



Public Health and Research Reforms in Controlled Substances Act of 2026

This bill updates the Controlled Substances Act framework for drug scheduling to better align it with public health priorities rather than a prime focus on criminalization.

- New schedules that allow for greater granularity and eliminate internal inconsistencies.
- New statutory factor analysis for drug scheduling, adding an external advisory committee that scores and weighs each factor to improve transparency.
- Altered some delegations of authority from the AG (delegated to DEA) to the Secretary of HHS;
 - In setting production quotas for drugs, transferred authorities to the HHS Secretary from the AG.
 - Researchers will now obtain their registration from HHS and the HHS Secretary will now schedule substances rather than the AG.
- Strengthened scientific research language in 2025's *HALT Fentanyl Act*.
- Created blanket Controlled Substances research licenses.
- Corrected the definition of the term “controlled substance analogue”.
- Enhanced White House Office of National Drug Control Policy (ONDCP) coordination efforts for emerging drug trends initially authorized in *SUPPORT Act*.
- Updated “emergency scheduling” of drugs or substances.
- Eliminated mandatory minimum drug penalties while preserving the ability for judges to issue sentences.
- Remove marijuana from the CSA.

Overview of Rationale:

The framework underlying the CSA has not been updated since it was enacted in 1970. Most Americans do not believe that the nation is making progress on the “war on drugs”^{1,2} despite a panoply of different government approaches. The Biden and Trump HHS and DOJ agree that “the rank order of [controlled substances] regarding harms does not consistently align with the relative scheduling placement[.]”^{3,4} A new approach is needed; under the current scheduling regime, overdose deaths

¹ Dimitri, C. (2026, July 16). Americans increasingly view illicit drug policy through a partisan lens, new analysis finds. *Phys.Org*. <https://phys.org/news/2026-07-americans-view-illicit-drug-policy.html>

² McCarthy, J. (2025, November 5). Americans much more positive about progress on drugs. *Gallup*. <https://news.gallup.com/poll/697445/americans-positive-progress-drugs.aspx>

³ Drug Enforcement Administration. (2026). Schedules of Controlled Substances: Rescheduling of Food and Drug Administration Approved Products Containing Marijuana from Schedule I to Schedule III; Corresponding Change to Permit Requirements (AG Order No. 6754-2026). Department of Justice Drug Enforcement Administration. <https://www.justice.gov/opa/media/1437751/dl>

⁴ Department of Health and Human Services. (2023). Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act. (Docket No. DEA-1362; A.G. Order No. 5931-2024). Department of Health and Human Services Office of the Secretary. <https://www.dea.gov/sites/default/files/2024-05/2016-17954-HHS.pdf>

have skyrocketed.^{5,6,7} This bill eliminates structural inconsistencies by creating a new scheduling apparatus that separately evaluates harms and benefits.

Moreover, it represents a flexible framework to ensure enhanced transparency, so that government agencies can more robustly track and coordinate strategies on emerging drug trends or chemicals, strengthen and streamline scientific research, and focus agency actions on their strengths – where HHS can focus on science and medicine, and DEA on preventing diversion and illicit use of controlled substances.

Authority refinement: Drug scheduling authority moves to HHS from DEA. *The Attorney General may* transmit relevant information, but HHS conducts the analysis and issues the rule. Research registrations shift from DEA to HHS and consolidate into a single controlled substances research license, streamlining applications while allowing DEA to maintain schedule-appropriate storage and security requirements. Import/Export/Production quotas will be managed by HHS rather than DEA, though DEA can transmit relevant information regarding quantities.

Transparent factor analysis: The revised factors explicitly consider the nature or actual magnitude of health problems from nonmedical use, misuse, and substance use disorders (SUD); therapeutic applications and market authorizations; industrial/veterinary uses; illicit trafficking; and the public-health risks of scheduling itself (including substitution with another drug). An advisory committee uses harm-benefit analysis to score and weigh each factor, enhancing transparency about which pieces of information are most critical to the government action.

Resolving scheduling contradictions: Under the existing single-axis test with three findings required for each schedule, internal inconsistency frequently arises, as noted by the Biden and Trump Administrations. For example, a substance with relatively low abuse potential and moderate dependence liability but no “currently accepted medical use” (CAMU) is placed into Schedule I. There are currently significantly more criminal penalties, research restrictions, and limitations affecting medical access for Schedule I compounds compared to Schedule III. The DEA has interpreted CAMU as requiring FDA approval for four decades. CAMU has no statutory definition, however, and the Biden Administration developed a legal test to allow cannabis rescheduling. Rather than utilize a framework with inconsistencies and no statutory definitions, this bill provides an alternative. The bill introduces dual dimensions: Schedules I–IV classify the likelihood of developing a SUD and the threat to public health, while Schedules A–E classify therapeutic value. Combined designations (e.g., 1A or 3E) reflect both harm and benefit profiles without forcing inconsistent placements. To build the dual-dimension schedules, the bill sets forth a framework for the definitions of “threat to the public health” and “therapeutic value” that the Secretary of HHS shall consider, and publish agency guidance subject to public comment.

⁵ Heather Saunders, Panchal, N., & Rudowitz, R. (2026, February 24). *Opioid overdose deaths: National trends and variation by demographics and states* | KFF. <https://www.kff.org/mental-health/opioid-overdose-deaths-national-trends-and-variation-by-demographics-and-states/>

⁶ Ahmad F. B., Cisewski J. A., Rossen L. M., Sutton P. Provisional drug overdose death counts. *National Center for Health Statistics*. 2026. DOI: <https://dx.doi.org/10.15620/cdc/20250305008>

⁷ Garnett, M. F., & Miniño, A. M. (2026). Drug Overdose Deaths in the United States, 2023-2024. *NCHS Data Brief*. 1-13.

Terminology modernization: The bill replaces the undefined, and 1960s-era. term “abuse” with non-medical use, misuse, and SUD consistent with clinical standards and public-health guidance. The National Institute on Drug Abuse uses this terminology, and SUDs are characterized by 11 characteristics, allowing for refinement in discussing the potential harms of use of a substance.

Enhanced interagency coordination in monitoring and responding to emerging drug trends and threats: 2018’s SUPPORT Act created an Emerging Threats Coordinator and Committee within the White House Office of National Drug Control Policy (ONDCP) to monitor and disseminate information regarding new drug trends. This bill codifies the Biden Administration’s monitoring and whole-of-government approach, adding coordination capabilities and grant-making authority. These changes will better allow the ONDCP to administer a uniform, government-wide system for identifying, monitoring, classifying, and responding to evolving drug threats. The Coordinator would coordinate interagency data collection and integration across DEA, FDA, CDC, NIH, SAMHSA, DHS, and others agencies, and oversee a four-tier threat classification system with varying levels of government action dependent on the classification level. It also ensures use of uniform federal criteria for surveillance and designation, manages regularly updated response plans with assigned agency actions, deadlines, performance measures, and data-sharing requirements, and facilitates continuous reclassification and rapid federal action when severity, spread, or novelty warrants it. These changes strengthen ONDCP’s capacity to detect threats earlier, synchronize federal actors, and implement whole-of-government responses before a substance or pattern of use reaches national-crisis scale.

Emergency scheduling: Updates the standard to “imminent significant threat to public health”, tying in the “threat to public health” definition, and sets the ONDCP as the initiator, rather than DEA, aligning emergency drug scheduling with the ONDCP’s coordinating function across surveillance networks.

Sentencing: Eliminates mandatory minimum penalties while enforcement remains focused on diversion and trafficking rather than inflexible sentencing that has not improved public health outcomes or meaningfully reduced trafficking or drug use.

