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Separation of Drug Scheduling Powers

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ABSTRACT. Drug scheduling places substances believed to be harmful and addictive under strict federal control. In 1970, Congress enacted the Controlled Substances Act (CSA), which split drug scheduling authority between executive departments to leverage their specialized expertise. Today, the CSA grants the Department of Health and Human Services (HHS) authority over scientific aspects of drug scheduling and the Drug Enforcement Administration (DEA) jurisdiction over nonscientific, law-enforcement-related matters. However, since 1970, the separation of scheduling powers has collapsed, and law enforcement officials have assumed powers reserved for public health experts. Bureaucratic drift, where policies diverge from what lawmakers attempted to achieve, has produced redundant responsibilities and unscientific scheduling outcomes that contradict the CSA text, purpose, and legislative history.

Statutory reforms could produce a more rational and reliable system. However, many shortcomings of drug scheduling stem from misinterpreting how the CSA splits agency authority. To produce more effective and economical scheduling actions, HHS should embrace its substantial yet frequently overlooked scheduling powers, including a categorical drug control veto that can override DEA regulatory proposals, as well as a more nuanced scheduling veto, which can guide and even constrain DEA scheduling options. DEA should conserve limited law enforcement resources and maintain the separation of scheduling powers by focusing on nonscientific aspects of drug scheduling. Courts, Congress, and the White House can also play a role.

INTRODUCTION

Politics recently thrust drug scheduling into the national spotlight.[1] In 2022, following campaign promises to decriminalize marijuana, President Joseph

1. *See* Julie Tsirkin & Monica Alba, *Justice Department Takes "Major Step" Toward Rescheduling Marijuana*, NBC NEWS (May 16, 2024, 3:53 PM EDT), https://www.nbcnews.com/politics/politics-news/reschedule-marijuana-drug-joe-biden-justice-department-rcna152603

Biden started proceedings to change marijuana's legal status.[2] During the 2024 presidential election, Kamala Harris and Donald Trump made similar pledges.[3] Delivering on their promises would require drug scheduling, a process governed by the Controlled Substances Act of 1970 (CSA).[4]

This Essay analyzes the administrative and judicial misallocation of drug scheduling authority between the Department of Health and Human Services (HHS) and the Drug Enforcement Administration (DEA). By enacting the CSA, Congress recognized drug use as a complex medical and social challenge requiring scientific and law enforcement expertise. Accordingly, Congress divided scheduling powers between executive departments focused on those disciplines.[5] The Department of Health, Education, and Welfare (HEW), which

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[https://perma.cc/J2JT-35WA] (reporting on the Biden Administration's initiation of marijuana rescheduling proceedings).

2. *Statement from President Biden on Marijuana Reform*, WHITE HOUSE (Oct. 6, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform [https://perma.cc/6SGG-SK8S] (arguing that "no one should be in jail just for using or possessing marijuana").

3. *See* Hannah Harris Green, *Kamala Harris Promises Full Marijuana Legalization—Is that a Gamechanger?* GUARDIAN (Oct. 19, 2024, 10:36 EDT), https://www.theguardian.com/us-news/ng-interactive/2024/oct/19/election-harris-marijuana-legalization [https://perma.cc/FQ2P-UKXF]. Harris said she would fully legalize marijuana for nonmedical adult use. *Id.*; Bill Chappell, *Trump Plans to Revoke Many Biden Policies. Where Does that Leave Marijuana?* NPR (Nov. 11, 2024, 12:15 PM ET), https://www.npr.org/2024/11/11/nx-s1-5184119/trump-biden-marijuana-legalization [https://perma.cc/8MGZ-VZF2]; Donald J. Trump (@realDonaldTrump), TRUTH SOC. (Sept. 8, 2024, 11:18 PM), https://truthsocial.com/@realDonaldTrump/posts/113105431683796730 [https://perma.cc/UUM9-JCPC] ("As I have previously stated, I believe it is time to end needless arrests and incarcerations of adults for small amounts of marijuana for personal use. We must also implement smart regulations, while providing access for adults, to safe, tested product.").

4. The Controlled Substances Act (CSA) regulates controlled drugs and other substances according to factors such as their potential for abuse and currently accepted medical use. *See* 21 U.S.C. §§ 811(c), 812(b) (2018). For simplicity, this Essay uses the terms drug and substance interchangeably.

5. *See* 21 U.S.C. § 811(a)-(b) (2018) (requiring interdepartmental coordination); *see* STAFFS OF H. COMM. ON WAYS & MEANS, COMPARISON OF BILLS TO REGULATE CONTROLLED DANGEROUS SUBSTANCES AND TO AMEND THE NARCOTIC AND DRUG LAWS 1-5 (1970) (presenting CSA statutory history, including early drafts giving the Attorney General (AG) sole scheduling authority and the enacted "Commerce Committee bill," H.R. 18583, which binds the AG to the Secretary of Health and Human Service's (the Secretary's) scientific and medical recommendations); 116 CONG. REC. 33,259, 33,308 (1970) [hereinafter 1970 House Record] (statement of Rep. Carter) (stating that the scientific and medical community had concerns about giving the AG final authority over drug scheduling were "taken care of by language" of H.R. 18583 that bound the AG to the Secretary's recommendations. "In this way, an appropriate balance was achieved between scientific interest and those of law enforcement."); Robert W. Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CALIF. L. REV. 1276, 1308-09 (1972)

became HHS, would make scientific and medical decisions, and the Attorney General (AG), who delegates scheduling authority to DEA, would make nonmedical, law-enforcement-related decisions.[6]

The combined efforts of these agencies produce four possible scheduling outcomes.[7] They can *control* previously uncontrolled substances by placing or *scheduling* them in one of five tiers or schedules, they can *reschedule* drugs by moving them between tiers, they can *deschedule* drugs by removing them from CSA control, or they can take no action.[8] Although DEA ostensibly plays a leading role in drug scheduling, the CSA limits DEA authority, which complements that of HHS.[9] In other words, the agencies hold exclusive, nonoverlapping scheduling-related powers.[10]

(describing congressional intent to create split authority that balances law enforcement criteria with those of medical and scientific communities).

6. *See* 21 U.S.C. § 811(b) (2018) (dividing agency authority); Hamilton, *supra* note 5, at 1308-09 (interpreting law enforcement scheduling authority as limited to three nonscientific factors: actual or relative abuse potential, current and historical patterns of abuse, and the significance of abuse); Department of Education Organization Act, Pub. L. No. 96-88, 93 Stat. 668, 670, 692 (1979) (creating the Department of Education and replacing the Department of Health, Education, and Welfare with the Department of Health and Human Services (HHS)); *MOU 225-85-8251 Memorandum of Understanding Between the National Institute on Drug Abuse and the Food and Drug Administration*, FOOD & DRUG ADMIN. [hereinafter NIDA-FDA MOU], https://www.fda.gov/about-fda/domestic-mous/mou-225-85-8251 [https://perma.cc/9KSR-JH6U] (stating that the Secretary subdelegated scheduling powers to the Assistant Secretary for Health and the Food and Drug Administration (FDA), which further delegates scheduling-related tasks to the National Institutes on Drug Abuse (NIDA)); *see* Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV. L. REV. 331, 335 (2013) (stating that the AG has delegated scheduling authority to the Drug Enforcement Administration (DEA) since 1973).

7. *See* 21 U.S.C. § 811(a)-(b) (2018) (describing the outcomes of interdepartmental coordination).

8. Generally, one might use "control" to describe adding a previously uncontrolled drug to any of the five schedules of controlled substances, and "schedule" to describe the assignment of a specific schedule. However, these terms are often used interchangeably. *See id.* (conferring authority to schedule uncontrolled substances); 21 U.S.C. § 812(b)(1)-(5) (2018) (listing five schedules and their inclusion criteria); 21 U.S.C. § 811(a)-(b) (2018) (granting authority to reschedule or deschedule controlled substances); 21 U.S.C. § 811(b) (2018) (describing HHS authority to veto DEA regulatory proposals and maintain the status quo); NIDA-FDA MOU, *supra* note 6.

9. *See* Gonzales v. Oregon, 546 U.S. 243, 265-67 (2006) (finding that the AG shares delegated CSA authority with the Secretary and must defer to the Secretary on scientific and medical matters).

10. Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201, 225 (stating that the CSA gave the Secretary "exclusive interpretive authority regarding health and medical practices.").

The statute also mandates interagency consultation, creating points where the Secretary of HHS (the Secretary) holds scheduling authority that can bind DEA.[11] For instance, the CSA expressly grants HHS power to override law enforcement scheduling proposals through a drug *control veto*.[12] If the Secretary advises against controlling a substance, DEA cannot control it.[13] By exercising this power, HHS can block scheduling of uncontrolled drugs or remove scheduled drugs from federal control.[14] In addition, the CSA requires the Secretary to make scientific and medical recommendations that bind DEA. The Secretary's binding recommendations provide a more nuanced form of influence: they can constrain DEA options and act as a *scheduling veto*, limiting the tiers in which DEA can place uncontrolled substance or preventing DEA from moving drugs to higher or lower tiers.[15] Together these inputs—the Secretary's control veto and scheduling veto—should balance law enforcement perspectives. However, while courts and agencies widely acknowledge the control veto, they dispute the effects of the binding recommendations.[16]

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11. *Id.*

12. *See* 21 U.S.C. § 811(b) (2018) (conferring the control veto); *see* Touby v. United States, 500 U.S. 160, 167 (1991) (referencing HHS "veto power"); 1970 House Record, *supra* note 5, at 33,304 (statement of Rep. Rogers) ("Through this legislation, the Attorney General has retained the mechanism of control and scheduling, but the Secretary of Health, Education, and Welfare has significant input concerning the health and scientific questions involving in the scheduling and importantly, has a veto power over the classification of a substance or the moving of a substance to a higher schedule if he thinks that it should not be done for scientific or medical reasons."); *Gonzales*, 546 U.S. at 265 (stating "the Secretary's recommendations on scientific and medical matters bind the Attorney General.").

13. 21 U.S.C. § 811(b) (2018).

14. *See Gonzales*, 546 U.S. at 265 (the AG cannot control drugs without the Secretary's assent).

15. *Id.*; *see* 21 U.S.C. § 811(b) (2018) (stating that the Secretary's recommendations bind the AG and providing no limitation); Frank J. Vocci, *The Drug Enforcement Administration: Scheduling Policy and Classification*, 35 FOOD, DRUG & COSM. L.J. 691, 691 (1980) (stating that DEA can select a lower schedule than recommended by the Secretary but "as a matter of policy," DEA "will not opt to control in a higher schedule"); 1970 House Record, *supra* note 5, at 33,308, 33,313 (statement of Reps. Carter and Satterfield).

16. *See* Grinspoon v. DEA, 828 F.2d 881, 897 (1st Cir. 1987) (stating that the Secretary's recommendations do not bind DEA); Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C., slip op. at 24 (Apr. 11, 2024) [hereinafter OLC Opinion], https://www.dea.gov/sites/default/files/2024-05/2024-04-11%20-%20AAG%20Fonzone%20-%20Marijuana%20Rescheduling.pdf [https://perma.cc/EE6A-89P3] (contrasting DEA's view that the Secretary's recommendations bind DEA only until it issues a notice of proposed rulemaking with HHS's view that the recommendations bind DEA throughout the scheduling process); *Gonzales*, 546 U.S. at 265-66 (concluding that the CSA structure prohibits ceding medical judgments to the AG, and the AG must defer to the Secretary regarding scientific and medical matters).

This Essay argues that although drug scheduling has numerous shortcomings, many stem from misinterpreting the separation of scheduling powers. It analyzes the statutory division of labor by reviewing the text, structure, and history of the CSA and analyzing their interpretation by courts, agencies, and legal scholars. The Essay concludes that although the CSA delegates substantial scientific authority to the Secretary, HHS often underutilizes it. Instead of balancing law enforcement perspectives, HHS frequently defers to DEA by adopting its scientific findings and regulatory proposals, or HHS delegates scheduling decisions to other agencies lacking expertise to solve complex sociomedical challenges. Meanwhile, courts and agencies have given less deference to the Secretary's recommendations than the CSA demands, deferring instead to DEA's statutory interpretations.[17] The resulting collapse of the separation of scheduling powers produces regulatory redundancy and unscientific scheduling actions that contradict the CSA text, purpose, and history.[18] Rather than advancing medical science and federal responses to public health challenges, scheduling frequently undermines those goals.

To reduce regulatory redundancy, promote scientific advancement, and protect public health, HHS should maintain the separation of scheduling powers by embracing its scheduling role. To remain within statutory bounds and conserve limited law enforcement resources, DEA should prioritize its non-scheduling-related CSA responsibilities, for which it is authorized and better qualified. DEA employs many intelligent and motivated people who can advance congressional objectives. But duplicating the scientific efforts of HHS or contradicting HHS recommendations diverts resources from DEA's areas of expertise and likely inhibits achieving CSA goals. All branches of government can help steer drug scheduling back on course.

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17. *See* 21 U.S.C. § 811(b) (2018) (regarding binding recommendations); OLC Opinion, *supra* note 16, at 1, 24-26 (acknowledging the CSA's categorical use of the word binding and substantial legislative and statutory history that place sole authority to make medical judgments in the Secretary's hands, but nonetheless concluding that the Secretary's recommendations do not bind DEA once rulemaking begins); JOINT COMM. ON INTERNAL REVENUE TAX'N, JCS-7-70, SUMMARY OF RECOMMENDATIONS ON H.R. 17463: A BILL TO REGULATE CONTROLLED DANGEROUS SUBSTANCES AND TO AMEND THE NARCOTICS AND DRUGS LAWS 2 (1970) [hereinafter H.R. 17463 Recommendations] (summarizing the statement of Rep. Pepper) (stating that the drug scheduling process is essentially scientific and medical, having only incidental law enforcement aspects).

18. *Gonzales*, 546 U.S. at 246 (finding that the AG exceeded his statutory authority by drawing medical conclusions, a power Congress delegated to the Secretary. Concluding that Congress would not have given the AG "such broad and unusual authority through an implicit delegation"); *see* Taleed El-Sabawi, *Why the DEA, Not the FDA? Revisiting the Regulation of Potentially-Addictive Substances*, 16 N.Y.U. J.L. & BUS. 317, 319-20 (2019) (explaining that the balance of scheduling power that Congress intended has not been realized and has tilted in favor of law enforcement).

The Essay proceeds in three Parts. Part I analyzes the complexity, redundancy, and ineffectiveness of drug scheduling, including misinterpretation of the separation of scheduling powers. It argues that Congress gave HHS scheduling authority far broader than many courts and agencies realize, and misinterpreting the distribution of scheduling powers has unbalanced scheduling actions to produce outcomes that frustrate congressional goals. Part II analyzes cases where HHS has fully exercised its scheduling powers to balance or override law enforcement proposals, as well as cases where HHS underutilized its authority, allowing DEA to overstep jurisdictional bounds. It concludes with recommendations to preserve the separation of scheduling powers.

I. DRUG SCHEDULING UNDER SPLIT AGENCY AUTHORITY

This Part analyzes how Congress split scheduling authority between agencies with different areas of expertise. The CSA grants HHS authority over scientific and medical facets of scheduling while granting the AG power over scheduling's nonmedical and law-enforcement-related aspects.[19] However, courts and agencies frequently misinterpret this division of scheduling responsibilities, blurring jurisdictional bounds and producing unscientific outcomes that undermine the CSA text, purpose, and history.[20] Examples include placing drugs in Schedule I despite their scientific and therapeutic potential,[21] listing substances

19. 21 U.S.C. § 811(a)-(b) (2018).

