*, we emphasized section 823(a)’s invocation of international obligations in concluding that DEA could promulgate regulatory controls necessary to meet certain of the United States’ obligations under the Single Convention. *See* 42 Op. O.L.C. __, at *24. Although section 823(e) does not include a similar requirement to

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In concluding that the CSA provides numerous sources of authority that could be used to impose a manufacturing quota, we recognize that section 826 expressly requires manufacturing quotas for drugs in Schedules I and II.¹⁰ But that requirement should not be read as implicitly foreclosing the imposition of such quotas for drugs in Schedules III through V. As the D.C. Circuit has recognized, “a congressional mandate in one section and silence in another often suggests not a prohibition but simply a decision . . . to leave the question to agency discretion.” *Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam) (quotation marks omitted).

We therefore conclude that both the Single Convention and the CSA permit DEA to place marijuana in Schedule III while imposing additional controls, pursuant to the CSA’s regulatory authorities, to close a modest gap between the requirements of the Single Convention and the requirements that follow from placement on Schedule III.

V.

For the reasons set forth above, we conclude, first, that DEA’s current approach to determining whether a drug has a CAMU is impermissibly narrow, and that satisfying HHS’s two-part inquiry is sufficient to establish that a drug has a CAMU even if the drug has not been approved by

consider international obligations, it does require the Attorney General to consider whether registration is “inconsistent with the public interest,” 21 U.S.C. § 823(e), and complying with the United States’ international obligations is plainly in the public interest. Against this backdrop, we do not read Congress’s silence with respect to international obligations in section 823(e) as precluding DEA from relying on that section to comply with international obligations. *See Catawba County v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (per curiam).

¹⁰ Although the CSA refers to quotas on the “production” of drugs and the Single Convention to quotas on the “manufacture” of drugs, we understand the scope of these terms to largely overlap. The CSA defines “production” to include the “manufacture, planting, cultivation, growing, or harvesting of a controlled substance,” 21 U.S.C. § 802(22), and, in turn, defines “manufacture” to include the “production, preparation, propagation, compounding, or processing of a drug,” *id.* § 802(15). The Single Convention defines “manufacture” to mean “all processes . . . by which drugs may be obtained and includes refining as well as the transformation of drugs into other drugs,” Single Convention art. 1(1)(n), but excludes “the separation of . . . cannabis and cannabis resin from the plants from which they are obtained,” *id.* art. 1(1)(t).

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FDA and would not satisfy DEA’s five-part test. Second, we conclude that HHS’s overall CAMU recommendation is not binding on DEA and that the scientific and medical determinations that underlie HHS’s CAMU recommendation are binding, but only until the initiation of formal rule-making proceedings. Once DEA initiates formal rulemaking, HHS’s determinations no longer bind DEA, but DEA must continue to accord HHS’s scientific and medical determinations significant deference, and the CSA does not allow DEA to undertake a *de novo* assessment of HHS’s findings at any point in the process. Finally, we conclude that neither the Single Convention nor the CSA requires marijuana to be placed into Schedule I or II. Both the Single Convention and the CSA allow DEA to satisfy the United States’ international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention’s requirements and the specific restrictions that follow from a drug’s placement on a particular schedule. As a result, DEA may satisfy the United States’ Single Convention obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the CSA’s regulatory authorities.

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