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Expansion and Restructuring of the 8-Factor Analysis of Drugs Allows Public Health Consideration and Transparency

When the government regulates the manufacturing, importation/exportation, possession, and use of a psychoactive drug or substance, or a direct precursor molecule, that drug or substance is “scheduled,” referring to the five Schedules within the Controlled Substances Act. The schedules vary in criminal sanctions, acceptable medical uses, storage requirements, production and importation/exportation quotas, and licensure.

The ultimate authority for drug scheduling under 21 U.S.C. § 811 & 812 lies with the Attorney General (AG), who vests their authority to the Administrator of the Drug Enforcement Administration (DEA).

The AG issues the final rule in placing a drug under control if they find that the drug or other substance has a “potential for abuse”⁸, and makes the three findings prescribed for each schedule.⁹ They may also remove it from the schedules if they find that the drug or other substance does not meet the requirements for inclusion in any schedule. The AG, prior to initiating scheduling of any drug or substance, must request from the Secretary of HHS, a “scientific and medical evaluation”, and their recommendations as to whether it should be controlled or removed from the schedules. The law constrains “scientific and medical” to mean Factors 2, 3, 6, 7, and 8, and to consider the “scientific and medical *considerations*” related to factors 1, 4, and 5 listed below. The recommendations of the Secretary of HHS to the AG are to be “binding” on the AG as to such “scientific and medical matters”; if the Secretary recommends that a drug or other substance not be controlled, the AG shall not control such chemical.

After HHS makes its evaluation and schedule recommendation, it transmits this information to DEA, which conducts its own evaluation, including law enforcement encounters and drug seizure data.

Having two agencies generate an analysis is redundant, and the 8-factors listed below are also inadequate for evaluating a substance with *potential* benefits. Further, it lacks transparency about each factor's relative weight and how, in practice, each factor largely determines scheduling. As such, these factors have been eliminated, combined with others, and expanded.

Enacted 8-Factor Analysis

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.

⁸ More on this term later; in this bill, it has been replaced with “substance use disorder”.

⁹ 21 U.S.C. § 812(b)

- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

New Factors Incorporate Benefits of a Drug or Substance as a Cost-Benefit Analysis.

The old 8-factor analysis might be adequate in a universe where drugs or substances have no benefit to a person – yet this analysis is also conducted when a drug with stimulant, depressant, or other psychoactive activity is reviewed by the FDA as part of a New Drug Application; the drug’s sponsors have submitted this application because they believe their data demonstrates a *benefit* from the drug. The 8-factor analysis is better suited to toxic substances, such as those governed by the Toxic Substances Control Act (TSCA), for example. In its original form, TSCA required the Administrator of the EPA to consider “(c) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and...(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.”¹⁰ Ingesting toxic substances such as per- and polyfluoroalkyl substances (PFAS) or mercury offers no benefit to humans; TSCA was amended in 2016 to shift from a risk-benefit balancing standard to a risk-based safety standard.¹¹

As many drugs have benefits, a risk-benefit balancing approach must be utilized to more completely capture the drug’s characteristics and best define the adequate level of control. Additionally, several of the current factors use terminology no longer widely used by the addiction-science or behavioral pharmacology community, such as “dependence”, and “abuse”. Current factor 6 typically details harms to public health from the “abuse” of the drug or substance, but could also be read to allow discussion of harms to the public from scheduling, such as reduced research access. Reduced research access may delay or prevent new therapeutics from developed. Accordingly, new factors 4 and 11 separate these considerations to allow robust discussion of both.

New Factors Analysis.

- (1) The state of current scientific knowledge regarding the drug or other substance, including routes of administration, and its pharmacological effects, if known.
- (2) Its actual or relative pattern or potential for nonmedical use, misuse, and developments of substance use disorders.
- (3) Its history and current trends of nonmedical use, misuse, and developments of substance use disorders, including subnational geographical trends.
- (4) The nature of, and actual (or, if unknown, the potential) magnitude of, threats to public health related to misuse, nonmedical use, and developments of substance use disorders, including drug-specific mortality, drug-related mortality, drug-specific damage, and drug-related damage.
- (5) Its therapeutic applications, including self-reported therapeutic use, and extent of therapeutic use and epidemiology of therapeutic use.
- (6) Prevalence of medical conditions or disease that the drug or substance is used in or has the potential for treatment for a currently met or unmet therapeutic utility.

¹⁰ P.L. 94-469

¹¹ P.L. 114-182

- (7) Whether the drug or other substance is an immediate precursor of a substance already controlled under this Act.
- (8) Its marketing authorizations as a medicinal product.
- (9) Its industrial, agricultural, and veterinary use.
- (10) Its illicit manufacture and traffic and related information.
- (11) What threat to public health, if any, from scheduling the drug or other substance, including replacement by alternative drugs or substances.
- (12) The extent to which the drug or other substance is used to reduce the severity of an individual's substance use disorder with respect to the use of another scheduled drug or substance, along with harms to the individual and society associated with use of that other scheduled drug or substance.
- (13) Other medical and scientific matters relevant for a recommendation on scheduling of the substance.
- (14) Other such factors which relate to harms to one's self or society, benefits to self or society, including economic indices.

The drug's formulations and routes of administration, and thus ensuing bioavailability, influence its risk-benefit profile. Intravenous drug use, such as for hospital morphine, provides rapid pain relief, but may injure the patient if the needle is not inserted properly. Intravenous drug use in non-hospital settings is associated with the spread of HIV and Hepatitis C, but the drug itself does not cause such disease. New Factor 1 and 4 capture pharmacological data on the drug or substance and its routes of administration, and data related to harms related to use of the drug alone.

This bill eliminates the word "abuse" and replaces it with "nonmedical use", "misuse", and "substance use disorder".¹² The factor analysis has therefore been updated to reflect these changes, and it mandates including data on subnational trends in drug use to better delineate the extent to which the drug or substance is causing problems, and where. It also requires public health data on these patterns of use and the problems associated with varying rates of use.

Cost-Benefit Analysis Increases Transparency

After the new factor review, the analysis will be forwarded to a new advisory Committee that will conduct a multi-criteria decision analysis, a type of cost-benefit analysis that supports decision-making when multiple policy goals are involved.¹³ This committee will *score* and *weigh* each factor based on the report they received, and compute a total score of harms and benefits for each substance. The Committee will then recommend to the HHS Secretary¹⁴ the appropriate schedule based on this computation. The Secretary may override the Committee if they determine that the facts and all other relevant data constitute substantial evidence to warrant control or removal from the Schedules. By scoring and weighing each factor and publishing this analysis, the public can better

¹² See sections *Elimination of the Word 'Abuse' Throughout the CSA; Replaced by Nonmedical Use, Misuse, or Substance Disorder Depending on the Context*

¹³ Definition 68 in this bill.

¹⁴ See subsection *Delegation of Drug Scheduling Authority to the Secretary of HHS* below.

understand the decision-making behind placing each substance in its respective schedule. These individual drug scores will clarify each drug's benefits and risks.

Creation of New Schedules Eliminates Internal Inconsistencies of Harms and Benefits

To be placed in any Schedule currently, three findings are made with respect to that drug or substance (Table 1).¹⁵ However, against plain reading of the text, the finding which is *deemed* to be most important for each schedule differs per substance or Schedule.