20. Grinspoon v. DEA, 828 F.2d 881, 886-87, 897-98 (1st Cir. 1987) (finding only harmless error when HHS shirked its statutory obligations and concluding that a substantive HHS scientific analysis is unnecessary and stating that DEA need not consider the potential impact of scheduling on research, and that the Secretary's scheduling recommendations do not bind DEA); *see* 1970 House Record, *supra* note 5, at 33,308 (statement of Rep. Carter) (stating that through CSA enactment, "an appropriate balance was achieved between scientific interest[s] and those of law enforcement.").

21. *See* TORSTEN PASSIE, THE HISTORY OF MDMA 117, 123-24 (2023) (Andrew Dennis trans., Oxford Univ. Press 2023) (describing DEA placement of Methylenedioxymethamphetamine (MDMA) in Schedule I over objections from researchers and healthcare professionals); Jacob Barsen, *DEA Rejects Psilocybin Rescheduling Petition*, JD SUPRA (Jan. 11, 2024), https://www.jdsupra.com/legalnews/dea-rejects-psilocybin-rescheduling-4296274 [https://perma.cc/5T4Q-VZ4P].

in schedules inappropriate for their benefits and risks,[22] and overlooking the impact of scheduling on scientific research, medical practice, and public health.[23]

A. Separating Drug Scheduling Powers

The CSA grants the AG broad law enforcement authority, which is delegated to DEA. The agency can execute search warrants, make arrests, seize property, inspect manufacturing facilities, enforce security and record-keeping requirements, register healthcare professionals who dispense controlled drugs, and prevent diversion from regulated settings to illicit channels.[24] Additionally, the CSA authorizes the AG to propose and adopt rules to schedule, reschedule, or deschedule drugs, subject to limitations imposed by 21 U.S.C. § 811 (Section 811).[25] Section 811(a) requires scheduling rules to be made "on the record after opportunity for a hearing," triggering formal rulemaking under the Administrative Procedure Act (APA).[26] Section 811(b) also mandates interagency consultation.[27] Before DEA initiates scheduling-related rulemaking, it must request that the Secretary make "a scientific and medical evaluation" and recommendations, which address whether a drug should be controlled and specify an appropriate schedule.[28]

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22. *See, e.g.*, Fred P. Graham, *National Commission to Propose Legal Private Use of Marijuana*, N.Y. TIMES (Feb. 13, 1972), https://www.nytimes.com/1972/02/13/archives/national-commission-to-propose-legal-private-use-of-marijuana.html [https://perma.cc/JMZ5-4UFA] (reporting on a national commission's conclusion that marijuana had not been shown to cause physical or psychological harm, and its recommendation to eliminate criminal penalties for marijuana possession and use); *see* Matthew W. Johnson, Roland R. Griffiths, Peter S. Hendricks & Jack E. Henningfield, *The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act*, 142 NEUROPHARMACOLOGY 143, 143, 162 (2018) (arguing that the Schedule I drug psilocybin should be scheduled no "more restrictively than Schedule IV").

23. *Grinspoon*, 828 F.2d at 886-87.

24. *See* 21 U.S.C. § 878 (2018) (granting the authority for search and arrest warrants, seizures, and law enforcement duties designated by the AG); Gonzales v. Oregon, 546 U.S. 243, 255-66 (2006) (granting the authority over practitioner registration, security, and record keeping); 21 U.S.C. §§ 880 (2018) (granting the authority for facility inspection); 21 U.S.C. § 886a (granting the authority for diversion control).

25. *See* 21 U.S.C.§ 811(a)(1) (2018) (scheduling and rescheduling); *id.* § 811(a)(2) (a)(2) (descheduling).

26. *Id.* § 811(a) (invoking on the record rulemaking and an opportunity to be heard); 5 U.S.C. § 553 (2018) (regarding application of the Administrative Procedure Act (APA) sections 556 and 557 when statutes require rules to be made on the record after an opportunity to be heard); *see, e.g.*, United States v. Fla. E. Coast Ry. Co., 410 U.S. 224, 241 (1973) (applying the APA).

27. *See* 21 U.S.C. § 811(b) (2018) (defining required interactions between the AG and Secretary).

28. *Id.* (requiring HHS to utilize eight scheduling factors listed by Section 811(c)).

Section 811(b) describes the Secretary's recommendations in a sentence with two main clauses.[29] The recommendations "shall be binding on the Attorney General . . . and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or substance."[30] The second clause explicitly confers to HHS a control veto.[31] Although courts and agencies widely recognize this HHS power to override DEA scheduling proposals, they dispute the meaning of the first clause, which states that HHS recommendations bind the AG.[32] Courts and DEA have argued that HHS recommendations constitute optional interagency advice that DEA can disregard.[33] The Office of Legal Counsel (OLC) of the Department of Justice (DOJ) has concluded that the second clause limits the meaning of the first, and the control veto is the only means through which the Secretary's recommendations can bind DEA.[34] OLC and DEA have argued that HHS recommendations are binding only before DEA publishes notice of proposed rulemaking.[35] However, HHS's view that its recommendations bind DEA continuously, throughout the drug scheduling process, properly interprets the CSA.[36] There are special cases where DEA can schedule drugs without HHS recommendations.[37] But the CSA

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29. *Id.*

30. *Id.*

31. *Id.*

32. *See* OLC Opinion, *supra* note 16, at 1, 24 (presenting the divergent views of DEA, HHS, and the Office of Legal Counsel (OLC) regarding the effects of the HHS Secretary's binding recommendations).

33. *See* Grinspoon v. DEA, 828 F.2d 811, 897 (1st Cir. 1987) (stating that the CSA merely requires DEA to request an evaluation from HHS, and that, even if provided, the Secretary's recommendations do not bind DEA).

34. *See* OLC Opinion, *supra* note 16, at 22-23 (interpreting Section 811(b) to bind the AG to the Secretary's recommendations only when the Secretary advises against scheduling a drug because Section 811(b) expressly identifies that scenario [in its second clause], and concluding that because Section 811(b) does not expressly reference a drug's currently accepted medical use, the Secretary's recommendations regarding currently accepted medical use do not bind the AG).

35. *See* Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV, 76 Fed. Reg. 77330, 77331 (Dec. 12, 2011) (codified at 21 C.F.R. pt. 1308) [hereinafter Carisoprodol Rule] (stating that the Secretary's recommendations cannot bind DEA once rulemaking begins); OLC Opinion, *supra* note 16, at 1, 7, 21, 24 (quoting DEA and adopting its view that HHS recommendations bind DEA only before rulemaking begins, and concluding that after that point, DEA must give HHS recommendations substantial deference).

36. *See* OLC Opinion, *supra* note 16, at 24 (describing the HHS view).

37. *See* 21 U.S.C. § 811(d), (e), (h) (2018) (requiring the AG to forego HHS recommendations if controlling a drug is necessary to meet drug treaty obligations, and allowing the AG to avoid seeking HHS recommendations when scheduling an immediate precursor of a controlled

generally requires HHS input, and the line between ordinary circumstances and special cases is not always clear.[38]

Since 1969, when Congress started debating drafts of the CSA, medical and legal experts have scrutinized its distribution of power.[39] The Nixon Administration submitted the first version, which gave the AG sole scheduling authority.[40] Subsequent House and Senate drafts maintained this structure.[41] If Congress had enacted those versions, the AG could solicit but would not be required to follow the Secretary's recommendations.[42] Health experts objected to giving law enforcement control over scientific and medical matters, fearful of curtailing

substance or when scheduling a substance is necessary to avoid an imminent hazard to public safety).

38. Although 21 U.S.C. § 811(d) (2018) requires controlling a substance when required by drug treaties, determining whether and to what extent treaties require control is open to interpretation. *See, e.g.*, OLC Opinion, *supra* note 16, at 28, 32 (concluding that drug treaties do not require marijuana to be placed in a specific schedule and observing that the CSA grants broad discretion to determine which schedule is appropriate to comply with the treaties).

39. *See, e.g.*, *Drug Abuse Prevention and Control: Hearing Before the Special Subcomm. on Alcoholism and Narcotics of the S. Comm. on Labor & Pub. Welfare*, 91st Cong. 145-47, 159 (1970) [hereinafter 1970 Senate Hearing] (statement of Joseph Cochin, Professor of Pharmacology, Boston University Medical School) (arguing that "[m]any of the substances in Schedule I are extremely valuable research tools that will enable us to understand the mechanisms underlying drug dependence, yet these will be almost impossible to obtain for legitimate experimental use," and therefore concluding that a Senate-approved CSA draft "contains many features dangerous to research in the field of drug abuse and drug use, and to the general practice of medicine."); *see also id.* at 244 (statement of the American Psychiatric Association) ("To our alarm and dismay, we have learned that the Department of Justice has developed draft legislation . . . which endows the department—not a health agency—with sweeping power to regulate medical research and practice. . . . [The Bill] turns the clock back to the era when physician's and other researchers were discouraged and afraid to undertake programs in treatment and investigation because enforcement authorities seemed to be dictating the practice of medicine."); Kreit, *supra* note 6, at 333, 352 (criticizing unfettered DEA scheduling discretion); PASSIE, *supra* note 21, at 130 (criticizing DEA's "de facto almost complete discretion" in defining currently accepted medical use").

40. STAFFS OF H. COMM. ON WAYS & MEANS, *supra* note 5, at 1.

41. *See id.* (describing the Senate draft as "essentially the same as the Administration proposal"); STAFF OF JOINT COMM. ON INTERNAL REVENUE TAX'N, 91ST CONG., SUMMARY OF H.R. 17463: A BILL TO REGULATE CONTROLLED DANGEROUS SUBSTANCES AND TO AMEND THE NARCOTICS AND DRUGS L. 3 (Comm. Print 1970) [hereinafter H.R. 17463 Summary] (authorizing the AG "to add, delete, or reschedule any substance as a controlled dangerous substance" while requiring him only to "seek the advice of the Secretary").

42. STAFFS OF H. COMM. ON WAYS & MEANS, *supra* note 5, at 1; H.R. 17463 Summary, *supra* note 41, at 3; *see also* OLC Opinion, *supra* note 16, at 7 (summarizing CSA statutory and legislative history).

research and innovation, impeding medical practice, and endangering public health.[43]

Dr. Henry Brill, Chair of the American Medical Association's Committee on Narcotics and Drug Dependence, recommended that the HEW Secretary make final decisions on the scientific and medical aspects of scheduling.[44] Dr. Daniel X. Freedman, Chair of the Department of Psychiatry at the University of Chicago, said the AG should not judge the public health risks of substances.[45] And Bruce J. Brennan, Vice President and General Counsel for the Pharmaceutical Manufacturer's Association, argued that qualified scientific and medical personnel should be the ultimate decision makers on matters of science and medicine.[46] Brennan endorsed Section 201(b) of H.R. 18583, codified as Section 811(b), which he believed contained "a satisfactory compromise." In response to expert feedback, Congress enacted H.R. 18583, which bound the AG to the Secretary's scientific and medical recommendations.[47]

While presenting H.R. 18583 on the House Floor, Representative Rogers summarized the statute's history:

> [T]he scientific community and medical community of this Nation were greatly upset over the fact that scientific and medical decisions in the Senate bill were entered in the [DOJ], with the [AG] having the responsibility to make scientific and medical determinations which were not in the competency of that Department.[48]

Rogers concluded, "We have changed that so that [HEW] will determine scientific and medical decisions. This is a most important change in the whole approach as it came from the Senate."[49] Representative Springer emphasized the split distribution of powers. "Let us also make a definite point of the fact that purely enforcement responsibilities are placed with [DOJ]," he said, whereas

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43. *See* 1970 Senate Hearing, *supra* note 39, at 159 (statement of Joseph Cochin, Professor of Pharmacology, Boston University Medical School); *id.* at 244 (statement of the American Psychiatric Association); *id.* at 322-25 (statement of Roger E. Myer, Assistant Professor of Psychiatry, Boston University) (objecting to granting the AG powers that should reside with health professionals, expressing concerns about AG discretion to authorize medical research, and claiming the proposed legislation would impede addiction treatment).

44. H.R. 17463 Recommendations, *supra* note 17, at 2 (summarizing the statement of Dr. Brill).

45. *Id.* (summarizing the statement of Dr. Freedman).

46. *Id.* at 3 (summarizing the statement of Mr. Brennan).

47. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, 1246.

48. 1970 House Record, *supra* note 5, at 33,304 (statement of Rep. Rogers).

49. *Id.*

"medical and scientific judgments necessary to drug control are left where they properly should lie and that is with [HEW]."[50]

Representative Boland explained how H.R. 18583 made important changes to prior CSA drafts.[51] The Senate bill required the AG to seek the Secretary's advice but did not require the AG to follow it. Boland and other members of Congress felt that because drug scheduling is informed largely by scientific information, it would be inappropriate for law enforcement officials to have the final say.[52] However, the Secretary's role was limited under the Senate bill.[53] Consequently, H.R. 18583 expanded the Secretary's authority and required the AG to follow the Secretary's scheduling recommendations. "These changes should be pointed out because they show a recognition of the vital part the scientific community should play in establishing an appropriate system for drug abuse control," said Boland.[54]

Representative Carter said the concerns of scientific and medical communities had been "taken care of" by H.R. 18583, which bound the AG to the Secretary's scheduling advice.[55] Carter ranked the Secretary's binding recommendations among the most important statutory amendments.[56] Rendering them nonbinding or temporarily binding frustrates the purpose for which Congress introduced them, not to mention the statutory text and the Supreme Court's interpretation.[57]

Congress acknowledged the societal role of controlled drugs and the importance of preserving access to them. The CSA's first line declares controlled drugs "necessary to maintain the health and general welfare of the American people."[58] Accordingly, it was logical to give HEW exclusive scientific and

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50. *Id.* at 33,300 (statement of Rep. Springer).

51. *Id.* at 33,316 (statement of Rep. Boland).

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.* at 33,308 (statement of Rep. Carter).

56. *Id.*

57. *See* Gonzales v. Oregon, 546 U.S. 243, 265 (2006) ("The Attorney General does not have the sole delegated authority under the CSA. He must instead share it with, and in some respects defer to, the Secretary, whose functions are likewise delineated and confined by the statute."); 1970 Senate Hearing, *supra* note 39, at 811 (statement of Robert G. Frazier, Executive Director, American Academy of Pediatrics) ("Section VI of this bill will transfer the authority for scientific concerns in drug abuse from the Attorney General to the Secretary of Health, Education, and Welfare.").

58. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 101(1), 84 Stat. 1236, 1242; *see* 1970 House Record, *supra* note 5, at 33,308 (statement of Rep. Carter) (claiming that the CSA will not impede medical research or practice).

medical authority.[59] HEW's mission encompassed enhancing the health and well-being of all Americans. In 2014, HHS added the mission of advancing "the sciences underlying medicine, public health, and social services," highlighting the central role of science in promoting health and human welfare.[60] However, despite congressional goals and the separation of scheduling powers, the outcomes scientists feared fifty-five years ago have largely materialized.[61]

Experts describe scheduling actions as arbitrary, confusing, harmful, and unscientific.[62] Criminalizing and restricting access to drugs with therapeutic, scientific, or commercial value has impeded research and innovation, reduced healthcare quality and access, and promoted overly punitive enforcement practices.[63] Some experts believe scheduling fuels illicit drug markets, promotes

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59. *See* 21 U.S.C. § 811(b) (2018) (requiring the Secretary to provide scientific and medical recommendations regarding scheduling to the AG, and stating that they "shall be binding on the Attorney General as to such scientific matters"); *Gonzales*, 546 U.S. at 265-67 ("The CSA allocates decisionmaking powers among statutory actors so that "medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary." Furthermore, the CSA structure "conveys unwillingness to cede medical judgments to [the AG,] an executive official who lacks medical expertise."); OLC Opinion, *supra* note 16, at 7 (describing the expansion of the Secretary's role regarding scientific and medical matters as reflected by the CSA's statutory history); Gersen, *supra* note 10, at 225 (describing the Secretary's exclusive CSA interpretive authority regarding health and medicine).

60. *Mission Statement*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/about/strategic-plan/2022-2026/introduction/index.html#mission [https://perma.cc/6D27-S3RJ]; *Strategic Plan FY 2018-2022*, U.S. DEP'T OF HEALTH & HUM. SERVS. 5 (2018), https://aspe.hhs.gov/sites/default/files/documents/feac346aca967bfadc446398679e14ec/hhs-strategic-plan-fy-2018-2022.pdf [https://perma.cc/F7ZF-8SGG].

61. *See* Michael R. Barnes, Yijia Luo, Jonathon M. Parker & Brian M. Shepler, *Prescribers' Perspectives: The Impact of the Controlled Substances Scheduling System on Providing Optimal Patient Care*, 16 EXPL. RSCH. CLINICAL & SOC. PHARMACOLOGY 1, 6 (2024) (surveying healthcare professionals to conclude that scheduling can hinder providing optimal care to patients requiring medications that become scheduled); Kreit, *supra* note 6, at 333, 352 (explaining DEA's nearly unfettered discretion to classify substances and the impact on scientific research).

62. *See* Joseph F. Spillane, *Debating the Controlled Substances Act*, 76 DRUG & ALCOHOL DEPENDENCE 17, 26 (2004) (stating that scheduling has stigmatized drugs with legitimate uses and threatened doctors with legal liability); Kreit, *supra* note 6, at 336-44 (describing the "fundamental flaws" of scheduling criteria, which can appear vague, redundant, or conflicting); Jennifer D. Oliva & Taleed El-Sabawi, *The New Drug War*, 110 VA. L. REV. 1103, 1144 (2024) (describing the seemingly arbitrary and contradictory reclassification of buprenorphine).

63. *See* Kreit, *supra* note 6, at 352 (blaming CSA scheduling criteria for the law's negative impact on scientific research); Mason Marks & Carmel Shachar, *Drug Scheduling Limits Access to Essential Medicines and Should Be Reformed*, 29 NATURE MED. 294, 294 (2023) (describing the negative impact of drug control on medical research); Letter from Brett P. Giroir, Assistant Sec'y for Health, U.S. Dep't of Health & Hum. Servs., to Uttam Dhillon, Acting Adm'r, Drug Enf't Admin., at 3-4 (Aug. 16, 2018) [hereinafter Kratom Letter], https://www.rilegislature.gov/Special/comdoc/House%20Corporations%202024/03-14-2024--H7231--

violence, spurs production of riskier synthetic analogues of existing drugs, and impedes public health approaches to the overdose crisis.[64] While the United States falls behind other countries in adopting evidence-based drug policies, it leads the wealthiest nations in fatal overdoses.[65] Under current scheduling practices, overdose deaths have skyrocketed.[66]

This Section analyzed the CSA text, statutory history, and purpose to define the separation of scheduling powers. The following Section explores why lawmakers create shared regulatory spaces and how drug scheduling practices have diverged from what Congress attempted to achieve.

B. Drug Scheduling's Bureaucratic Drift

Congress often creates shared regulatory spaces, where it delegates jurisdiction to multiple agencies.[67] One can distinguish cases where agency authority

US%20Dept%20of%20Health%20Human%20Services%20-%20Dr.%20Brett%20Giroir.pdf [https://perma.cc/EHM6-UTW5] (describing the negative impact scheduling would have on kratom research); Alex Kreit, *Safe Injection Sites and the Federal "Crack House" Statute*, 60 B.C. L. REV. 413, 429-433 (2019) (describing the impact of scheduling on safe consumption sites); Barnes et al., *supra* note 61, at 24-27 (regarding the impact on medical practice); Oliva & El-Sabawi, *supra* note 62, at 1119 (arguing that CSA scheduling institutionalized punitive drug control approaches that preceded it, prioritizing racial and social stereotypes over scientific evidence).

64. *See* James Martin, Jack Cunliffe, David Décary-Hétu & Judith Aldridge, *Effect of Restricting the Legal Supply of Prescription Opioids on Buying Through Online Illicit Marketplaces: Interrupted Time Series Analysis*, 361 BMJ art. no. k2270, at 5-6 (2018) (observing a correlation between the scheduling of hydrocodone and purchases of hydrocodone from illicit markets, and proposing a possible causal connection between scheduling and illicit traffic); Audrey Redford, *Don't Eat the Brown Acid: Induced "Malnovation" in Drug Markets*, 30 REV. AUSTRIAN ECON. 215, 216-18, 223-25, 229 (2017) (claiming that drug prohibition rather than drug use begets violence, observing that the number of PCP-related emergencies and deaths soared after PCP was listed on Schedule II, arguing that drug scheduling incentivizes "malnovation," where chemists produce new synthetic drugs, often variants of existing substances, to circumvent legal restrictions, and noting that many individuals sell synthetic variants under the name of the original drug, creating confusion and compounding health risks).

65. Jenessee Miller, *American Drug Overdose Death Rates the Highest Among Wealthy Nations*, SCHAEFFER CTR. FOR HEALTH POL'Y & ECON. (Feb. 21, 2019), https://healthpolicy.usc.edu/article/american-drug-overdose-death-rates-the-highest-among-wealthy-nations [https://perma.cc/F49Y-7433].

66. *See* Merianne R. Spencer, Matthew F. Garnett & Arialdi M. Miniño, *Drug Overdose Deaths in the United States, 2002-2022*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Mar. 2024), https://www.cdc.gov/nchs/data/databriefs/db491.pdf [https://perma.cc/DP6C-CQ6U].

67. Gersen, *supra* note 10, at 208 (stating "statutes that parcel out authority or jurisdiction to multiple agencies may be the norm, rather than an exception"); *see* Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1134 (2012) (observing that Congress often divides authority between multiple agencies, making each one responsible

partially or completely overlaps, creating redundancies, from those where authority is split or fragmented rather than redundant. Imagine two agencies, *A* and *B*, each having some degree of jurisdiction over field *X*. Their authority could completely overlap and cover the entire field.[68] Alternatively, it might partially overlap if they share authority over parts of *X*, while each retains exclusive jurisdiction over other parts.[69] Congress could cleanly divide authority between agencies *A* and *B*, giving each exclusive jurisdiction over different areas of *X*, avoiding any overlap or regulatory redundancy while regulating the entire field.[70] Or each agency might hold exclusive jurisdiction over some areas, while others remain unregulated, creating gaps constituting regulatory underlap.[71] Finally, a regulated space could include areas of exclusive, nonoverlapping jurisdiction, as well as points of overlap and underlap.[72]

Congress might intentionally create regulatory overlap to achieve certain goals, or lawmakers might unwittingly produce it. Overlap could result from political negotiations during legislative drafting.[73] When stakeholders advocate for different distributions of authority, disagreement and compromise can produce overlapping jurisdiction.[74] Regardless of their origin or structure, shared regulatory spaces have benefits and drawbacks.[75] Underlap could incentivize interagency competition to create the best policies for underregulated areas.[76] Meanwhile, overlap might do the same while shielding against underregulation and regulatory failure.[77] Importantly, shared regulatory spaces allow Congress to leverage agency expertise.[78] Lawmakers might distribute power based on

for part of the regulated whole); Jason Marisam, *Duplicative Delegations*, 63 ADMIN. L. REV. 181, 184, 212-17 (2011) (describing overlapping agency authority as common and providing several examples).

68. Gersen, *supra* note 10, at 209 (describing congressional delegation of "perfectly overlapping" authority).

69. *Id.*

70. *Id.*

71. *Id.* at 208.

72. *Id.* at 209.

73. *See* Marisam, *supra* note 67, at 190-98 (summarizing the causes of regulatory overlap).

74. Gersen, *supra* note 10, at 233-35.

75. Freeman & Rossi, *supra* note 67, at 1134, 1144.

76. *See* Gersen, *supra* note 10, at 212-14 (arguing that underlap might promote competition, decrease drift, and incentivize developing expertise to fill regulatory gaps); Freeman & Rossi, *supra* note 67, at 1142 (suggesting that competition could aid or clarify agency missions).

77. Marisam, *supra* note 67, at 222; *see* Gersen, *supra* note 10, at 213 (asserting that overlap might incentivize action under threat of losing jurisdiction to a competing agency).

78. *See* Freeman & Rossi, *supra* note 67, at 1142, 1146 (dispersing regulatory authority to harness agency expertise and address complex problems).

agencies' technical knowledge regarding different facets of a field.[79] Congress can encourage or require interagency consultation to pool information and expertise,[80] potentially nudging agencies with polarized perspectives to consider other viewpoints, or bind them to outside input.[81] If Congress seeks to balance one agency's power, it can counteract its tendencies by distributing authority to a second agency with different inclinations.[82] In other words, within the executive branch, Congress might emulate the constitutional separation of powers to create administrative checks and balances.[83]

On the other hand, shared regulatory spaces can require substantial coordination, raise regulatory costs, and complicate congressional and public oversight, making it difficult to hold regulators accountable.[84] Overlapping responsibilities can produce inefficiency, overregulation, and overspending.[85] Justice Kavanaugh has decried rampant duplication of agency jurisdiction, which causes confusion over agency roles.[86] Overlapping authority can also incentivize abdication of responsibilities — a form of administrative free riding — if regulators believe another agency could pick up the slack or is already doing the work.[87] Shirking responsibilities by neglecting issues that arise in shared regulatory spaces can result in underregulation or in bureaucratic drift, where agency policies diverge from what lawmakers attempted to achieve.[88]

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79. Freeman & Rossi, *supra* note 67, at 1142, 1146; *see* Gersen, *supra* note 10, at 212 (regarding the delegation to the best-informed agency).

80. Freeman & Rossi, *supra* note 67, at 1184 (pooling data and expertise).

81. *Id.* at 1158-59 (showing that mandatory consultation can constrain agency options).

82. *See* Sharon B. Jacobs, *The Statutory Separation of Powers*, 129 YALE L.J. 378, 400-05 (2019) (describing statutory checks and balances, including veto gates, agenda setting, and sequential decision making).

83. *Id.* at 381.

84. Freeman & Rossi, *supra* note 67, at 1135; Todd S. Aagaard, *Regulatory Overlap, Overlapping Legal Fields, and Statutory Discontinuities*, 229 VA. ENV'T L.J. 237, 288 (2011).

85. Freeman & Rossi, *supra* note 67, at 1138.

86. Brett M. Kavanaugh, *Separation of Powers During the Forty-Fourth Presidency and Beyond*, 93 MINN. L. REV. 1454, 1469-70 (2009) (arguing that regulatory overlap produces "redundancy, inefficiency, conflict, and unnecessary finger-pointing).

87. *See* Aagaard, *supra* note 84, at 288 (stating that overlap might incentivize free riding on the actions of other agencies with whom one can share blame for regulatory failures); Freeman & Rossi, *supra* note 67, at 1138; Jacob E. Gersen, *Designing Agencies*, *in* RESEARCH HANDBOOK ON PUBLIC CHOICE AND PUBLIC LAW 352 (Daniel A. Farber & Anne J. O'Connell eds., 2011) (describing agency free riding and shirking); Marisam, *supra* note 67, at 211-13 (agencies might abdicate to avoid duplication by adopting narrow statutory interpretations or deferring to another agency's determinations).

88. *See* Aagaard, *supra* note 84, at 288 (defining shirking); David L. Noll, *Administrative Sabotage*, 120 MICH. L. REV. 753, 764 (2022) (defining drift); Freeman & Rossi, *supra* note 67, at 1187

When shirking creates areas of functional regulatory underlap, less qualified agencies with different priorities might fill the gaps, potentially exacerbating drift. Collusion is another concern. Under the pretext of coordination, agencies might collaborate to advance their own interests at the expense of congressional goals.[89] Nonoverlapping jurisdiction with regulatory underlap may also promote interagency conflict.[90] When Congress fails to clearly describe which agency controls an underregulated area of the landscape, agencies might adopt conflicting views on the scope of their statutory authority.[91] Although disagreements could be productive and drive policy innovation, conflicts can trigger time-consuming "turf battles."[92]

The drug scheduling process illustrates several drawbacks of shared regulatory spaces. Despite extensive support for the separation of scheduling powers in the CSA and its legislative and statutory history, courts and agencies often misinterpret how the statute divides agency authority.[93] When HHS abdicates scheduling responsibilities, creating areas of functional regulatory underlap, DEA exerts its influence, and courts and other agencies defer to DEA interpretations of CSA terms, expanding DEA's apparent jurisdiction.[94] DEA has effectively assumed scientific decision-making responsibilities without statutory authority, producing regulatory redundancy that judges and legal scholars caution

(stating that delegation confers agency discretion, which risks drift, and fragmented or overlapping jurisdiction might increase the chance of shirking, a type of drift).

89. Freeman & Rossi, *supra* note 67, at 1189 (discussing the risks of agency collusion); *see* Noll, *supra* note 88, at 761, 764 (defining administrative sabotage, and explaining that the intent to nullify or kill Congressional programs distinguishes administrative sabotage from drift).

90. Marisam, *supra* note 67, at 215 (describing disputes over blurred boundaries); *see* Gersen, *supra* note 88, at 352.

91. Marisam, *supra* note 67, at 215; *see* Gersen, *supra* note 88, at 352 (describing agencies' adoption of conflicting statutory interpretations); Freeman & Rossi, *supra* note 67, at 1150. *See generally* Gonzales v. Oregon, 546 U.S. 243 (2006) (determining the bounds of the Department of Justice and HHS authority under the CSA).

92. Freeman & Rossi, *supra* note 67, at 1142, 1186; *see* Kavanaugh, *supra* note 86, at 1469-70.

93. OLC Opinion, *supra* note 16, at 24 (describing "sharply different views" regarding the extent to which the HHS Secretary's recommendations are binding).

94. *See* Grinspoon v. DEA, 828 F.2d 811, 892 (1st Cir. 1987) (concluding that HHS performed unadmirably by failing to perform its own analysis and rubber-stamping DEA's eight-factor analysis, yet HHS performance constituted only harmless error); All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1134 (D.C. Cir. 1994) (deferring to DEA interpretations of ambiguous CSA terms).

against.[95] Even where courts suspected that HHS was best-suited for making scheduling-related decisions, under *Chevron*, courts often deferred to DEA.[96]

Scheduling can occur through legislative, administrative, or judicial action.[97] When enacting the CSA, Congress scheduled dozens of substances, including well-known drugs such as marijuana and heroin, and chemicals with obscure industrial or scientific uses.[98] Congress can amend the CSA to add substances to schedules, reclassify drugs, or deschedule them.[99] However, administrative scheduling without legislative involvement is the conventional path. Any interested party, including government officials and members of the public, can petition DEA to initiate scheduling procedures.[100] If DEA declines, petitioners can ask courts to intervene.[101] Although rescheduling litigation has repeatedly failed, it has shaped the tests that courts and agencies use in scheduling actions.

The statutory provision 21 U.S.C. § 812 (Section 812) lists inclusion criteria for each CSA schedule.[102] The criteria might appear straightforward because they address three traits of a substance: potential for abuse, whether it has a currently accepted medical use, and its safety or dependence risk under medical supervision.[103] However, each schedule applies these factors differently, as summarized in Table 1.[104] Some schedules require categorical determinations for certain variables such as potential for abuse, while others require comparative judgments for the same variables. For instance, Schedules I and II require a high

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95. Kavanaugh, *supra* note 86, at 1469-70 (arguing that regulatory overlap produces "redundancy, inefficiency, conflict, and unnecessary finger-pointing); Freeman & Rossi, *supra* note 67, at 1138 (acknowledging the view that regulatory redundancy can be wasteful and create opportunities for agency abdication of responsibility).

96. *See Grinspoon*, 828 F.2d at 892 (stating that an "HHS recommendation to schedule a substance is not binding."); *All. for Cannabis Therapeutics*, 15 F.3d at 1134 (deferring to DEA interpretations of ambiguous CSA terms).

97. Marks & Shachar, *supra* note 63, at 294.

98. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, 1248-52 (providing the initial scheduling of well-known substances, as well as obscure chemicals such as chlorhexadol and N-methyl-3-piperidyl benzilate).

99. *See* Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 12619(b), 132 Stat. 4490, 5018 (removing tetrahydrocannabinols in hemp from Schedule I).

100. Robert A. Mikos, *The False Promise of Rescheduling* 8 (Vand. Univ. L. Sch. Legal Stud. Rsch. Paper Series, Working Paper No. 24-21, 2024), https://ssrn.com/abstract=4814284 [https://perma.cc/6K2R-J4L7].

101. *See, e.g.*, *All. for Cannabis Therapeutics*, 15 F.3d at 1133-34; Ams. for Safe Access v. DEA, 706 F.3d 438, 441-42 (D.C. Cir. 2013).

102. 21 U.S.C. § 812(a)-(b) (2018).

103. *Id.* § 812(b)(1)-(5).

104. *See infra* Table 1 for a comparison of scheduling criteria and examples of substances in each category.

potential for abuse—a categorical determination—whereas Schedules III through V define potential for abuse relative to that of substances in more-restrictive schedules. Congress did not define key terms such as *potential for abuse*, *currently accepted medical use*, and *dependence risk*.[105] It may have seemed obvious that medical professionals would define those terms. Indeed, legislative history suggests that Congress and agency officials saw them as scientific or medical terms within HEW jurisdiction.[106] In contrast, the existence of actual "abuse" (as opposed to "potential for abuse") was seen as a factual, legal question within DOJ authority.[107]

105. *See* 21 U.S.C. § 802 (2018) (providing definitions for the subchapter but including no definitions for "potential for abuse," "currently accepted medical use," and "dependence risk"); 21 U.S.C. § 812 (2018) (setting out criteria for classifying substances, but including no definitions for "potential for abuse," "currently accepted medical use," and "dependence risk").

106. *See, e.g.*, *Part 2 Drug Abuse Control Amendments—1970: Hearings Before the Subcomm. on Pub. Health & Welfare of the H. Comm. on Interstate & Foreign Com.*, 91st Cong. 718-19 (1970) [hereinafter 1970 Health & Welfare] (statement of Mr. Rogers) (asking Mr. Sonnenreich, Deputy Chief Counsel of the Bureau of Narcotics and Dangerous Drugs [the agency that preceded DEA] if evaluating currently accepted medical use is a medical decision); *id.* (statement of Mr. Sonnenreich) (acknowledging that determining the pharmacologic effects of drugs and whether they have currently accepted medical uses are medical decisions, describing the evaluation of potential for abuse as a scientific determination, and distinguishing these scientific and medical decisions from law enforcement determinations).

107. *See id.* at 718 (statement of Mr. Sonnenreich) (stating that evaluating the actual abuse of a drug is a law enforcement determination to distinguish the process from scientific and medical determinations such as evaluating the potential for abuse and currently accepted medical use).

TABLE 1. CONTROLLED SUBSTANCE SCHEDULING CRITERIA

Criteria	Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
Potential for Abuse	High	High	Lower than Schedules I and II	Lower than Schedule III	Lower than Schedule IV
Currently Accepted Medical Use	None	Accepted with severe restrictions	Accepted	Accepted	Accepted
Safety with Strict Medical Supervision	Lacks safety even with strict supervision	Safe with strict supervision	Safe without strict supervision	Safe without strict supervision	Safe without strict supervision
Dependence Risk When Abused	Not applicable	May cause severe psychological or physical dependence	Low to moderate physical dependence or high psychological dependence	Limited physical or psychological dependence	Limited physical or psychological dependence
Examples	Heroin, psilocybin, marijuana, mescaline	Cocaine, fentanyl, oxycodone, amphetamine, methylphenidate (Ritalin)	Ketamine, anabolic steroids, acetaminophen (Tylenol) with codeine	Alprazolam (Xanax), Diazepam (Valium), Zolpidem (Ambien)	Cough syrups with limited amounts of codeine

In the absence of statutory definitions, DEA has defined key CSA terms. Citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, courts have adopted DEA interpretations.[108] However, judicial deference has produced undesirable scheduling outcomes and undermined the CSA text, structure, statutory history, and legislative history.[109] For instance, deference to DEA definitions of "potential for abuse" and "currently accepted medical use"—medically related CSA terms central to drug scheduling—gave DEA authority meant for public health officials and made researching controlled substances more difficult. Still, *Gonzales v. Oregon*, the only Supreme Court case to analyze the bounds of CSA authority, found a clear separation of powers: writing for the majority, Justice

108. *See, e.g.*, Grinspoon v. DEA, 828 F.2d 811, 892 (1st Cir. 1987) (citing *Chevron U.S.A., Inc. v. Natural Resource Defense Council, Inc.*, 467 U.S. 837, 843 (1984), and stating, "Congress has implicitly delegated to the [DEA] Administrator the authority to interpret these portions of the CSA, and we must therefore refrain from imposing our own statutory interpretation upon the agency"); All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991). *All. for Cannabis Therapeutics*, 15 F.3d at 1134 (recounting the deference given to DEA interpretations of ambiguous CSA terms in the previous case three years earlier, *All. for Cannabis Therapeutics*, 930 F.2d at 939).

109. *See supra* notes 61-64 and accompanying text (unscientific scheduling outcomes contrary to public health and congressional goals); Gonzales v. Oregon, 546 U.S. 243, 266 (2006) (CSA structure); *see also*, *supra* notes 39-56 and accompanying text (providing CSA statutory and legislative history).

Kennedy concluded that the CSA structure "conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise.[110] Since *Loper Bright Enterprises v. Raimondo* overruled *Chevron*, courts may resist accepting DEA interpretations, or they may simply decline to pay them deference.[111]

C. Blurred Jurisdictional Boundaries Bias Drug Scheduling

DEA's asymmetric treatment of anecdotal evidence—accepting it for the purposes of upscheduling and rejecting it for downscheduling or descheduling—produces systemic biases in drug regulation. DEA uses many factors to evaluate potential for abuse, including anecdotal reports.[112] But elsewhere, the agency criticizes anecdotal evidence as unreliable. When denying a petition to reschedule marijuana, the DEA Administrator wrote that petitioners had presented stories by people who used marijuana and claimed to experience benefits. "Scientists call these stories anecdotes," wrote the Administrator.[113] "They do not accept them as reliable proofs."[114] DEA's practice of relying on anecdotal evidence to schedule uncontrolled drugs while criticizing anecdotal evidence in the context of rescheduling illustrates the evidence asymmetries of drug scheduling. Courts and agencies require large volumes of high-quality evidence to reschedule substances, while they accept small amounts of relatively low-quality, anecdotal evidence as sufficient to schedule drugs or upschedule controlled substances.[115] These asymmetries create a one-way ratcheting effect, where

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110. 546 U.S. at 266.

111. Courts are to give no deference to agency interpretations of statutory ambiguity. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412-13 (2024).

112. *See* Marks & Shachar, *supra* note 63, at 294 (stating that small volumes of anecdotal evidence became sufficient to place drugs in Schedule I); Drug Enf't Admin., Diversion Control Div., Drug & Chem. Evaluation Section, *Schedule of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I*, U.S. DEP'T OF JUST. 3-5, 8-9 (Aug. 2021) (on file with author) (citing anecdotal evidence, including "[a]necdotal reports on the Internet" and anecdotal reports that drugs are available "on the street" to draw conclusions regarding the potential for abuse, pharmacologic effects, and history and current pat-tern of abuse of two substances).

113. Marijuana Scheduling Petition: Denial of Petition; Remand, 57 Fed. Reg. 10499, 10502 (Mar. 26, 1992) (claiming that "sick people are not objective scientific observers, especially when it comes to their own health").

114. *Id.*

115. *See* Marks & Shachar, *supra* note 63, at 294-97; Ams. for Safe Access v. DEA, 706 F.3d 438, 451-52 (D.C. Cir. 2013) (adopting DEA's requirement for scientifically rigorous data, comparable to what FDA requires when considering whether to approve a drug, to establish currently accepted medical use); Grinspoon v. DEA, 828 F.2d 811, 886 (1st Cir. 1987) (stating the DEA Administrator's perspective that "currently accepted medical use" requires FDA approval. However, the court found this interpretation "strained and unpersuasive.").

upscheduling is more frequent than downscheduling, and far more drugs are added to the schedules than are removed.[116]

Since its founding in 1973, DEA has completed about 550 scheduling actions.[117] It has downscheduled drugs in Schedule I seven times and descheduled them three times.[118] More often, scheduling actions move drugs onto and up the schedules than down or off the list.[119] This ratcheting effect has stifled research because it is burdensome and expensive to work with Schedule I drugs. Strict requirements regarding storage, security, and record keeping increase costs.[120] Yet without more research, scientists cannot obtain the quantities of high-quality evidence required for rescheduling or descheduling. Evidence asymmetries created a catch-22 that sustains drug prohibition while impeding scientific progress and therapeutic innovation.[121]

DEA interpretation of currently accepted medical use exacerbates the evidence asymmetries by setting an unrealistically high bar for rescheduling. To evaluate currently accepted medical use, DEA created an eight-factor test.[122] Although a court held that it would be impossible to meet three of the factors (prompting DEA to remove them), the resulting five-part test has proven nearly

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116. The author reached this conclusion by counting all scheduling actions prior to December 31, 2024. The author counted 16 instances of upscheduling, 10 instances of downscheduling, 487 instances where uncontrolled substances were added to the controlled substances list, and 19 instances of descheduling. *See generally* Drug Enf't Admin., Off. of Diversion Control, *Scheduling Actions—Chronological Order*, U.S. DEP'T OF JUST. (Dec. 31, 2024), https://www.deadiversion.usdoj.gov/schedules/orangebook/b_sched_chron.pdf [https://perma.cc/5XEL-RRYL] (listing all instances of drug scheduling, rescheduling, and descheduling prior to December 31, 2024).

117. The author reached this estimate by counting all scheduling actions prior to December 31, 2024, yielding a total of 535, which excludes rare cases where DEA withdrew a proposed scheduling rule or temporary scheduling expired. *See generally id.* (listing all drug scheduling actions prior to December 31, 2024).

118. *See id.*

119. *See id.*

120. *See* Robert A. Mikos, *Marijuana and the Tyrannies of Scheduling*, FORDHAM L. REV. 473, 489 (2024) (describing the challenges of conducting research with Schedule I substances); Alex Kreit, *Federal Marijuana Reform and the Controlled Substances Act*, 101 B.U. L. REV. 1231, 1248, 1250 (2021) (arguing that these costs impede scientific breakthroughs).

121. *See* Marks & Shachar, *supra* note 63, at 296 (describing the catch-22 of drug scheduling).

122. Although there may be some overlap of their content, DEA's eight-factor test for evaluating currently accepted medical use differs from the eight CSA scheduling factors of Section 811(c), which the Secretary considers when drafting binding recommendations under Section 811(b) and the AG considers during scheduling actions under Section 811(a). 21 U.S.C. § 811(a)-(c) (2018). All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994) (noting DEA's reduction of its eight-factor test for "currently accepted medical use" to a five-factor test); Ams. for Safe Access v. DEA, 706 F.3d 438, 449 (D.C. Cir. 2013) (noting the court's express approval of the new test in *Alliance*).

impossible to pass.[123] Consequently, when drugs are placed in Schedule I, they often become trapped.[124]

In addition to biasing scheduling actions in favor of initial scheduling and upscheduling, judicial deference to DEA has produced regulatory redundancy. Where the CSA authorizes the AG to initiate scheduling actions or the Secretary to make binding recommendations, the statute may appear to ask them to use identical scheduling factors, which are listed in Section 811(c).[125] This section ostensibly requires the AG to "consider" all eight factors that the Secretary utilizes to make binding recommendations. DEA has leveraged this apparent redundancy to claim scheduling jurisdiction comparable to that of HHS, including scientific decision-making authority.[126] Consequently, DEA performs an eight-factor analysis in parallel with HHS.[127] However, taking a structural view that considers how multiple provisions fit together reveals that the CSA limits DEA to evaluating scheduling criteria that involve nonmedical judgments. For instance, reading Section 811(c) in conjunction with Section 811(b) and the CSA's legislative history casts 811(c) in new light.

Section 811(b) requires the Secretary to consider five CSA scheduling factors that have inherently medical qualities when drafting binding recommendations, as well as "any scientific or medical considerations" regarding the remaining three factors, which are not inherently medical.[128] This provision suggests that all eight factors have at least some scientific or medical qualities. Because 811(b) binds DEA to the Secretary's recommendations, and Congress gave the Secretary exclusive authority to make scientific and medical judgments, DEA authority

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123. *See All. for Cannabis Therapeutics*, 15 F.3d at 1134 (deeming three factors in DEA's eight-factor test impossible to meet because they assumed marijuana was available for medical use despite its Schedule I status).

124. Marks & Shachar, *supra* note 63, at 294, 296 (describing Schedule I as a regulatory blackhole).

125. *See* 21 U.S.C. § 811(b), (c) (2018).

126. Drug Enf't Admin., *Scheduling of Controlled Substances: 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I, Government's Prehearing Statement*, U.S. DEP'T OF JUST., Docket No. 22-21, at 4, 5 (June 13, 2022) (describing planned DEA testimony regarding DEA review of pharmacology, chemistry, trafficking, abuse, and dependence of DOI and DOC, and stating that DEA performed its own eight-factor analysis).