	Potential for Abuse	Currently Accepted Medical Use	Safety or Dependence Liability
Schedule I	High potential for abuse	No currently accepted medical use	Lack of accepted safety for use under medical supervision
Schedule II	High potential for abuse	Has a currently accepted medical use	Abuse may lead to severe dependence
Schedule III	Potential for abuse less than Schedules I and II	Has a currently accepted medical use	Abuse may lead to moderate or low physical or high psychological dependence
Schedule IV	Low potential for abuse relative to Schedule III	Has a currently accepted medical use	Abuse may lead to limited physical or psychological dependence relative to Schedule III
Schedule V	Low potential for abuse relative to Schedule IV	Has a currently accepted medical use	Abuse may lead to limited physical or psychological dependence relative to Schedule IV

Table 1: Schedules currently under 21 U.S.C. § 812(b)

Conflicting criteria within the CSA

The CSA states that a “drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance.”¹⁶ This indicates that all three findings must be made, and they carry equal weight. Conflict arises, however, when the three factors do not align. Take, for example, Drug X: it has a lower potential for abuse relative to other substances in Schedule IV, a risk of dependence liability comparable to a Schedule III substance, but no currently accepted medical use (CAMU).¹⁷ Per Table 1, the abuse potential finding indicates it

¹⁵ 21 U.S.C. § 812(b)

¹⁶ 21 U.S.C. § 812(b)

¹⁷ DEA equated CAMU solely with the standards for new drug approval under the Federal Food, Drug, and Cosmetic Act, and uses a five-part test developed after a previous eight-part test was struck down by the courts (57 Fed. Reg. 10,499, 10,503–04,

belongs to Schedule V, the dependence liability finding indicates it belongs in Schedule III, but the CAMU finding indicates it belongs in Schedule I. DEA has deemed that because this drug has no CAMU, it must slot into Schedule I, which is the only category with no CAMU.¹⁸ Schedules II – V list dependence and abuse as prongs; Schedule I does not list dependence as a prong, yet Drug X has the dependence liability of a Schedule III substance. Drug X does not meet the scheduling requirements for any one category. This scenario is typical.

What about a drug that Congress placed in any Schedule other than I? Has Congress now deemed itself the arbiter of CAMU? A bill in the current Congress proposes to place marijuana in Schedule III from Schedule I.¹⁹ Or placement of xylazine in Schedule III – xylazine has no CAMU for treatment of *humans* but is widely used in veterinary applications, yet there is a bill in the House and Senate which, if enacted, will place Xylazine in Schedule III.^{20,21} If xylazine is placed in Schedule III, is there sufficient precedent to deem that CAMU can be granted for animal approvals? If perhaps a psychedelic substance, such as psilocybin, were to be found to treat anxiety in cats, could this now qualify as a CAMU and be sufficient to remove this drug from Schedule I as well? CAMU does not specify it must be found for treatment in *humans*. There are other drugs on Schedules other than Schedule I that do not have a CAMU. Phencyclidine (PCP), for example, is not prescribed by any physician for treatment of any disease in the United States. It was, however, used in the early 1960s under the brand name Sernyl as an anesthetic, only to later have its FDA authorization revoked; it does not have a *currently* accepted medical use – it has not had an accepted medical use for treatment in humans since before the CSA was drafted or signed into law in 1970. Yet the DEA has not proposed to place it in Schedule I; to what extent does the DEA take literal meaning of ‘currently’?

Most revealing of this problem: a 2026 Government Accountability Office Report stated that “DEA does not have any policies or procedures regarding how its staff is to conduct evaluations or schedule substances.”²²

A classification apparatus premised on criteria that can conflict and can’t be applied consistently is structurally flawed and must be corrected.

New Schedules Eliminate Conflict Between Criteria

New Schedules eliminate conflict through subcategorization; Schedule V is eliminated, however

10,506 (Mar. 26, 1992). In 2023, under the Biden Administration, HHS devised a new two-part CAMU test when it recommended marijuana be placed in Schedule III of the CSA.

¹⁸ E.g., Drug Enforcement Administration. (2011, July 8). *Denial of petition to initiate proceedings to reschedule marijuana* (Docket No. DEA-352N; 21 CFR Chapter II) [Proposed rule]. 76 Fed. Reg. 40552–40589. Retrieved from <https://www.federalregister.gov/documents/2011/07/08/2011-16994/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana>

¹⁹ Marijuana 1-to-3 Act of 2025, H.R.4963, 119 Cong. (2025). <https://www.congress.gov/bill/119th-congress/house-bill/4963>

²⁰ Combating Illicit Xylazine Act, H.R. 1266, 119th Cong. (2025). <https://www.congress.gov/bill/119th-congress/house-bill/1266>

²¹ Combating Illicit Xylazine Act, S. 545, 119th Cong. (2025). <https://www.congress.gov/bill/119th-congress/senate-bill/545>

²² Government Accountability Office. (2026). Drug Scheduling: While DEA Decisions Have Aligned with Recent HHS Recommendations, Both Need Comprehensive Policies (GAO-26-108623). GAO. <https://www.gao.gov/products/gao-26-108623>, Page 2

Schedules A – E are created. Schedules I – IV will solely ask about the extent to which a person using the drug or substance is likely to develop a substance use disorder, AND the extent to which that behavior is harmful to the public health. Schedules A – E ask, “To what extent is this substance *therapeutically* valuable?”

		Decreasing rates of development of substance use disorders and threat to the public health			
		Schedule I	Schedule II	Schedule III	Schedule IV
Decreasing rates of therapeutic value	Schedule A				
	Schedule B				
	Schedule C				
	Schedule D				
	Schedule E (unknown or none)				

Table 2: New Drug Schedule Tables

Schedules I-IV are as follows:

- SCHEDULE I.—The drug or other substance presents a high risk of misuse or development of a substance use disorder and the consequences of the use of the drug or other substance pose a particularly high threat to public health.
- SCHEDULE II.—The drug or other substance presents a lower risk of misuse or development of a substance use disorder than those in schedule I and the consequences of the use of the drug or other substance pose a threat to public health less than the particularly high threat to public health referred to in sub-paragraph (A).
- SCHEDULE III.—The drug or other substance presents a lower risk of misuse or development of a substance use disorder than those in schedule II and the consequences of the use of the drug or other substance pose a threat to public health less than the threat to public health referred to in subparagraph (B).
- SCHEDULE IV.—The drug or substance presents a risk of misuse or development of a substance use disorder lower than those in schedule III and the consequences of the use of the drug or other substance pose a threat to public health less than the threat to public health referred to in subparagraph (B).

Schedules A-E are as follows:

- SCHEDULE A.—The drug or other substance has high therapeutic value.
- SCHEDULE B.—The drug or other substance has moderate therapeutic value.
- SCHEDULE C.—The drug or other substance has low therapeutic value.
- SCHEDULE D.—The drug or other substance is of limited therapeutic value.
- SCHEDULE E.—The drug or other substance is of unknown or has no therapeutic value.

By addressing distinct questions, regulators can tailor drugs or substances to their unique properties without conflicting criteria. Substances therefore could be Schedule 1A (highest level of therapeutic value, and highest potential for the development of a substance use disorder), or 3E (lower potential for the development of a substance use disorder than those in Schedule I or II, but no or unknown therapeutic value). The hinge point between Schedule III and IV will be the risk of misuse or development of a substance use disorder, as the threat to public health is the same between the two Schedules.

The CSA, as currently enacted, does not provide a scale of *potential for abuse* that can be applied consistently. The scalar *threat to public health* used in Schedules I-IV of this bill does, however. Its definition includes a number of factors the HHS Secretary must utilize when making the finding that the particular use of a drug or other substance represents a *threat to public health*. This allows for comparison of drug trends and potential harms that result from the consequences of use.

Delegation of Drug Scheduling Authority to the Secretary of HHS

An agency that promulgates regulations with quasi-legislative authority to enforce criminal penalties creates an unusual conflict of interest and does not provide adequate separation of powers. As previously discussed, drug scheduling affects controls and restrictions on importation/exportation and production; the practice of medicine by healthcare providers; scientific research; and criminal sanctions for possession. I believe drug scheduling authority should not rest with a law enforcement agency, one that sets the rules and enforces criminal penalties.

This bill shifts drug scheduling authority from the DEA to the Secretary of Health and Human Services.²³ Under this new design, the AG may transmit information they believe is relevant, such as law enforcement encounters with a substance, to the Secretary for scheduling consideration, but HHS will generate the analysis and issue the final Rule.

Changes to Scientific Research Protocols

Combine Schedule I and Schedule II – V Registration into One Controlled Substance License for Scientific Research

The CSA, through law and regulation, requires separate registration and licensure for Schedule I and Schedule II – V research.²⁴ The barriers to conducting Schedule I research have been well

²³ See also Marks, M. (2025). *Separation of Drug Scheduling Powers*. SSRN. <https://doi.org/10.2139/ssrn.5174715> for a thoughtful discussion of this issue.

²⁴ 21 U.S.C. § 823(g); 21 CFR 1301.13

documented^{25,26,27,28,29,30}, and the 2025 HALT Fentanyl Act sought to reduce *some* barriers to research.^{31,32} However, the regulations to implement the research provisions from the HALT Fentanyl Act are now 11 months delayed, despite my urging the DEA to finish them 8 months ago.³³ The current law's impact on research was entirely predictable; witnesses before the House Committee drafting the CSA testified to that. For example, the Pharmaceutical Manufacturers Association (PhRMA) testified that the requirements on Schedule I research would “inevitably hinder research and evaluation relating to potential legitimate medical and scientific use of such substances.”³⁴ Currently, registration submissions for Schedule I research require approval from both the FDA and DEA, rather than only the DEA for Schedule II – V research. See Table 3 for an illustration of the differences between these registrations, and the barriers to research imposed by Schedule I work.³⁵

Requirement for Registration	Schedule I	Schedule II - V
Approval from HHS Secretary	✓	☒
Approval from Attorney General	✓	✓
Preapproved research protocol	✓	☒
Amendments and renewal require reapproval from FDA and DEA	✓	☒
State-specific controlled substance registration	Often required	Sometimes required

²⁵ Nutt, D. J., King, L. A., & Nichols, D. E. (2013). Effects of Schedule I drug laws on neuroscience research and treatment innovation. *Nature Reviews Neuroscience*, 14(8), 577–585. <https://doi.org/10.1038/nrn3530>

²⁶ National Academies of Sciences, Engineering, and Medicine. (2017). Challenges and Barriers in Conducting Cannabis Research. In *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. National Academies Press (US). <https://www.ncbi.nlm.nih.gov/books/NBK425757/>

²⁷ Volkow, N. *Hearing on Cannabis Policies for the New Decade: Hearing before the Subcommittee on Health of the Energy and Commerce Committee*, 116th Cong. (2020). <https://www.congress.gov/event/116th-congress/house-event/110381>

²⁸ Henningfield, J. E., Coe, M. A., Griffiths, R. R., Belouin, S. J., Berger, A., Coker, A. R., Comer, S. D., Heal, D. J., Hendricks, P. S., Nichols, C. D., Sapienza, F., Vocci, F. J., & Zia, F. Z. (2022). Psychedelic drug abuse potential assessment research for new drug applications and Controlled Substances Act scheduling. *Neuropharmacology*, 218, 109220.

<https://doi.org/10.1016/j.neuropharm.2022.109220>

²⁹ Barnett, B. S., Vest, M. F., Delatte, M. S., King IV, F., Mauney, E. E., Coulson, A. J., Nayak, S. M., Hendricks, P. S., Greer, G. R., & Murnane, K. S. (2025). Practical considerations in the establishment of psychedelic research programs. *Psychopharmacology*, 242(1), 27–43. <https://doi.org/10.1007/s00213-024-06722-6>

³⁰ See Table 3

³¹ P.L. 119-26

³² Jaster, A., Hennessy, J., Anderson, T., Tsyrlunikov, A., Pradhan, A., Giorgio, G., & Ullman, E. (2026). Reducing research harms: Analysis and recommendations for researching schedule I substances under the HALT fentanyl act. *Journal of Science Policy & Governance* 28(01). https://www.sciencepolicyjournal.org/article_1038126_jspg280109.html

³³ Cohen, S. (2026). *Letter to AG Pam Bondi and DEA Administrator Terrance Cole*. https://cohen.house.gov/sites/evo-subsites/cohen.house.gov/files/evo-media-document/letter-to-ag-bondi-and-dea-administrator-reschedule-and-halt_v2.pdf

³⁴ Serial No. 91-46 (House Hearing) - Drug abuse control amendments--1970. Part 2: hearings before the Subcommittee on Public Health and Welfare of the Committee on Interstate and Foreign Commerce, House of Representatives, Ninety-first Congress, second session, on H.R. 11701 and H.R. 13743, bills to provide for increasing research and training of personnel to deal with drug abuse problems; increased educational and informational efforts to attempt to prevent drug abuse; providing facilities for the care and rehabilitation of drug abusers; and with revision of existing restrictions on distribution of drugs subject to abuse (and related bills). <https://www.govinfo.gov/app/details/CHRG-91hhrg42121p1/context>, Page 468

³⁵ Supra at 17

Additional documentation from research organizations (FDA, IRB, IACUC)	✓	☒
Institution specific requirements	✓	✓
Pre-approval laboratory inspections	Often required	Rarely required
Processing timeline	Up to 1 year	Several months

Table 3: Differences in Research Between Drug Schedules Currently Enacted; adapted from
<https://doi.org/10.38126/JSPG280109>

Under this bill, the issuance of research registrations has moved from the AG to HHS; I view research as a public health and scientific matter, and the Secretary is better equipped to evaluate a proposal's merits than a law enforcement agency (DEA). Schedule I and Schedule II–V substances have different research restrictions, and this bill eliminates those restrictions while maintaining DEA authority to set storage and recordkeeping regulations for different schedules. Under this new legislation, one license would have shared approval requirements.

Because HHS will now have the authority to register researchers, now called scientific investigators, rather than the DEA, deleting the dual-approval requirement from FDA and DEA was necessary. Additionally, as the Schedules have been rewritten, Schedule I is no longer solely for substances without FDA authorization, and therefore the distinctions between Schedule I and II – IV research must be readjusted.

Addition of Limited Exemption from Registration for Pilot Experiments

To support increased interdisciplinary work into controlled substances, a new provision is included³⁶ to permit the Secretary of HHS to establish a process within the National Institute on Drug Abuse for qualified researchers *without* a controlled substance license to apply for, and receive a *limited* quantity of a controlled substance from the Drug Supply Program to conduct a “single set of experiments”. The definitions of “limited quantity” and “single set of experiments” are to be left to the discretion of the Director of the National Institute on Drug Abuse. The storage and recordkeeping requirements may be similar or less stringent than for investigators with a controlled substance registration.

Such research will be limited to preclinical (cell- or animal-based), nonhuman research that the researcher shall describe to the Secretary. This provision will allow those without a license to test a novel idea and decide whether to apply for full registration if the experimental results are promising.

Elimination of the Word ‘Abuse’ Throughout the CSA; Replaced by Nonmedical Use, Misuse, or Substance Disorder Depending on the Context

The CSA uses the term “abuse” throughout, without a formal definition. The word is used in common parlance to describe both the *single* event of using a drug or substance in such quantities that cause

³⁶ Under 21 U.S.C. § 823(m).

harm to self and or society, **and** to indicate an individual's *ongoing pattern* of use which cause harm to self and or to society.

The term “drug abuse” was, however, defined in 1963 for the President's Advisory Commission on Narcotic and Drug Abuse³⁷ to exist when an individual takes drugs under any of the following circumstances:

- (a) in amounts sufficient to create a hazard to his own health or to the safety of the community; or
- (b) when he obtains drugs through illicit channels; or
- (c) when he takes drugs on his own initiative rather than on the basis of professional advice.