127. *Id.*; Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I, 88 Fed. Reg. 86278, 86281 (proposed Dec. 13, 2023) (to be codified at 21 C.F.R. pt. 1308) (stating that DEA "completed its own eight factor review"); Grinspoon v. DEA, 828 F.2d 811, 897 (1st Cir. 1987) (stating that HHS had rubber-stamped the eight-factor analysis that DEA had already performed).

128. The five inherently medical CSA scheduling factors considered by the Secretary under Section 811(b) are distinct from DEA's five-factor test for evaluating currently accepted medical use described in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994). 21 U.S.C. § 811(b) (2018).

under 811(c) is more limited than it might appear. Specifically, the Secretary's recommendations bind DEA regarding the five scheduling factors that are inherently medical as well as the three non-inherently medical factors.[129] At most, DEA might have authority to draw conclusions independently regarding non-medical aspects of the three scheduling factors that are not inherently medical, but not regarding the five inherently medical factors on which it must defer to the Secretary.

Grinspoon v. DEA illustrates what can happen when HHS fails to meet its scientific CSA responsibilities and DEA exceeds its statutory authority.[130] In 1985, DEA initiated proceedings to place 3,4-Methylenedioxymethamphetamine (MDMA), which was previously uncontrolled, on Schedule I. After administrative hearings and subsequent litigation, DEA succeeded despite objections from scientists, healthcare professionals, and DEA's administrative law judge (ALJ).[131] Following MDMA's Schedule I classification, research on the drug

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129. *Id.*; 21 U.S.C. § 811(c) (2018); OLC Opinion, *supra* note 16, at 22 n.6 ("HHS's recommendations with respect to 'scientific and medical matters' are binding for all eight factors listed in section 811(c)." (quoting H.R. REP. NO. 91-1444, at 33 (1970))).

130. *See* 1970 Health & Welfare, *supra* note 106, at 590–91 (statement of Rep. Pepper) (endorsing the House Select Committee on Crime's conclusion that drug scheduling is a scientific and medical process, and rather than falling to law enforcement, it would "more logically lie with the Department of Health, Education, and Welfare," because scheduling "involves the public health of this country, and major participation is required by that department of government which is charged with that overall responsibility."); *Grinspoon*, 828 F.2d at 897 (observing that HHS underperformed by failing to consult any medical professionals, including FDA's expert panel, and rubberstamping DEA's eight-factor analysis, concluding that FDA failed to forward to the Assistant Secretary for Health information that contradicted evidence cited by DEA, and finding that DEA's interpretation of two Schedule I criteria contravened congressional intent).

131. *Grinspoon*, 828 F.2d at 883, 884, 885, 896–97 (describing DEA's 1984 recommendation to place MDMA in Schedule I, citing the testimony of healthcare experts at a DEA scheduling hearing who argued that MDMA had a currently accepted medical use, referencing the presiding ALJ's conclusion that based on their testimony MDMA fit none of three CSA criteria necessary for classifying a drug as Schedule I, noting the ALJ's recommendation that MDMA be placed in Schedule III instead of Schedule I as well as DEA's rejection of the ALJ's recommendation, dismissing claims that placing MDMA on Schedule I would negatively impact medical research after finding such claims irrelevant to drug scheduling even if they are accurate, and relying on *Chevron* to accept DEA's argument that MDMA has a high potential for abuse, while also acknowledging that evidence provided by the petitioner, a physician and Harvard Medical School professor, could potentially have opened the door to another outcome if the court had not been bound by *Chevron* and could have conducted its own review of the evidence "*de novo*"); Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act; Remand, 53 Fed. Reg. 5156, 5156–58 (Feb. 22, 1988) (codified at 21 C.F.R. pt. 1308), https://maps.org/research-archive/dea-mdma/pdf/0200.PDF [https://perma.cc/AV27-GCZ8] (placing MDMA on Schedule I after the *Grinspoon* court remanded the case to DEA for reconsideration because

stopped for about twenty years, and it took another twenty to reemerge and over thirty to reach the point of seeking FDA approval.[132] Today, despite substantial commercial investment, progress on MDMA research remains slow and expensive.[133]

During DEA-initiated proceedings to place MDMA on Schedule I, an ALJ concluded that "the material received from HHS is of little assistance to us in this case."[134] HHS performed no independent tests and completed no studies or scientific examinations.[135] "Relevant and material facts and opinions, within the knowledge of some at [the Food and Drug Administration (FDA)], were not brought to the attention of higher officials," wrote the ALJ, "including the Assistant Secretary who signed the formal communication to the Administrator of DEA."[136] Furthermore, "FDA did not see fit to consult its panel of experts created for this purpose, the Drug Abuse Advisory Committee" (DACA).[137] That panel

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the court found that DEA's interpretation of two Schedule I criteria conflicted with congressional intent).

132. PASSIE, *supra* note 21, at 136-37 (describing the formation of the Multidisciplinary Association for Psychedelic Studies (MAPS) in 1986 by Rick Doblin after DEA initiated proceedings to place MDMA on Schedule I, explaining that it took MAPS over thirty years to start phase 3 clinical testing of MDMA in 2019, and reporting that MAPS had raised over $100 million by 2020); Mason Marks, *Psychedelic Therapy Scrutinized by FDA Advisory Committee?*, 332 JAMA 963, 963 (2024) (describing the formation by MAPS of a for-profit subsidiary, the MAPS Public Benefit Corporation, in 2014 to take over clinical testing of MDMA, and discussing that company's restructuring and rebranding as Lykos Therapeutics in 2024).

133. *See id.* at 963-94 (describing the outside investment of $100 million in Lykos Therapeutics, discussing the 2024 review of the company's phase 3 clinical trial data by an FDA advisory committee after the company sought FDA approval of its combination of MDMA and psychotherapy for treating posttraumatic stress disorder, and explaining why the committee recommended against FDA approval of the treatment); Sara Reardon, *FDA Rejects Ecstasy as a Therapy: What's Next for Psychedelics?*, NATURE (Aug. 13, 2024), https://www.nature.com/articles/d41586-024-02597-x [https://perma.cc/PJD8-RGVF] (reporting on FDA's 2024 decision to reject MDMA as a treatment for posttraumatic stress disorder and the agency's request for a third phase 3 clinical trial, which Lykos Therapeutics said could take years to complete); *VA Funds First Study on Psychedelic-Assisted Therapy for Veterans*, U.S. DEP'T VETERANS AFFS. (Dec. 3, 2024, 9:00 AM), https://news.va.gov/press-room/va-funds-first-study-on-psychedelic-assisted-therapy-for-veterans [https://perma.cc/UCG5-2EMM] (announcing that the Veteran's Administration would provide $1.5 million to fund research on MDMA as a potential treatment for posttraumatic stress disorder and alcohol use disorder, which would be the first VA-funded research on psychedelic medicine since the 1960s).

134. Drug Enf't Admin., *Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge on Issues Two Through Seven*, U.S. DEP'T OF JUST., Docket No. 84-48, at 64 (1986), https://maps.org/wp-content/uploads/1988/11/0112.pdf [https://perma.cc/XUE5-WGVF].

135. *Id.*

136. *Id.*

137. *Id.*

"would undoubtedly have had helpful input for our consideration of the 'acceptable medical use' issue, and the 'degree of abuse potential' issue, among others," the ALJ said.[138] Potentially acknowledging that HHS recommendations usually bind DEA, the ALJ concluded that the HHS communication contained no binding recommendations. Instead, the communication merely repeated or summarized what DEA had initially sent to HHS, containing nonbinding opinions.[139] In written testimony, one attorney argued that DEA could not schedule MDMA because the Secretary had not performed the steps required by Section 811(b).[140] The attorney believed the Secretary's failure had deprived DEA of "jurisdiction" to schedule MDMA.[141] The ALJ rejected this argument, claiming Section 811(b) requires only that DEA "request" an HHS evaluation, and since DEA made that request, the statutory requirements had been met.[142]

Upon review, the First Circuit described the performance of HHS as "less than admirable."[143] The court observed that "HHS failed to look beyond its own files" and "neglected to consult any organization of medical professionals or even the FDA's own panel of experts [DACA]."[144] Moreover, when FDA analysts received a letter from NIDA contradicting some DEA conclusions, FDA failed to forward it to the Assistant Secretary for Health before HHS sent recommendations to the DEA Administrator.[145] HHS had "simply rubber-stamped" DEA's eight-factor analysis.[146] Despite these deficiencies, the court adopted the ALJ's conclusion. At most, the Administrator's reliance on HHS constituted harmless error, wrote the court.[147] However, the CSA text, structure, and purpose demand more.

When Congress intends for interagency consultation to be optional, it requires agencies to request outside input without requiring them to obtain or follow it.[148] For example, the Federal Insecticide, Fungicide, and Rodenticide Act

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138. *Id.*

139. *Id.* at 65.

140. *Id.* at 66-67 (testimony of attorney Lyn B. Ehrnstein).

141. *Id.*

142. *Id.*

143. Grinspoon v. DEA, 828 F.2d 881, 897 (1st Cir. 1987).

144. *Id.*

145. *Id.*

146. *Id.*

147. *Id.* at 897-98 (stating that "we fail to see how the procedure followed by HHS tainted the Administrator's determination.").

148. The CSA's statutory history indicates that Congress discarded early House and Senate drafts, which required only that the AG seek the Secretary's advice. *See* H.R. 17463 Summary, *supra* note 41, at 3; Freeman & Rossi, *supra* note 67, at 1157 ("Congress sometimes merely authorizes

requires only that the Environmental Protection Agency solicit opinions from HHS and the Department of Agriculture.[149] In contrast, the CSA requires consulted agencies to respond by furnishing "assistance, including technical advice" regarding controlled substances, when requested by the AG.[150] Furthermore, it states that the Secretary's recommendations "shall be made in writing and submitted to the Attorney General."[151] Congress presumably selected the phrases "shall consider" and "shall be made" to require completion of the steps described.[152] In other words, it is insufficient for the AG to request the Secretary's input, or for HHS to rubberstamp DEA proposals without performing an independent scientific analysis.

The Endangered Species Act requires the Secretary of the Interior to consult with the Fish and Wildlife Service and the National Marine Fisheries Service.[153] In rendering advice, these agencies must "use the best scientific and commercial data available" to ensure that their actions are unlikely to jeopardize endangered or threatened species or adversely impact their habitat.[154] The National Environmental Policy Act requires agencies to prepare environmental impact statements for review by the Environmental Protection Agency.[155] Some statutes require agencies seeking outside advice to defer to external recommendations by default, unless the recipient explains why following outside advice would breach the recipient's statutory duties or otherwise violate the law.[156] For instance, the Federal Power Act requires the Federal Energy Regulatory Commission to follow recommendations from other agencies unless doing so would be inconsistent with the

interagency consultation without requiring it."); 7 U.S.C. § 136s(a)-(b) (2018) (requiring the solicitation of comments).

149. 7 U.S.C. § 136s(a)-(b) (2018).

150. 21 U.S.C. § 873(b) (2018); *see also* OLC Opinion, *supra* note 16, at 7 (regarding the AG's statutory obligation to obtain HHS advice).

151. 21 U.S.C. § 811(b) (2018).

152. *See* Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 27 (1998) (concluding that the word "shall" typically "creates an obligation impervious to judicial discretion."); Kratom Letter, *supra* note 63, at 2 (describing the completion of HHS evaluation and recommendations as a responsibility delegated by the Secretary to the Assistant Secretary for Health).

153. 16 U.S.C. § 1536(a)(2) (2018).

154. *Id.*

155. 42 U.S.C. §§ 4332, 7609 (2018).

156. Freeman & Rossi, *supra* note 67, at 1159; Electric Consumption Protection Act of 1986, Pub. L. No. 99-495, 100 Stat. 1243, 1244-45 (codified at 16 U.S.C. § 803(j)).

Act's purposes or other applicable laws.[157] The CSA requires more than deference by default.[158]

Instead of creating a rebuttable presumption to follow the Secretary's recommendations, the CSA declares that they bind the AG.[159] One must be cautious when using the text of one statute to interpret another.[160] Nevertheless, if in some cases Congress specifies that agencies should be influenced by outside recommendations, or requires deferring to them by default, while in another instances Congress uses stronger language to bind agencies to outside recommendations, it follows that binding recommendations warrant more than a rebuttable presumption of deference.[161] The legislative history strengthens this interpretation. Because Congress placed medical judgments solely in the Secretary's hands and bound the AG to them, DEA owes more than deference to the Secretary's recommendations; DEA must follow them.[162] However, courts and DEA Administrators often give HHS recommendations far less consideration.[163]

When HHS failed to provide binding recommendations in *Grinspoon*, it shirked statutory responsibilities and disrupted the separation of scheduling powers.[164] Abdication can be framed as administrative underreach, where agencies fail to act despite legal authorization or obligation to act.[165] If intentional, it might constitute administrative sabotage, and if coordinated with another

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157. 16 U.S.C. § 803(j)(1)-(2) (2018) (requiring agency consideration of outside recommendations and publication of findings if the agency deviates from the recommendations).

158. 21 U.S.C. § 811(b) (2018).

159. *Id.*; *see* 16 U.S.C. § 803(j)(1)-(2) (2018) (requiring licenses issued by the Federal Power Commission to include conditions based on the recommendations of other agencies).

160. *See* Anuj C. Desai, *The Dilemma of Interstatutory Interpretation*, 77 WASH. & LEE L. REV. 177, 182 (2020) (describing the practice of interstatutory interpretation using the *in pari materia* principle).

161. *See* 16 U.S.C. § 803(j)(1)-(2) (2018) (defaulting to outside agency recommendations and attempting to resolve disagreements by "giving due weight to the recommendations, expertise, and statutory responsibilities" of the agencies that provided recommendations); 21 U.S.C § 811(b) (2018) (regarding the Secretary's binding recommendations).

162. *See* Gonzales v. Oregon, 546 U.S. 243, 266 (2006); OLC Opinion, *supra* note 16, at 26.

163. Grinspoon v. DEA, 828 F.2d 881, 897-98 (1st Cir. 1987).

164. *See id.* at 897 (finding that HHS had merely rubber-stamped DEA recommendations and FDA had withheld relevant information); 21 U.S.C. § 873(b) (2018); 1970 Health & Welfare, *supra* note 106, at 590-91 (statement of Rep. Pepper) (anticipating substantial participation in the scheduling process by the executive department responsible for public health, which is currently HHS).

165. Administrative underreach is analogous to executive underreach. *See* David E. Pozen & Kim Lane Scheppele, *Executive Underreach, in Pandemics and Otherwise*, 114 AM. J. INT'L L. 608, 609 (2020) (defining executive underreach as the failure to address a substantial public problem, which the executive is functionally and legally equipped to handle, and describing underreach in terms of expectations created by national or international law).

agency, it could reflect administrative collusion.[166] Considering the stakes of drug scheduling and the express authority delegated to the Secretary, HHS should have done more in *Grinspoon*.[167] In contrast, scheduling MDMA without the requisite recommendations reflects DEA overreach. Congress reserved authority to make scientific and medical determinations for the Secretary. By scheduling MDMA without substantive HHS input, DEA substituted its scientific judgment for the Secretary's.[168]

In 2005, the Supreme Court addressed an analogous situation regarding the division of CSA powers.[169] After Oregon legalized physician-assisted suicide, the AG determined that dispensing Schedule II drugs to hasten one's death was not a legitimate medical use.[170] Following advice from OLC, the AG issued an interpretive rule prohibiting the practice and threatening to revoke DEA registration from doctors who administered drugs for this purpose.[171] Although *Gonzales* focused on DEA registration rather than drug scheduling, the Court explained how the AG could exceed his statutory authority, which Congress had narrowly defined.[172] Here, as in *Grinspoon*, the AG made medical judgments that Congress reserved for the Secretary.[173] "The authority desired by the Government is inconsistent with the design of the statute in other fundamental respects," wrote Justice Kennedy.[174] For example, "the Attorney General does not have the sole delegated authority under the CSA. He must instead share it with, and in some respects defer to, the Secretary, whose functions are likewise delineated and confined by the statute."[175] The text carefully divides decision-making authority among governments actors to ensure that the Secretary makes all federal-level

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166. *See* Noll, *supra* note 88, at 763-65 (defining administrative sabotage); Freeman & Rossi, *supra* note 67, at 1189 (defining administrative collusion).