It was then refined modestly during the development of the 1965 Drug Abuse Control Amendments (DACA) to the Food, Drug, and Cosmetic Act, but never inserted into bill text. In the House Committee Report for DACA, it stated that, “It is not intended by the committee that a drug's potential for abuse be determined on the basis of the drug's having a **potential for isolated or occasional nontherapeutic purposes**. The committee feels that a drug's "potential for abuse" should be determined on the basis of its having been demonstrated to have such depressant or stimulant effect on the central nervous system as to make it reasonable to assume that there is a substantial potential for the occurrence of significant diversions from legitimate drug channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community.”³⁸

In the CSA in 1970, again, “abuse” was never defined, but the Committee Report indicated the following criteria to be evidence of “abuse”.³⁹

- (a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.
- (b) There is a significant diversion of the drug or drugs containing such a substance from legitimate drug channels.
- (c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.
- (d) The drug or drugs containing such a substance so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

³⁷ President's Advisory Commission on Narcotic and Drug Abuse. (1963). *Final Report of the President's Advisory Commission on Narcotic and Drug Abuse*. U.S. Government Printing Office. <https://www.ojp.gov/pdffiles1/Digitization/738NCJRS.pdf>

³⁸ Drug Abuse Control Amendments of 1965, Senate Report No. 337, June 21, 1965, Page 5

³⁹ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970) reprinted in U.S.C.C.A.N. 4566, 4603, Page 34

The DEA has no published standards or protocols for evaluation that define or describe what a “hazard to their health or to the safety of other individuals or to the community” is. Abuse, to the Drug Enforcement Administration, is any use of a drug outside ‘legitimate’ medical channels; an indicator that a drug has a potential for abuse is that “[i]ndividuals are taking the drug...on their own initiative rather than on the basis of medical advice.”⁴⁰ Thus, the prescription of a drug acts as a talisman that transforms one's behavior from “abuse” to “legitimate medical purpose”, potentially free from “abuse”. The above four-part test from the Committee Report also serves as DEA’s definition.

The National Institute on Drug Abuse (NIDA) has recommended for the last several years to use the words “use” for illicit drugs, and “misuse” to be the use of a prescription medication outside the parameters described by the prescriber, rather than using “abuse”.⁴¹ NIDA even sought to have its name changed in the FY25 budget to the *National Institute on Drugs and Addiction* to better reflect that the word “abuse” is outdated.⁴²

The DEA’s definition differs from that of the drafters of the drug control bills⁴³, and from that of the NIH agency devoted to studying the “abuse” of drugs. Words and their meanings change over time; why shouldn't this word?

This bill replaces “abuse” with “substance use disorder”.

In 2013, with the publication of the 5th Edition of the Diagnostic and Statistical Manual (DSM-V), “substance use disorder” (SUD) replaced “substance abuse” and “substance dependence”.⁴⁴ A SUD is marked by levels of severity on a spectrum of 11 symptoms. While it takes many individual use events of a drug to lead to the development of a SUD, a mere sporadic or isolated consumption event is not indicative of a problematic pattern of behavior. However, isolated use may still cause health problems.

Consider, if one were to take their partner’s Ambien sleeping medication one time to sleep - this too would fall under the DEA’s definition of “abuse”.

The DEA uses “potential for abuse” too but has never adopted a method for measuring and comparing the relative “potential for abuse” between drugs or substances. This leaves the agency with vast authority, with criminal penalties and potential loss of SNAP benefits or voting rights, depending on the state. The stakes are clearly high, and it is critical that the data underlying these decisions be based on the best, most comprehensive data. Indeed, a 2026 GAO report indicates that the DEA and FDA should

⁴⁰ Drug Enforcement Administration. (2024). *Drugs of abuse a DEA resource guide / 2024 EDITION*.

<https://www.dea.gov/sites/default/files/2024-12/2024-Drugs-of-Abuse-508.pdf>, Page 8

⁴¹ National Institute on Drug Abuse. (2021, November 29). *Words matter - terms to use and avoid when talking about addiction*. U.S. Department of Health and Human Services. National Institute on Drug Abuse. <https://nida.nih.gov/nidamed-medical-health-professionals/health-professions-education/words-matter-terms-to-use-avoid-when-talking-about-addiction>

⁴² National Institute on Drug Abuse. (2024, March 11). *Fiscal year 2025 budget information - congressional justification for National Institute on drugs and addiction | National Institute on Drug Abuse*. National Institute on Drug Abuse. <https://nida.nih.gov/about-nida/legislative-activities/budget-information/fiscal-year-2025-budget-information-congressional-justification-national-institute-drug-abuse>

⁴³ Supra at 38

⁴⁴ See Nathan, P. E., Conrad, M., & Skinstad, A. H. (2016). History of the concept of addiction. *Annual Review of Clinical Psychology*, 12(1), 29–51. <https://doi.org/10.1146/annurev-clinpsy-021815-093546>

“clearly define the criteria and process for determining a substance’s “potential for abuse,” including its abuse potential relative to other substances.”⁴⁵ The report continues that, “FDA officials told us that the lack of a written definition of “potential for abuse,” including “high potential for abuse,” presented challenges for determining the relative abuse potential and appropriate schedule recommendation for some substances”.⁴⁶

The terms “abuse” and “dependence” have therefore been eliminated; the CSA never defined them, and the terms are long outdated. Substance use disorder, misuse, and nonmedical use are all well-defined and characterized, and allow for a relative scale in those actions.

Changes to Controlled Substances Analogues

Updated the Definition of “Controlled Substance Analog”

The Anti-Drug Abuse Act of 1986 was a sweeping piece of drug policy legislation. Amongst many changes, it established mandator minimum criminal penalties for simple possession of controlled substances; established criminal penalties for employing those 18 years old and younger in drug operations; enhanced criminal penalties for drug operations near schools; amended the Federal criminal code to establish money laundering as a Federal offense; increased funding for international narcotics control efforts; authorized appropriations for State and local drug abuse education and prevention preventions; and amended the CSA to treat controlled substance analogues as Schedule I substances.

In the mid-1980s, these controlled substances analogues were called “designer drugs”, substances that were designed to evade controlled substance laws; a chemist could modify the molecular structure of a controlled substance, potentially retaining the psychoactive effect, but by changing it, the chemical was no longer the same controlled substance. Therefore, law enforcement needed a tool to counter the rise of designer drugs.

Three bills emerged in the 99th Congress to counter this issue: the Designer Drug Enforcement Act of 1985⁴⁷, the Designer Drug Enforcement Act of 1986⁴⁸, and the clean version of the 1986 bill reported out of committee, also called the Designer Drug Enforcement Act of 1986⁴⁹, and its committee report denotes the changes.⁵⁰ It was then incorporated into the aforementioned omnibus, Anti-Drug Abuse Act of 1986.⁵¹

⁴⁵ Government Accountability Office. (2026). *Drug Scheduling: While DEA Decisions Have Aligned with Recent HHS Recommendations, Both Need Comprehensive Policies* (GAO-26-108623). <https://www.gao.gov/products/gao-26-108623>, Page 14

⁴⁶ *Id.*

⁴⁷ Designer Drug Enforcement Act of 1985, H.R. 2977, 99th Cong. (1985). <https://www.congress.gov/bill/99th-congress/house-bill/2977>

⁴⁸ Designer Drug Enforcement Act of 1986, H.R. 5231, 99th Cong. (1986). <https://www.congress.gov/bill/99th-congress/house-bill/5231>

⁴⁹ Designer Drug Enforcement Act of 1986, H.R. 5246, 99th Cong. (1985). <https://www.congress.gov/bill/99th-congress/house-bill/5246>

⁵⁰ House Report 99-848 (H. Rept. 99-848, Part 1), Sept 19, 1986

⁵¹ P.L. 99-570

In the Designer Drug Enforcement Act of 1986, as reported out of committee, a controlled substance analog was to be defined as:

Except as provided in subparagraph (B), the term 'controlled substance analog' means a substance—

- (i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II; **and**
- (ii)(I) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system; or
- (II) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance.