167. *See* Pozen & Scheppele, *supra* note 165, at 609 (stating that in cases of executive underreach, an executive should have done more, considering the severity of the public problem and power delegated to the executive to address it).

168. *See* 21 U.S.C. § 873(b) (2018) (requiring agencies and other federal institutions to assist the AG upon request); *c.f.* Gonzales v. Oregon, 546 U.S. 243, 266 (2006) (stating that the CSA structure prohibits ceding medical judgments to the AG or other federal officials lacking medical expertise).

169. *Gonzales*, 546 U.S. at 265.

170. *Id.* at 253-54.

171. *Id.* at 253-54, 262; *see also* Gersen, *supra* note 10, at 205 (quoting the AG's interpretative rule and referencing his reliance on OLC legal analysis).

172. 546 U.S. at 264.

173. *Id.* at 265 (finding the AG's claim that his rule was legal rather than medical unpersuasive); Grinspoon v. DEA, 828 F.2d 881, 897 (1st Cir. 1987).

174. *Gonzales*, 546 U.S. at 265.

175. *Id.*

medical judgments.[176] Justice Kennedy cited the 1974 Congressional Record, which states, "All decisions of a medical nature are to be made by the Secretary . . . . Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General."[177]

Part I of this Essay analyzed the CSA text, purpose, and history to describe the separation of drug scheduling powers, as well as instances where HHS fell short of its scheduling obligations and DEA exceeded its authority. Part II analyzes cases where HHS fully exercised its scheduling authority by broadly interpreting CSA scheduling factors, utilizing its control veto, and making binding recommendations to balance and constrain law enforcement perspectives.

II. CORRECTING DRUG SCHEDULING'S BUREAUCRATIC DRIFT

Since Congress enacted the CSA, the separation of scheduling powers has drifted due to HHS's abdication of scheduling authority and judicial deference to DEA's interpretation of the CSA and its jurisdictional boundaries. The resulting unbalanced scheduling actions have undervalued public health perspectives. Consequently, courts and federal agencies should restore the separation of scheduling powers by embracing the scientific authority of HHS and limiting DEA to nonscientific scheduling determinations. Restoring this statutory division of power would align with congressional goals, reduce regulatory redundancy, and conserve limited law enforcement resources. DEA could emphasize non-scheduling-related agency priorities such as enforcing anti-diversion, drug trafficking, and money laundering provisions of the CSA. This Part further defines HHS authority by analyzing cases where HHS utilized its powers to counteract drug control's tendency toward bureaucratic drift.

A. The Categorical HHS Control Veto

This Section describes two cases where HHS utilized its control veto to override DEA scheduling proposals. In 2002, DEA temporarily placed the drug 1-[3-(Trifluoro-methyl)-phenyl]piperazine (TFMPP) in Schedule I using its

176. *Id.* at 265-67, 274 (citing 21 U.S.C. § 811(b) and stating that the AG is an "unlikely recipient" of broad interpretive authority under the statute, "given the Secretary's primacy in shaping medical policy under the CSA, and the statute's otherwise careful allocation of decisionmaking powers.").

177. *Id.* at 266; *see* H.R. REP. NO. 93-884, at 6 (1974) (reaffirming the CSA's statutory separation of powers); Gersen, *supra* note 10, at 225 (analyzing the *Gonzales* majority's reliance on agency expertise and stating that according to Justice Kennedy's opinion, the CSA gave the Secretary "exclusive interpretive authority regarding health and medical practices.").

emergency scheduling powers.[178] DEA described TFMPP as a hallucinogen with MDMA-like effects.[179] It concluded that TFMPP has a high potential for abuse and no currently accepted medical use.[180] When temporary scheduling was about to expire and could no longer be extended, DEA sought to control TFMPP permanently and requested HHS recommendations.[181] However, FDA and NIDA advised HHS against controlling TFMPP, and HHS exercised its control veto.[182] This case illustrates the Secretary's power to override DEA scheduling proposals.[183] Despite DEA's conclusions regarding the drug's potential for abuse and its lack of any currently accepted medical use, the veto blocked permanent scheduling and removed TFMPP from federal control.[184]

In 2018, use of the control veto illustrated the breadth of HHS scheduling authority, which includes assessing the impact of scheduling on scientific research and public health.[185] The Assistant Secretary for Health vetoed control of the Southeast Asian plant *Mitragyna speciosa*, commonly known as kratom.[186] In Southeast Asia, people chew kratom leaves for their stimulant effect.[187] At high

178. Schedules of Controlled Substances: Temporary Placement of Benzylpiperazine and Trifluoromethylphenylpiperazine into Schedule I, 67 Fed. Reg. 59161, 59161 (Sept. 20, 2002) [hereinafter TFMPP Rule 2002] (codified at 21 C.F.R. § 1308.11); *Piperazines*, UNODC LAB'Y & SCI. SERV. PORTALS, https://www.unodc.org/LSS/SubstanceGroup/Details/8242b801-355c-4454-9fdc-ba4b7e7689d5 [https://perma.cc/DS83-V39Z] (reporting that 1-[3-(Trifluoro-methyl)-phenyl]piperazine (TFMPP) belongs to a class of drugs called piperazines, which are described as "failed pharmaceuticals" without medical utility).

179. TFMPP Rule 2002, *supra* note 178, at 59161-62 (reporting that TFMPP was promoted as "Ecstasy" or a legal alternative to MDMA).

180. *Id.* at 59161.

181. Schedules of Controlled Substances: Placement of 2,5-Dimethoxy-4-(n)-propylthiophenethylamine and N-Benzylpiperazine into Schedule I of the Controlled Substances Act, 69 Fed. Reg. 12794, 12794-95 (Mar. 18, 2004) [hereinafter TFMPP Rule 2004] (codified at 21 C.F.R. pt. 1308).

182. *Id.*

183. 21 U.S.C. § 811(b) (2018); *see* Mason Marks, *Automating FDA Regulation*, 71 DUKE L.J. 1207, 1233-36 (2022).

184. TFMPP Rule 2004, *supra* note 181, at 12794-95.

185. *See* Kratom Letter, *supra* note 63, at 2-4.

186. Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on the Agency's Scientific Evidence on the Presence of Opioid Compounds in Kratom, Underscoring Its Potential for Abuse (Feb. 6, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-scientific-evidence-presence-opioid-compounds [https://perma.cc/9C79-SAE3].

187. *See, e.g.*, Darshan Singh, Suresh Narayanan, Balasingam Vicknasingam, Ornella Corazza, Rita Santacroce & Andres Roman Urrestarazu, *Changing Trends in the Use of Kratom (Mitragyna Speciosa) in Southeast Asia*, 32 HUM. PSYCHOPHARMACOLOGY: CLINICAL & EXPERIMENTAL art. no. e2582, at 2 (2017) (stating that many people in Southeast Asia consume kratom in the morning to increase alertness and enhance productivity).

doses, kratom acts as a depressant and pain reliever. Its best-known active ingredients are mitragynine and 7-hydroxymitragynine (the mitragynines). In 2016, DEA announced plans to control them as Schedule I drugs.[188] While HHS initially agreed under President Obama, HHS reversed positions during President Trump's first term in recommendations notable for emphasizing scientific, medical, and public health implications. The Assistant Secretary explained that millions of people reportedly use kratom in the United States, often as an opioid substitute.[189] He concluded that controlling the mitragynines could have dire public health consequences.[190] Notably, FDA supported controlling kratom. However, by utilizing the control veto, HHS broke with FDA and bound DEA, ending the debate.[191]

The HHS kratom veto illustrates the breadth of CSA scheduling factors.[192] Although some factors confine deliberations to a drug's chemical traits or physiologic effects,[193] factor six does not.[194] It requires considering "[w]hat, if any, risk there is to the public health."[195] Naturally, HHS should consider all public health implications.[196] The Assistant Secretary described several risks, including harms potentially imposed on vulnerable individuals.[197] Controlling kratom

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188. *Id.*

189. Kratom Letter, *supra* note 63, at 3-4.

190. *Id.*

191. 21 U.S.C. § 811(b) (2018).

192. *See* Kratom Letter, *supra* note 63, at 3-4. In 2021, Giroir tweeted that he rejected former FDA Commissioner Scott Gottlieb's kratom recommendations due to "embarrassingly poor evidence & data, and a failure to consider overall public health." *See* Marks, *supra* note 183, at 1235.

193. Factor three references "[t]he state of current scientific knowledge regarding the drug," and factor 1 references "[i]ts actual or relative potential for abuse." 21 U.S.C. § 811(c)(1), (c)(3) (2018).

194. *Id.* § 811(c)(6).

195. *Id.*; *see id.* § 811(b) (requiring the Secretary of HHS to consider factor six when contemplating whether a substance should be controlled or removed from federal control).

196. *See* Johnson et al., *supra* note 22, at 158-59 (noting the FDA's increasing recognition that analysis regarding risks to public health must include consideration of the benefits of a substance to ensure a balanced risk-benefit analysis); *see also* 21 U.S.C. § 811(c)(1)-(8) (2018) (listing eight drug scheduling factors, which can and should be interpreted broadly by qualified public health experts, including factor six, which considers any risks to public health associated with controlling or rescheduling substances). If Congress intended to limit factor six to the public health effects of drug consumption, as opposed to drug scheduling, it could have tied factor six to a drug's traits as it did other factors, such as factor two, which considers scientific evidence of a drugs pharmacologic effects. Even factors that weigh a drug's chemical or pharmacologic properties should be interpreted broadly to encompass all potential scientific and medical impacts of scheduling decisions.

197. Kratom Letter, *supra* note 63, at 4.

would remove it from legal markets, and people who consumed it for pain relief might experience "intractable pain" or psychological distress and be at increased risk for suicide.[198] Some might shift to riskier drugs such as heroin or fentanyl.[199] Deaths due to overdose or infection from intravenous drug use could increase.[200] Furthermore, controlling kratom would criminalize and stigmatize people, potentially causing additional harm by deterring them from openly discussing kratom with healthcare professionals.[201]

When properly utilized, HHS scheduling authority should balance DEA perspectives and reduce the evidence asymmetries of scheduling. DEA and FDA had planned to schedule the mitragynines based on anecdotal evidence, some of which had been discredited.[202] By considering the broader public health effects of drug control, HHS balanced the scheduling process. It also addressed the potential impact of scheduling on kratom research.[203] The role of research impact in scheduling is debated. In 2024, DEA announced a hearing on its proposed rule to classify two uncontrolled substances (DOI and DOC) as Schedule I drugs.[204] Opponents emphasized the negative impact scheduling would have on research

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198. *Id.* at 3.

199. *Id.* at 4.

200. *Id.*

201. *Id.*

202. *See* Robert Kronstrand, Markus Roman, Gunilla Thelander & Anders Eriksson, *Unintentional Fatal Intoxications with Mitragynine and O-Desmethyltramadol from Herbal Blend Krypton*, 35 J. ANALYTICAL TOXICOLOGY 242, 242, 245-46 (2011) (describing the contents of krypton, a mixture of kratom and the opioid O-desmethyltramadol, and reporting nine cases where people died after consuming krypton. At the time of death, all nine had at least two other drugs in their blood, and seven had between three and eight other drugs in their systems, such as benzodiazepines, alcohol, amphetamines, sedatives, anticonvulsants, or an antipsychotic, which made it unclear what contribution, if any, kratom made to their deaths); Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule I, 81 Fed. Reg. 59929, 59930, 59932 (proposed Aug. 31, 2016) (to be codified at 21 C.F.R. pt. 1308) (reporting the nine krypton-associated fatalities as "deaths related to kratom exposure," and using them to establish a kratom-related risk to public health under scheduling factor six, while also utilizing calls made to poison control as evidence to establish a history and current pattern of kratom abuse under scheduling factor 4); O. Hayden Griffin & Megan E. Webb, *The Scheduling of Kratom and Selective Use of Data*, 50 J. PSYCHOACTIVE DRUGS 114, 118 (2018) (reporting that the 263 calls to poison control regarding kratom in 2015 constituted approximately 0.000091 percent of the total calls to poison control, and kratom-related calls were dwarfed by calls made that year regarding battery ingestion (9,104 or 0.42 percent), cosmetics and personal care products (192,596 or 8.9 percent), household cleaning products (195,974 or 9 percent), and pain relievers (287,843 or 1e percent)).

203. Kratom Letter, *supra* note 63, at 4 (citing CSA scheduling factor six).

204. Announcement of Hearing: Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I, 89 Fed. Reg. 24750, 24750-51 (Apr. 9, 2024).

and attempted to introduce witnesses who could testify regarding research impact.[205] DEA moved to exclude them, arguing that testimony should be limited to evidence relevant to Section 811, Section 812(b)(1), and the agency's five-part test for currently accepted medical use.[206] DEA claimed that research impact is irrelevant and that allowing experts to testify would waste time and judicial resources.[207] Nevertheless, DEA concluded that its Administrator could consider written comments regarding research impact, which presumably involves making scientific or medical judgments.[208]

DEA's claim that research impact is irrelevant contradicts the HHS kratom decision.[209] The expansive language of scheduling factor six (regarding "[w]hat, if any, risk there is to public health") inherently encompasses research impact because research plays a central role in advancing the science and medicine underlying public health. The CSA's text and legislative history reflect the importance of research impact to scheduling deliberations, and the statutory authority granted to HHS appears too broad to exclude it.[210] Section 811(b) requires the Secretary to consider all eight CSA scheduling factors, including factor three, which involves the "state of current scientific knowledge regarding the drug or other substance."[211] Nothing limits the Secretary to applying factor three in one direction, for instance, by considering only the impact of existing scientific knowledge on whether to schedule a drug, as opposed to the impact of scheduling a drug on existing scientific knowledge.[212] Because research is key to advancing the sciences underlying public health, which is expressly part of HHS's mission, it is difficult to imagine how Section 811(b) could not encompass research impact.[213]

Stakeholders have also raised the importance of considering scheduling's impact on medical practice.[214] This effect is especially relevant when DEA seeks to

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205. Drug Enf't Admin., *Response in Opposition to Government's Motion in Limine*, U.S. DEP'T OF JUST., Docket No. 24-24, at 4-5 (2024).

206. Drug Enf't Admin., *Government's Motion in Limine*, U.S. DEP'T OF JUST., Docket No. 24-24, at 2, 4, 10 (2024) (arguing that the proposed testimony would be redundant and lack relevance to the scheduling factors of 21 U.S.C. § 811(c) and 21 U.S.C. § 812(b)(1)).

207. *Id.* at 10.

208. *Id.* (maintaining that the evidence remains irrelevant to CSA scheduling factors).

209. *Id.*; Kratom Letter, *supra* note 63, at 4.

210. 21 U.S.C. § 811(b) (2018).

211. *Id.* § 811(c)(3).

212. *Id.*

213. *See Mission Statement*, *supra* note 60.

214. Carisoprodol Rule, *supra* note 35, at 77,330 ("Meda Pharmaceuticals . . . objected to the proposed rule on the ground that [it gave] 'inadequate weight to the negative impact on patient care of scheduling carisoprodol.'").

schedule uncontrolled drugs utilized in healthcare settings.[215] Aside from illustrating the breadth of HHS scheduling authority, the kratom and carisoprodol cases demonstrate why FDA might not be the best recipient of scheduling authority. When HHS delegates scheduling responsibilities to FDA, the agency often relies on its Drug Safety and Risk Management (DSaRM) Advisory Committee, an independent panel of experts. This panel replaced DACA and advises FDA's Commissioner on abuse potential and other scheduling-related matters.[216] Sometimes FDA relies on other agencies such as NIDA and the Substance Abuse and Mental Health Services Administration.[217]

The DSaRM Advisory Committee is relatively homogeneous, comprised largely of toxicologists and pharmacoepidemiologists who focus largely on identifying drug-related adverse events.[218] These highly trained specialists are undoubtedly qualified to assess the potential risks of drug use. However, they may be less qualified to evaluate the public health risks of scheduling a drug. Much like holding a hammer makes everything resemble a nail, training in toxicology or pharmacoepidemiology could make many drugs look like good candidates for strict regulation or prohibition. That may be particularly true for illicit, non-FDA-approved drugs. DSaRM might erroneously conclude that because a drug is illegal, or lacks FDA approval, it should be placed on Schedule I.

But FDA approval and drug scheduling are separate regulatory processes with different functions. Furthermore, as the kratom case illustrates, people who make scheduling decisions should consider an array of variables beyond the risks of drug consumption, including the risks associated with drug scheduling and prohibition. To utilize the extent of its scheduling authority and maintain the separation of powers, HHS could form new committees with broader experience and delegate scheduling responsibilities to them, or it could make greater use of expertise within the Office of the Assistant Secretary for Health (OASH) or the Centers for Disease Control (CDC).[219]

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215. *See id.* (controlling carisoprodol, which was previously uncontrolled, in Schedule IV).

216. Request for Nominations for Members on Public Advisory Committees; Drug Safety and Risk Management Advisory Committee (Formally Drug Abuse Advisory Committee), 67 Fed. Reg. 45981, 45981-82 (July 11, 2002).

217. Ctr. for Drug Evaluation & Rsch., *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*, U.S. FOOD & DRUG ADMIN. 8 (Aug. 28, 2023), https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf [https://perma.cc/7K4L-TNJU] (describing FDA's consultation with NIDA).

218. *See Drug Safety and Risk Management Advisory Committee Roster*, FOOD & DRUG ADMIN. (Nov. 13, 2024), https://www.fda.gov/advisory-committees/drug-safety-and-risk-management-advisory-committee/drug-safety-and-risk-management-advisory-committee-roster [https://perma.cc/9VAT-G53G].

219. 42 U.S.C. § 217a (2018) (authorizing the Secretary to appoint new advisory committees).

B. The Nuanced HHS Scheduling Veto

The control veto requires HHS to make a categorical recommendation to control a drug or not, which can override DEA scheduling proposals. If HHS had only this all-or-nothing power, it might hesitate to engage in interagency dialogue that could benefit the scheduling process. For example, when facing only two options, such as adopting DEA proposals for stricter scheduling or exercising the control veto, HHS could be incentivized to avoid using the control veto, which some might view as a nuclear option. If HHS believes the proper path lies somewhere in between, it might elect to rubber-stamp DEA proposals, as it did in *Grinspoon*.[220] However, Congress gave HHS a more subtle power in the form of binding scientific recommendations that could serve as a scheduling veto and counteract the tendency for one-way ratcheting.

Describing the CSA on the House floor, Representative Satterfield said:

> I wish to point out the fact that we have fully protected the medical community their views and their knowledge will be reflected through the participation of the Secretary of Health, Education, and Welfare in this process. I point specifically to the provision which will give the Secretary the power and the authority to prohibit control of a drug which he determines from a medical or scientific standpoint should not be controlled, *and by the same token to prohibit transfer of a drug from one category to another*.[221]

Satterfield's reference to prohibiting control reflects the HHS control veto, a powerful yet blunt instrument. It applies only where DEA proposes controlling an uncontrolled drug and the Secretary opposes it, or where DEA supports maintaining federal control and HHS recommends removing it. When Satterfield said the Secretary can "prohibit transfer of a drug from one category to another," he was describing a second power that is subtler and more broadly applicable than the control veto: by issuing binding recommendations, the Secretary can constrain DEA scheduling options, potentially prohibiting a drug from being transferred between schedules. The recommendations can thereby serve as a scheduling veto, something the binary control veto cannot achieve.

Imagine that DEA proposes transferring the Schedule IV drug alprazolam (Xanax) to Schedule II. If HHS disagrees, the Secretary could invoke the control veto to block the transfer. However, as a blunt instrument, it would remove alprazolam from federal control. Alternatively, if HHS believes alprazolam should remain under federal control but lacks the high potential for abuse

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220. Grinspoon v. DEA, 828 F.2d 881, 897 (1st Cir. 1987).

221. 1970 House Record, *supra* note 5, at 33,313 (statement of Rep. Satterfield) (emphasis added).

necessary for placement in Schedule II, then the Secretary could recommend that alprazolam remain in Schedule IV. To the extent that the recommendation is based on scientific or medical judgments, it should bind DEA throughout rulemaking and prevent it from classifying alprazolam as Schedule II. In this respect, the recommendation would act as a scheduling veto and block DEA's proposal while maintaining federal control. Accordingly, Representative Rogers apparently referred to the Secretary's control veto and scheduling veto collectively as "a veto power over the classification of a substance or the moving of a substance to a higher schedule," which the Secretary can invoke "if he thinks that it should not be done for scientific or medical reasons."[222]

In the decade following the CSA's enactment, legal experts confirmed the Secretary's power to prevent DEA from moving drugs to higher schedules.[223] "DEA can opt to control [drugs] in a lower schedule than that recommended by the Assistant Secretary for Health but will not control in a higher schedule," wrote the Chief of FDA's Drug Abuse Staff in 1980.[224] More recently, courts and agencies have claimed that DEA can perform its own parallel investigations and disregard HHS recommendations.

In some ways, recent recommendations to reschedule marijuana might reflect renewed appreciation for HHS's scientific role and illustrate how HHS can utilize its scheduling authority to diverge from DEA practices and maintain the separation of scheduling powers. In other respects, these recommendations demonstrate how HHS underutilizes its authority and effectively cedes power to DEA. Instead of vetoing federal control of marijuana, HHS made binding recommendations to reschedule it.[225] In a case of interagency conflict, HHS argued that its recommendations bind DEA throughout rulemaking, while DEA claimed it was not bound by the recommendations once it commenced rulemaking.

Following his campaign pledge to decriminalize marijuana, President Biden asked the Secretary and the AG to evaluate marijuana's legal status.[226] In 2023, the Assistant Secretary sent recommendations to DEA.[227] HHS urged DEA to move marijuana from Schedule I to Schedule III.[228] To support this

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222. *Id.* at 33,304 (statement of Rep. Rogers).

223. *See* Vocci, *supra* note 15, at 691.

224. *Id.*

225. Letter from Rachel L. Levine, Assistant Sec'y for Health, U.S. Dep't of Health & Hum. Servs., to Anne Milgram, Adm'r, Drug Enf't Admin. (Aug. 29, 2023) [hereinafter Levine Letter], https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf [https://perma.cc/ZY5B-HCJB].

226. *Statement from President Biden on Marijuana Reform*, *supra* note 2.

227. Levine Letter, *supra* note 225.

228. *Id.*

recommendation, HHS introduced new criteria for establishing currently accepted medical use.[229] Instead of relying on DEA's five-part test and evidence from adequate, well-controlled trials, HHS unveiled a more flexible two-part test that reflects how patients use state-regulated, federally-illicit drugs on doctors' advice.[230] Part one requires evidence that licensed healthcare professionals have "widespread current experience with medical use" of a controlled substance "in accordance with implemented state-authorized programs, where the medical use is recognized by entities that regulate the practice of medicine."[231] Part two requires "some credible scientific support for at least one of the medical uses."[232] To satisfy part one, HHS pointed to the more than thirty thousand healthcare professionals authorized to recommend marijuana for patients across forty-three U.S. jurisdictions.[233] To meet part two, HHS found "some credible scientific support" for using marijuana to treat pain, anorexia, and chemotherapy-induced nausea and vomiting.[234]

By replacing DEA's five-part test for currently accepted medical use, HHS made a significant policy move. It emphasized that currently accepted medical use should be determined by state-regulated communities of healthcare professionals rather than federal regulators. However, although HHS replaced DEA's narrower five-part test with something more flexible, the outcome was unremarkable. While the two-part test might allow DEA to reschedule marijuana, moving the substance to Schedule III will have few practical effects.[235] HHS could have gone further. It narrowly interpreted the CSA's scheduling factors.

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229. Mikos, *supra* note 100, at 4, 12.

230. *Id.*; OLC Opinion, *supra* note 16, at 3-4, 10-11.

231. Mikos, *supra* note 100, at 12; OLC Opinion, *supra* note 16, at 3.

232. OLC Opinion, *supra* note 16, at 3.

233. Levine Letter, *supra* note 225, at 4 (stating that thirty-eight states, four territories, and the District of Columbia "have laws that authorize the use of marijuana for medical use(s)"); *see also* Mikos, *supra* note 100, at 2-3, 6, 14-15 (stating that HHS claimed it could establish currently accepted medical use by referencing the large number of doctors recommending marijuana to patients under state law).

234. Levine Letter, *supra* note 225.

235. Moving marijuana to Schedule III would not decriminalize or legalize its manufacturing, distribution, sales, or possession (apart from the limited exceptions already granted for research or FDA's expanded access program for people with serious or immediately life-threatening conditions). *See* 21 U.S.C. § 841(a) (2018) (outlawing, among other things, the manufacture and distribution of controlled substances)); Kreit, *supra* note 120, at 1235; Michelle Simakis, *'Deschedule or Do Nothing:' Drug Policy Alliance Says Rescheduling Cannabis Would Not End Criminalization*, CANNABIS BUS. TIMES (Mar. 1, 2024), https://www.cannabisbusinesstimes.com/cannabis-rescheduling/news/15686889/deschedule-or-do-nothing-drug-policy-alliance-says-rescheduling-cannabis-would-not-end-criminalization [https://perma.cc/ST3N-MX9J].

Unlike its kratom recommendations, HHS's marijuana recommendations overlooked the broader public health implications of scheduling, including its potential impacts on research and medical practice.

Biden's AG sought input from OLC on three questions: whether a drug could have a currently accepted medical use if it lacked FDA approval and would fail DEA's five-part test; the extent to which the Secretary's recommendations bind DEA; and whether U.S. treaty obligations require DEA to classify marijuana as a Schedule I or II drug.[236] OLC concluded that DEA's five-part test was too narrow and that HHS's two-part test could establish a currently accepted medical use in the absence of FDA approval, even when DEA's five-part test would not.[237] This part of OLC's opinion validated the Secretary's CSA authority to make scientific judgments. "The more difficult question," wrote OLC, "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."[238]

DEA claimed the Secretary's recommendations are binding only "at the beginning of the [scheduling] process," before DEA publishes a notice of proposed rulemaking.[239] Once rulemaking starts, "DEA can—and must—consider [other] material submitted during the administrative process in reaching a final scheduling determination."[240] HHS disagreed, claiming its recommendations bind DEA throughout rulemaking.[241] OLC addressed the question broadly regarding all HHS recommendations and more narrowly in the context of determining whether drugs have currently accepted medical uses.[242] In the narrower case, although OLC acknowledged that DEA is bound to the scientific and medical findings underlying the Secretary's conclusions regarding currently accepted medical use, OLC found that DEA need not adopt the Secretary's conclusions.[243] OLC reasoned that although some aspects of evaluating currently accepted medical use are undoubtedly scientific or medical, the process is also at least partly a

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236. OLC Opinion, *supra* note 16, at 3-4.

237. *Id.* at 4.

238. *Id.* at 24.

239. *Id.*; *see* Carisoprodol Rule, *supra* note 35, at 77,334-36 (adopting this position).

240. OLC Opinion, *supra* note 16, at 24.

241. *Id.* (citing a memorandum from HHS General Counsel Samuel R. Bagenstos to Deputy Assistant Attorney General Gillian E. Metzger).

242. *Id.* at 23-26 (stating that the AG need not follow HHS conclusions regarding currently accepted medical use, and more broadly, DEA is not bound by HHS recommendations once rulemaking begins).

243. *Id.* at 1, 4, 21 (stating that the AG is bound only by the scientific and medical determinations underlying an HHS conclusion regarding currently accepted medical use, but only until formal rulemaking begins).

nonmedical, legal question, and consequently, DEA need not follow the Secretary's determination.[244]

More broadly, OLC wrote that [o]nce DEA initiates formal rulemaking, HHS's determinations no longer bind DEA."[245] However, "DEA must continue to accord HHS's scientific and medical determinations significant deference."[246] According to OLC, the statute's "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."[247] However, that interpretation sounds more fitting for language of the Federal Power Act, which requires that recommendations be given "due weight," rather than the CSA command that HHS recommendations bind the AG.[248]

OLC based its conclusion partly on the text and structure of the CSA, stating that when taken together, Sections 811(a) and 812(b) "commit exclusively to the Attorney General the ultimate responsibility for making the findings required to schedule a drug," a view that contradicts the CSA's plain text, its structural limitations, and its legislative and statutory history.[249] OLC also relied on the APA, reasoning that binding DEA to HHS recommendations would deprive interested parties of opportunities to provide testimony that contradicts HHS recommendations and would prevent DEA from making rules after considering the "whole record" as described by 5 U.S.C. § 556(d).[250] The DEA Administrator made this argument when scheduling carisoprodol in 2011. In that case, DEA followed HHS recommendations and published a final rule to place carisoprodol in Schedule IV.[251] However, before the final rule was published, a manufacturer challenged the proposed rule during a DEA scheduling hearing by offering

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244. OLC Opinion, *supra* note 16, at 23, 24 (describing the assessment of currently accepted medical use as "neither wholly scientific nor wholly medical," for instance, evaluating "whether some credible scientific support exists for a particular widespread clinical use" of a drug is relevant to establishing a currently accepted medical use and is therefore undoubtedly a scientific and medical question, while also concluding that identifying a currently accepted medical use "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").

245. *Id.*

246. *Id.*

247. *Id.* at 25. (stating that the CSA prohibits DEA from engaging in *de novo* assessment of scientific and medical matters).

248. *See* 16 U.S.C. § 803(j)(2)(A) (2018) (regarding due weight); 21 U.S.C. § 811(b) (2018).