The “and” between prongs (i) and (ii) was strongly supported by the American Chemical Society⁵² which strongly urged that both chemical structure and central nervous system effect be required in the definition of a controlled substance analogue to protect legitimate research. Prong (i) is necessary to link the unknown substance to the controlled substance it is derived from. Prong (ii) meanwhile tests for a “substantially similar” effect to such controlled substances. The committee report gives the example of coffee, it has a stimulant effect on the central nervous system but is not chemically similar to a controlled substance. Punishing someone under the CSA for effect alone was not viewed as logical.

The House version of H.R. 5454, the Anti-Drug Abuse Act of 1986 that was introduced for consideration on September 11, 1986 included the Committee reported approach with the conjunctive “and”.⁵³ However, some members argued that requiring both elements created too great a burden upon the prosecution of manufacturers and distributors of these analogs. Letters from the DEA and HHS objecting to that approach were introduced into the Congressional Record and that was the approach that the House and Senate leadership agreed to allow the Senate version to become law.⁵⁴ Prior to passage, the text of the Anti-Drug Abuse Act of 1986 was replaced by H.R. 5729, with the same name, incorporating amendments.⁵⁵ In this replaced version, (ii)(I) became just (ii), and additional language was added to (ii) to require that the stimulant, depressant, or hallucinogenic effect is “...greater than” the effect of substances in Schedule I or II. In this version, enacted as P.L. 99-570, the conjunctive “and” was removed. Current law allows a substance to be designated as a controlled substance analogue if the substance meets prongs (i), (ii), or (iii).

This bill amends definition 32 of the CSA to restore the conjunctive “and”. I recognize the concerns of DEA and HHS in this change, but criminal penalties for violations of this law may include jail or prison

⁵² May 1, 1986 to Rep. William J. Hughes from George C. Pimentel, President, American Chemical Society, page 3; and letter of July 23, 1986 to Eric E. Sterling, Assistant Counsel, Subcommittee on Crime from Anna Fotias, Manager, Department of Governmental Relations and Science Policy, American Chemical Society reprinted in Hearings before the Subcommittee on Crime of the House Committee on the Judiciary on Legislation relating to the Problem of Designer Drugs, May 1, 1986, 99th Cong. 2d sess.

⁵³ 132 Cong. Rec. 22892, Sept. 11, 1986

⁵⁴ 132 Cong. Rec. 22916-22919, Sept. 11, 1986

⁵⁵ See 132 Cong. Rec. 22914-22916, Sept. 11, 1986 for the amendments pertaining to this section and the debate.

time and the loss of federal benefits. This change reflects that of the American Chemical Society, chemistry and pharmacology PhDs I had discussed this with, and my belief that where there are great consequences for actions, rigorous data is necessary.

Conforming Amendment to Schedules of Controlled Substance Analogues

In current law, a substance will only be evaluated to be an analogue if it is derived from a Schedule I or II substance. The law designates only Schedule I as the Schedule for an analogue.⁵⁶ Because this bill alters the Schedules, an analogue shall now be placed in Schedule E and the numerical Schedule from which the Secretary has found that the compound is derived. Schedule E is for drugs or other substances in which the therapeutic effect is unknown, or there is none.

Elimination of Mandatory Minimum Penalties for Drugs and Retain Existing Penalties

The modern era of Federal mandatory minimum drug penalties began with the Anti-Drug Abuse Act of 1986, which created tiered minimum and potentially maximum sentences based on the drug and/or Schedule and quantities. The penalties included financial sanctions and/or imprisonment for one year to life.^{57,58} The penalties apply to manufacturing, distribution, dispensing, or possession of controlled substances. Mandatory minimums limit judicial discretion to tailor a sentence to the offense's severity or the individual's culpability in the drug enterprise. The mandatory minimum sentences were enacted because Congress believed that stiff penalties would deter people from engaging in illegal drug activities. However, they are marked by several key issues:

1. They limit judicial discretion – disconnect considerations of a defendant's culpability and role in the drug operation from the sentence, especially at the lower end.
2. Unintended Consequences – when mapped on specific scenarios, the mandatory minimum sentence may result in a low-level offender receiving a longer sentence than high-level dealers or traffickers for their respective offenses.

The mandatory minimum laws have not meaningfully reduced drug demand or supply, nor have they proven to be a cost-effective use of judicial or law enforcement resources.^{59,60,61} The mandatory minimum sentences were widely criticized by federal judges, and a number resigned in protest as well.⁶² Separate resolutions adopted by the Mississippi, Louisiana and Texas Federal District Judges all

⁵⁶ 21 U.S.C. § 813(a)

⁵⁷ 21 U.S.C. § 841(b)(3) for offenses involving Schedule V drugs or substances

⁵⁸ 21 U.S.C. § 841(b)(1)(A) for offenses involving certain listed drugs at specified quantities

⁵⁹ Caulkins, J. P. (2019). *Are mandatory minimum drug sentences cost-effective?* RAND Corporation. Rand.Org. https://www.rand.org/pubs/research_briefs/RB6003.html

⁶⁰ Mascharka, C. (2001). Mandatory Minimum Sentences: Exemplifying the Law of Unintended Consequences. *Florida State Law Review*, Vol. 28(Issue 4). <https://doi.org/https://ir.law.fsu.edu/cgi/viewcontent.cgi?httpsredir=1&article=1643&context=lr>

⁶¹ Vincent, B., & Hofer, P. (1994). The Consequences of Mandatory Minimum Prison Terms: A Summary of Recent Findings. *Federal Judicial Center*.

⁶² See for example, Nichols, J. (2003, June 25). Judge resigns over congressional meddling. *The Nation*. <https://www.thenation.com/article/archive/judge-resigns-over-congressional-meddling/>; Cassens Weiss, D. (2017, April 17). Federal judge steps down and denounces mandatory minimum sentences. *ABA Journal*. https://www.abajournal.com/news/article/federal_judge_steps_down_and_denounces_mandatory_minimum_sentence; Special to the New York Times. (1990, September 30). Criticizing sentencing rules, U.S. judge resigns. *The New York Times*. <https://www.nytimes.com/1990/09/30/us/criticizing-sentencing-rules-us-judge-resigns.html>

condemned the mandatory minimum sentences as they "often require the imposition of sentences which are manifestly unjust".⁶³ While some data show that increasing the cost to the offender, in financial, criminal, or combined terms, reduces crime, 40 years of data have not shown the level of punishment needed to deter crime. The current mandatory minimums have not led to a decrement in demand for drugs, nor in purity.⁶⁴ Drug-seeking is a demand-side issue, not a supply issue; demand drives supply.^{65,66,67} In 1986, during the development of the Anti-Drug Abuse Act, no hearings were held to gather input on establishing the weight-based mandatory minimum, and federal judges, the DEA, and the Bureau of Prisons were not asked for their opinions or data.⁶⁸

The Judicial Conference of the United States has opposed mandatory minimum drug penalties since the early 1990s, and recommended their repeal.^{69,70,71} As a former Chairman of the House Judiciary Subcommittee on the Constitution, Civil Rights, and Civil Liberties, I have long believed the mandatory minimum drug penalties are unjust, have discriminatory impacts, and pose significant due process concerns. They should be eliminated.⁷²

Changes to 21 U.S.C. § 841

Sections 841(b)(1)(A), (B) and (D) have been eliminated. (A) and (B) were the weight-based mandatory minimum penalties for specified substances. Those sections required long, specific sentences even if the judge believes the role of the person in the narcotics operation was minimal; (D) were mandatory minimum sentences for marijuana, and since the bill removes it from the CSA, this subsection was removed too.

Subsection C details criminal penalties and fines for a person or group of persons in a narcotics trafficking operation for Schedule I and Schedule II substances. This section has been retained but

⁶³ United States Sentencing Commission. (1991). *Special report to the Congress: Mandatory minimum penalties in the federal criminal justice system*. U.S. Sentencing Commission. https://www.ussc.gov/sites/default/files/pdf/news/congressional-testimony-and-reports/mandatory-minimum-penalties/1991_Mand_Min_Report.pdf

⁶⁴ Murphy, R. (2025). *2025 National Drug Threat Assessment*. Drug Enforcement Administration. <https://www.dea.gov/sites/default/files/2025-07/2025NationalDrugThreatAssessment.pdf>

⁶⁵ U.S. Department of State & Bureau for International Narcotics and Law Enforcement Affairs. (1998). *International Narcotics Control Strategy Report, 1997*: Washington, D.C., March 1998. *Trends in Organized Crime*, 4(2), 68–77. <https://doi.org/10.1007/BF02900343>

⁶⁶ Narcotics supply and demand reduction strategies must work together, report at UN says. (2005, March 1). *UN News*. <https://news.un.org/en/story/2005/03/130392>

⁶⁷ Boyd, C., & Shortall, J. (2025). *Safer Solutions: Why Focusing Exclusively on Drug Supply Isn't Enough*. *R Street Institute*. <https://www.rstreet.org/commentary/safer-solutions-why-focusing-exclusively-on-drug-supply-isnt-enough/>

⁶⁸ Sterling, E. (1999). *Pro/Con—Eric E. Sterling | Snitch | FRONTLINE | PBS* [Interview]. Retrieved October 27, 2026, from <https://www.pbs.org/wgbh/pages/frontline/shows/snitch/procon/sterling.html>

⁶⁹ Supra at 63

⁷⁰ Trump Barry, M. (1993, October 19). *Letter to all Members of Congress Regarding Mandatory Minimums* [Letter]. https://www.archives.gov/files/research/foia/garland/6862153_Box1_Folder28.pdf, Pages 5-9

⁷¹ Edwards, D. (1993, July 7). Opinion | Congress Swamped the Courts. *The Washington Post*. <https://www.washingtonpost.com/archive/opinions/1993/07/07/congress-swamped-the-courts/396a0e6e-886b-4804-9679-5a29d0f33fb3/>

⁷² See, for example, The Office of Congressman Steve Cohen. (2015, October 6). *Cohen: Release of 6,000 Drug Offenders Brings Justice to Americans Serving Needlessly Long Sentences*; The Office of Congressman Steve Cohen. (2013, August 12). *Cohen Applauds New Approach to Federal Drug Crime Sentencing*. Congressman Steve Cohen. <https://cohen.house.gov/press-release/cohen-applauds-new-approach-federal-drug-crime-sentencing>

increases the financial penalties for violations to conform with the enhancements made to Subsections (A) and (B) by the Fair Sentencing Act of 2010⁷³; The fines increased from \$1,000,000 to \$10,000,000 for an individual defendant and from \$5,000,000 to \$50,000,000 for a defendant who is not an individual. It also increases the penalties if the drug offense results in death or serious bodily injury from \$2,000,000 to \$20,000,000 if the defendant is an individual and from \$10,000,000 to \$75,000,000 if the defendant is other than an individual. Since the financial penalties in this section were enacted in 1986, the increase keeps the penalties significantly substantial by adjusting for inflation. Reflecting this increase in fines for Schedule I and II offenses, the maximum fines for Schedule III and Schedule IV offenses are also increased, as well as the other offenses in Section 841 relating to production of drugs on federal property, the poisoning of aquifers and watersheds, the placement of boobytraps, and the use of a controlled substance to commit a violent crime such as rape. As the bill eliminates Schedule V, the penalties for drugs in that Schedule effective the day before enactment will become tied to such substances, and not be made more severe.

Changes to 21 U.S.C. § 960

Congress enacted this section as part of Title III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as the Controlled Substances Import and Export Act, to regulate the importation and exportation of listed chemicals and controlled substances. Like in Section 841, the mandatory minimum sentences and excessively long maximum sentences have been eliminated or reduced.

Amended Subsection (b)(1) carries forward the maximum term of imprisonment under current law for the overwhelming majority of Schedule I drugs for each count, a maximum of 20 years for a first offense, and 30 years for a subsequent conviction. Serious offenders who are convicted of multiple counts can be sentenced to many decades of imprisonment when appropriate. In addition, if death or serious bodily injury occurs because of the use of the controlled substance that has been distributed by the defendant, imprisonment up to life may be imposed.

An important modernization of the penalty structure is amending the maximum fine structure. The current level of maximum fines of \$1,000,000 for an individual and \$5,000,000 are raised to the levels applied to the high-level traffickers by the Fair Sentencing Act of 2010 of \$10,000,000 for an individual and \$50,000,000 for an organization for a first offense, and \$20,000,000 for an individual and \$75,000,000 for an organization for subsequent offenses. Reflecting this increase in fines for Schedule I and II offenses, the maximum fines for Schedule III and Schedule IV offenses, as well as other offenses related to listed chemicals, are also increased.

Directing the US Sentencing Commission to Update Sentencing Guidelines

Congress created the US Sentencing Commission (USSC) to eliminate and prevent “unwarranted sentencing disparity” as part of the Comprehensive Crime Control Act of 1984.⁷⁴ These sentencing guidelines determine sentences for many federal crimes, and their amendments take effect unless Congress affirmatively modifies or rejects them.⁷⁵ Mandatory minimum penalties set a floor for

⁷³ P.L. 111-220

⁷⁴ H.R.Rep.No. 1017, 98th Cong., 2d Sess. 34 (1984); S.Rep.No. 225, 98th Cong., 1st Sess. 41 (1983)

⁷⁵ 28 U.S.C. § 944(p)

sentences, but within the congressionally imposed ranges, the Sentencing Commission’s guidelines are still applied. Federal courts impose a sentence within the guideline ranges unless (1) they expressly authorize departure; (2) the government moves to depart based upon the defendant’s cooperation with law enforcement; (3) the court feels that the Commission failed to sufficiently consider the aggravating or mitigating kind of circumstances raised by a particular case when it developed the otherwise applicable guidelines.⁷⁶

This bill adds a new Title, Title V – Revision of US Sentencing Guidelines, which directs the USSC to review and amend the guidelines relating to Unlawful Manufacturing, Importing, Exporting, or Trafficking (including Possession with Intent to Commit These Offenses); Attempt or Conspiracy, and related policy statements.⁷⁷ These changes should account for amendments to § 841 and 960 and promulgate guidelines that punish violators based on their culpability, role in the offense, and the Schedules of the substances involved, reflecting their “threat to public health.”⁷⁸ This title further provides for the retroactive application of these amendments.

A low-level street dealer should not have the same or similar sentence to the “kingpin” of the operation. Weight-based mandatory minimums, which this bill eliminates, seldom punish the kingpins, and instead capture the couriers, or low-level dealers who tend to have more drug weight than cash on hand.⁷⁹ The kingpins often outsource the possession and transportation of the drugs, despite maintaining control of the illicit substances and profiting from their distribution and sale. In practice, drug weight alone is a poor proxy for culpability in the operation.

These revisions should better tailor an individual’s sentence to the individual’s particular conduct, including their role in narcotics operation, the drug’s schedule (as adjusted for the substance’s specific properties described in other sections of this bill, which account for the substance’s relative “threat to the public health.”). In sum, this offers a more sophisticated, nuanced sentencing tool, replacing the blunt, unjust mandatory minimums currently in effect.