249. OLC Opinion, *supra* note 16, at 21.

250. *Id.* at 24-25 (arguing that binding the AG to the Secretary's recommendations during rulemaking would violate the APA by preventing DEA from considering contrary scientific or medical evidence submitted by parties during rulemaking).

251. Carisoprodol Rule, *supra* note 35, at 77,330.

scientific evidence to rebut the Secretary's recommendation.[252] The presiding ALJ concluded that HHS recommendations bind the AG continuously and cannot be relitigated at scheduling hearings. She wrote, "[T]he plain language and legislative history of § 811(b), federal case law, and [HHS's] process for conducting its administrative review, make clear that Congress intended that the Secretary's scientific and medical fact-findings bind the DEA during the hearing and the subsequent scheduling determination."[253] Furthermore, "Congress did not intend the DEA to secondarily review those findings."[254]

Although the ALJ allowed the manufacturer to present scientific evidence, she believed the CSA "limits the scope of the administrative hearing to those issues outside the medical and scientific fact-findings of FDA."[255] The manufacturer claimed the ALJ's interpretation deprived it of a meaningful hearing, rendering the proceeding "largely superfluous."[256] The DEA Administrator agreed with the manufacturer and overruled the ALJ. The Administrator argued that if HHS recommendations continuously bound DEA and could not be "secondarily reviewed," that would undermine congressional intent for expeditious scheduling proceedings that fully consider all factors.[257] She further argued that the APA obligates DEA to consider scientific evidence at hearings, including evidence that might contradict the Secretary's recommendations.[258] The Administrator wrote, "[W]hile the Secretary is the expert as to the scientific and medical matters at issue in the scheduling decision, the Attorney General is obligated to conduct a hearing and to consider contrary evidence even as to these issues."[259]

However, the Administrator's statement misinterpreted the CSA's separation of scheduling powers. It illustrates why the carisoprodol ALJ's interpretation was correct. Because Congress identified the Secretary as the expert on scientific matters, HHS recommendations must bind DEA throughout the scheduling process. Otherwise, DEA would make scientific and medical judgments without statutory authority.

Like DEA's carisoprodol rule, OLC's interpretation of "binding" reduces the CSA's use of a categorical term to something weaker. OLC claimed that giving force to the statute's command that HHS recommendations "shall be binding"

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252. *Id.* at 77,338-42.

253. *Id.* at 77,331 (quoting the ALJ decision at 18) (alteration in original).

254. *Id.* at 77,335 (quoting the ALJ decision at 17).

255. *Id.* 77,331, 77,334 (quoting the ALJ decision at 11).

256. *Id.* at 77,334 (quoting a carisoprodol manufacturer who was quoted in the ALJ decision at 11).

257. *Id.* at 77,335-36.

258. *Id.* at 77,334-36 (citing Grinspoon v. DEA, 828 F.2d 881, 882-83 (1st Cir. 1987) and 5 U.S.C. § 556(d)).

259. *Id.* at 77,335 (referencing *Grinspoon*).

requires only that they bind DEA until it publishes notice of proposed rulemaking. Yet, OLC's conclusion renders that command without effect. The Secretary makes binding recommendations to affect DEA rulemaking. The CSA contemplates no other use for them. If the recommendations bind DEA only before rulemaking begins, then they effectively bind DEA to nothing, contradicting the statute's text and purpose. OLC's argument would be more persuasive if Congress had not used "binding" to modify the term "recommendations," since one might intuitively understand recommendations to represent optional advice. But the statute's explicit use of "binding" dramatically alters the meaning of "recommendations," transforming optional advice into constraints. Accordingly, courts should presume that DEA must follow the Secretary's recommendations. OLC's interpretation overlooks textual and structural elements of the CSA, as well as its substantial legislative and statutory history.[260]

Preventing DEA review of HHS recommendations honors the CSA's division of scheduling authority. Rather than impeding expedient scheduling actions, it promotes efficiency by reducing regulatory redundancy and protecting the most competent actor's authority.[261] In contrast, DEA duplication of the Secretary's eight-factor analysis under Section 811(b) slows scheduling actions and crosses statutory boundaries.[262] Although the CSA requires the Secretary to provide binding recommendations prior to rulemaking, it does not limit their effect to the pre-rulemaking period.[263] Inferring such limits renders the Secretary powerless, contradicting Section 811(b), the CSA's legislative and statutory history, and Supreme Court precedent.[264] Additionally, the trial-like hearings of formal rulemaking are expensive and burdensome, and for several decades,

260. *See* Gonzales v. Oregon, 546 U.S. 243, 265-67 (2006) (stating that the CSA structure "conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise"); *supra* notes 39-57 and accompanying text.

261. *See* Kavanaugh, *supra* note 86, at 1469-70 (observing the link between regulatory overlap and redundancy and inefficiency); Aagaard, *supra* note 84, at 295-96 (stating that redundant regulation is closely associated with inefficiency); Freeman & Rossi, *supra* note 67, at 1138 (highlighting the belief that "redundancy is wasteful," while acknowledging that it can simultaneously be beneficial "as a form of insurance against a single agency's failure").

262. *See* 21 U.S.C. § 811(b) (2018).

263. *See id.*

264. *See* Carisoprodol Rule, *supra* note 35, at 77,331 (debating the ALJ regarding statutory interpretation, legislative history, and legal precedent); *Gonzales*, 546 U.S. at 266 (quoting H.R. REP. NO. 93-884 (1974)) ("This section preserves the distinctions found in the [CSA] between the functions of the Attorney General and the Secretary. . . . All decisions of a medical nature are to be made by the Secretary . . . . Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General" (alteration and omissions in original)).

administrative law has increasingly disfavored them.[265] Narrowing the scope of scheduling proceedings to nonscientific matters arguably reduces regulatory costs and expedites scheduling actions, allowing DEA to conserve limited resources.

Some agencies have streamlined formal rulemaking by adopting rules allowing for alternative procedures that can vary aspects such as the submission of witness testimony or the scope of cross-examination.[266] Furthermore, administrative law scholars acknowledge that an agency's organic statute can supplant APA requirements to "impose different or additional" procedures.[267] Because the CSA defines DEA's scheduling authority, the statute's requirement of different procedures, such as implicitly limiting the scope of scheduling hearings, may not violate the APA as OLC and DEA have claimed.[268] Moreover, binding DEA to the Secretary's recommendations throughout rulemaking is not necessarily incompatible with making rules based on the whole record — the recommendations and their binding effect are ostensibly imported into the record, and contradictory evidence may be viewed as "irrelevant, immaterial, or unduly repetitious" under 5 U.S.C. § 556(d).[269]

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265. *See* Hamilton, *supra* note 5, at 1286, 1309 (describing the administrative burdens of trial-like evidentiary hearings and concluding that a trial-type hearing on scientific and medical questions "would likely bog down in a morass"). *See generally* Admin. Conf. of the U.S., Adoption of Recommendations and Statement Regarding Administrative Practice and Procedure, 59 Fed. Reg. 4669 (Feb. 1, 1994), https://www.govinfo.gov/content/pkg/FR-1994-02-01/html/94-2225.htm [https://perma.cc/9WAS-9MPZ] (advising Congress that formal proceedings can be unnecessarily burdensome or confusing and should be repealed).

266. *See* Rules of Practice and Procedure Governing Formal Rulemaking Proceedings Instituted by the Secretary, USDA, 82 Fed. Reg. 51149, 51150-52 (Nov. 3, 2017) (allowing for the implementation of alternative procedures in USDA formal rulemaking that "are consistent with 5 U.S.C. 556 and 557").

267. Aram A. Gavoor & Steven A. Platt, *Administrative Records and the Courts*, 67 KAN. L. REV. 1, 11, 30 (2018).

268. *See id.*; Hamilton, *supra* note 5, at 1309 (distinguishing three scheduling-related matters within law enforcement jurisdiction, for which the CSA requires a hearing, from the Secretary's binding scientific and medical recommendations, for which a trial-type hearing would be inefficient and unreasonable); OLC Opinion, *supra* note 16, at 24-25; Carisoprodol Rule, *supra* note 35, at 77,334-36.

269. Gavoor & Platt, *supra* note 267, at 19 (stating that reading organic statutes in conjunction with the APA suggests that "the whole record" incorporates materials used and created by an agency); 5 U.S.C. § 556(d) (2018) (allowing "for the exclusion of irrelevant, immaterial, or unduly repetitious evidence").

C. Preserving the Separation of Scheduling Powers

Since Congress enacted the CSA, DEA has acquired expansive de facto scheduling authority. This Section makes preliminary suggestions for restoring and preserving the separation of scheduling powers.

Congress could have the greatest impact. Lawmakers could amend the CSA to highlight jurisdictional boundaries that split scheduling authority. They could address the evidence asymmetries of drug scheduling by increasing the quality and quantity of evidence required to control drugs and lowering requirements for downscheduling or descheduling. Congress could shift scheduling authority to a single agency. Giving HHS primary control with input from DEA is a sensible option reminiscent of at least one congressional CSA draft.[270] Alternatively, Congress could establish a framework like that of the Federal Power Act.[271] DEA would presumptively follow HHS recommendations unless DEA articulated a legal justification for deviating from them. However, such an amendment might not effectively balance scheduling authority, and because HHS already holds veto powers, it might decrease current HHS authority.

Even in the absence of congressional action, agencies could coordinate their scheduling responsibilities and reduce regulatory redundancy by signing a memorandum of understanding (MOU).[272] In 2015, FDA and DEA signed an MOU that expires in 2026. Instead of describing their respective roles to reduce redundancy, a common purpose for MOUs, the FDA-DEA memorandum merely facilitates interagency communication.[273] HHS and DEA could draft an MOU that clearly defines their roles. However, OLC's 2024 opinion might make this outcome unlikely because OLC concluded that HHS recommendations do not bind DEA, and DEA might resist efforts to clarify jurisdictional boundaries.[274] If an MOU proves infeasible, HHS could use its control veto more frequently to balance DEA influence. The Secretary need only find a scientific or medical justification, and as the HHS kratom recommendation illustrates, CSA scheduling factors provide a broad basis for vetoing control.[275]

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270. Joseph F. Spillane, *Debating the Controlled Substances Act*, 76 DRUG & ALCOHOL DEPENDENCE 17, 22 (2004) (stating that Congress considered at least one version of the CSA that gave primary scheduling authority to HEW).

271. *See supra* note 158-159 and accompanying text.

272. Freeman & Rossi, *supra* note 67, at 1161-65; Marisam, *supra* note 67, at 212-13.

273. *See* NIDA-FDA MOU, *supra* note 6; Marisam, *supra* note 67, at 212 (stating that agencies often sign memorandums of understanding to divide and clarify tasks and reduce redundancy).

274. OLC Opinion, *supra* note 16, at 21-23.

275. Kratom Letter, *supra* note 63, at 3-4 (analyzing the potential impact of scheduling a substance on public health and scientific research).

HHS could help restore the separation of scheduling powers by seeking a wider variety of public health inputs. Currently, HHS relies heavily on FDA's DSaRM Advisory Committee. This group's homogeneity likely narrows its perspective.[276] To broaden the discussion, the Secretary could shift responsibility for scheduling evaluations to another HHS entity within the OASH or CDC that is accustomed to thinking about broader public health implications and the risks and benefits of regulation.[277]

The President might also play a key role. Congressional delegation of authority to department heads typically limits presidential influence.[278] However, presidents can reconcile jurisdictional disputes in areas of shared regulation.[279] They have previously utilized executive orders and the White House Office of Management and Budget to determine which agency has controlling authority in cases of regulatory overlap.[280] Furthermore, Congress authorized the President to ensure coordination among agencies to implement the National Drug Control Strategy. The President sets drug-control priorities through the Office of National Drug Control Policy (ONDCP), within the Executive Office of the President.[281] ONDCP coordinates drug-control agencies and oversees their budgets, and the President appoints its director. Accordingly, as a matter of agency coordination, rebalancing drug scheduling arguably falls within the powers of the President and ONDCP. The President could ask OLC to reconsider its conclusions regarding binding scheduling recommendations. Other cabinet members, including the Secretary, could make similar requests. Alternatively, upholding the constitutional duty to take care that federal laws are faithfully executed, the President could order agencies to follow the statutory separation of scheduling powers, which would align with the CSA text and purpose.[282]

Finally, courts can guard against agencies exceeding their statutory authority or coordinating around statutory obligations by reviewing their policy decisions and legal interpretations. Although the Supreme Court declined to defer to DEA interpretations of CSA terms in *Gonzales*, *Chevron* governed scheduling cases at the circuit court level for decades. Courts claimed that *Chevron* tied their hands, requiring them to defer to DEA. While *Loper Bright*'s effects are difficult to

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276. *See Drug Safety and Risk Management Advisory Committee Roster*, *supra* note 218.

277. 42 U.S.C. § 217a (2018) (authorizing the Secretary to appoint new advisory committees).

278. Jason Marisam, *The President's Agency Selection Powers*, 65 ADMIN. L. REV. 821, 833 (2013).

279. *Id.* at 837-38 (describing a presidential agency overlap power).

280. *Id.* at 838-89.

281. *See* LISA N. SACO & KRISTIN FINKLEA, CONG. RSCH. SERV. IN10912, THE ROLE OF THE OFFICE OF NATIONAL DRUG CONTROL POLICY (ONDCP) 1 (2018), https://crsreports.congress.gov/product/pdf/IN/IN10912/3 [https://perma.cc/49P2-8A5U].

282. U.S. CONST. art. II, § 3.

predict, health policy experts fear its medical and public health implications. Nevertheless, in the field of drug control, *Loper Bright* could help maintain the separation of scheduling powers. Where courts previously deferred to DEA under *Chevron*, *Loper Bright* might free them to consider broader interpretations.

CONCLUSION

Congress split drug scheduling authority to leverage the expertise of specialized agencies and create administrative checks and balances. HHS scientific expertise should balance DEA law enforcement perspectives. However, in practice, HHS abdication of scheduling authority has blurred jurisdictional boundaries, producing regulatory redundancy and scheduling outcomes that frustrate congressional objectives. Rather than engaging in substantive scientific analysis to drive scheduling actions, public health officials frequently defer to DEA's scientific judgments, producing bureaucratic drift.

Instead of preserving access to controlled drugs for legitimate scientific purposes, scheduling actions often impede medical research and innovation, optimal healthcare delivery, and evidence-based approaches to addressing the overdose crisis. In the long term, statutory reforms are needed to overhaul federal drug laws and create a more rational and reliable system. In the meantime, agencies can reduce regulatory redundancy and improve scheduling outcomes by clarifying their roles and coordinating their efforts. MOUs are one potential coordinating mechanism. But if agreement cannot be achieved, HHS can restore the separation of scheduling powers by leveraging features of the existing framework that are often overlooked or misunderstood. For instance, the Secretary could more diligently exert HHS scheduling powers, including its drug control veto and its binding recommendations, which can effectively balance law enforcement powers. HHS can subdelegate scheduling authority to agencies better equipped to assess the costs and benefits of scheduling. And to reduce regulatory redundancy, DEA can redirect resources from scheduling actions to higher-priority areas such as international drug trafficking. After the *Loper Bright* opinion overturned *Chevron*, courts may feel less constrained by DEA statutory interpretations, allowing public health experts to resume their guiding role in drug scheduling.

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