Transferring the Production Quota Authority to HHS from DEA

The CSA sought to create a “closed loop” of the distribution and production of controlled substances to account for each person in the drug supply chain and their handling of such substances, to prevent diversion. It allows the DEA to establish aggregate production quotas for each class of controlled substance listed in Schedule I or Schedule II, and for several listed chemicals. This system controls how much of a specific substance each manufacturer may produce, and its effectiveness affects patients, healthcare providers, scientists, and industry. The drug supply chain includes active

⁷⁶ 18 U.S.C. § 3553(a) and (b)

⁷⁷ U.S. Sentencing Guidelines § 2D1.1

⁷⁸ Definition 69 in this bill

⁷⁹ Caulkins, J. P., Reuter, P., & Midgette, G. (2026). Revising Federal Drug Sentencing Guidelines to better match sanctions to harms. *Federal Sentencing Reporter*, 38(3), 193–204. <https://doi.org/10.1215/10539867-12442726>

pharmaceutical ingredient manufacturers, drug manufacturers, packagers, repackagers, labelers, relabelers, pharmacies, and end users.

This system was established to meet two important objectives: prevent diversion while ensuring an adequate, uninterrupted supply of controlled substances for medical and scientific purposes. The underlying question, though, is whether a law enforcement agency should, in essence, regulate the practice of medicine by setting quotas that affect the medications a physician can prescribe, over the nation's health-focused department, HHS. DEA's mission is directed toward preventing diversion and illicit use. That mission is essential, but it creates incentives to prioritize preventing diversion, even when doing so may reduce the supply available to legitimate patients. However, the DOJ's Office of Inspector General did not identify the quota production system as a diversion-control tool for the opioid supply, instead making 9 other recommendations.⁸⁰

This bill seeks to balance authorities; it does not eliminate DEA's role in diversion control. DEA continues to regulate registrants, conduct inspections, establish security and recordkeeping requirements, investigate criminal violations, monitor suspicious activity, and enforce the Controlled Substances Act. DEA likewise retains the ability to transmit law-enforcement information relevant to quota-setting decisions, and the bill expressly preserves consultation between HHS and DOJ. The change instead recognizes that production quotas are a supply-management tool

Estimating demand requires analysis of disease prevalence, prescribing patterns, expected utilization, therapeutic alternatives, supply-chain vulnerabilities, manufacturing capacity, and the consequences to patients if supply is interrupted.

Shortages of controlled substances have been shown to, in certain circumstances, drive chronic pain or ADHD patients to illicit drug markets, where drug purity, quality, and other safety-relevant information is unknown, in addition to exposing them to the legal risks of illicit drug markets.⁸¹

The DEA has sought to address the quota system's issues by soliciting stakeholder feedback, but because of institutional roles and priorities, it is unlikely to fully solve them.⁸² Numerous think tanks and industry groups have written public comments and offered recommendations to improve the

⁸⁰ Office of the Inspector General. (2019). *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids* (Nos. 19–05). Department of Justice.

<https://www.oversight.gov/sites/default/files/documents/reports/2019-12/e1905.pdf>

⁸¹ For example, Bardwell, G., Small, W., Lavalley, J., McNeil, R., & Kerr, T. (2021). "People need them or else they're going to take fentanyl and die": A qualitative study examining the 'problem' of prescription opioid diversion during an overdose epidemic. *Social Science & Medicine*, 279, 113986. <https://doi.org/10.1016/j.socscimed.2021.113986>; Martin, J., Cunliffe, J., Décary-Hétu, D., & Aldridge, J. (2018). Effect of restricting the legal supply of prescription opioids on buying through online illicit marketplaces: Interrupted time series analysis. *BMJ*, k2270. <https://doi.org/10.1136/bmj.k2270>; Centers for Disease Control and Prevention. (2024, June 13). *Disrupted access to prescription stimulant medications could increase risk of injury and overdose*. U.S. Department of Health and Human Services. <https://www.cdc.gov/han/2024/han00510.html>

⁸² For example, Drug Enforcement Administration. (2026, May 20). *Revision of Applications for Manufacturing and Procurement Quotas* (Docket No. DEA-2026-0793). Department of Justice. <https://www.federalregister.gov/documents/2026/05/20/2026-10128/revision-of-applications-for-manufacturing-and-procurement-quotas>

system⁸³, including separating quota management from the DEA.⁸⁴

FDA and other HHS agencies already oversee drug approvals, monitor shortages, inspect manufacturing facilities, evaluate production capacity, and meet with manufacturers when supply disruptions occur. Because HHS oversees many of the events that follow quota decisions, assigning quota authority to it makes the same entity responsible for both identifying supply problems and using available regulatory tools to address them.

For these reasons, the bill transfers to HHS the authority to set quotas. It is consistent with a recommendation from President Kennedy’s Commission on Narcotic and Drug Abuse to deliberately split drug enforcement and trafficking investigations from the regulation of licit manufacturing.⁸⁵

Updates to the Office of National Drug Control Policy to Facilitate Interagency Coordination in Novel Drug Trends and Threats

The Anti-Drug Abuse Act of 1988 established the Office of National Drug Control Policy (ONDCP) within the White House, whose Director is called the ‘Drug Czar’. Its mission is to lead and coordinate the nation’s drug policy to improve the health and lives of the American people. Every two years, it publishes and coordinates the National Drug Control Strategy as required by law.⁸⁶ Broadly, its purpose is to reduce illicit drug use, manufacturing, and trafficking; drug-related crime and violence; and drug-related health consequences.^{87,88,89,90,91}

⁸³ For example, Knapp, J. (2026, July 20). *Premier Comments on Revision of Applications for Manufacturing and Procurement Quotas*, Docket No. DEA-1278. <https://cdn.sanity.io/files/pwlchz92/production/21e89bb71e8d0034e885e2e704b88eed77790416.pdf>; Wosińska, M. E. (2026, July 20). *Comments on Revision of Applications for Manufacturing and Procurement Quotas*, Docket No. DEA-1278. Brookings Institute. <https://www.brookings.edu/wp-content/uploads/2026/07/DEA1278CommentLetterWosinskaGrahamFINALPDF.pdf>; McKenna, S. (2023, November 28). *R Street Comments on DEA’s Proposed Aggregate Production Quota 2024*, Docket No. DEA-1228P. <https://www.rstreet.org/outreach/r-street-comments-on-deas-proposed-aggregate-production-quota-2024/>

⁸⁴ For example, Wosińska, M. E. (2026). *Fixing The Controlled Substance Quota System: Why the Law and the Regulator Must Change*. Center on Health Policy at Brookings. https://www.brookings.edu/wp-content/uploads/2026/09/Wosinska_DEA-to-FDA-quota-move_FinalPDF-1.pdf

⁸⁵ Supra at 37

⁸⁶ 21 U.S.C. § 1705

⁸⁷ Congressional Research Service. (2021). *Office of National Drug Control Policy and Its Role in Federal Drug Control (R46889)*. Library of Congress, Congressional Research Service. <https://www.congress.gov/crs-product/R46889>

⁸⁸ Office of National Drug Control Policy. (2001). *Office of National Drug Control Policy FY 2001-FY 2007 strategic plan (NCJ 189713)*. Executive Office of the President of the United States, Office of National Drug Control Policy. https://www.ojp.gov/ondcppubs/publications/pdf/strategic_plan.pdf

⁸⁹ Office of National Drug Control Policy. (2010). *Office of National Drug Control Policy Open Government Plan*. Executive Office of the President of the United States, Office of National Drug Control Policy. https://obamawhitehouse.archives.gov/sites/default/files/ondcp/about-content/open_government_plan.pdf

⁹⁰ Office of National Drug Control Policy. (2024). *National Drug Control Strategy*. Executive Office of the President of the United States, Office of National Drug Control Policy. <https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/05/2024-National-Drug-Control-Strategy.pdf>

⁹¹ Office of National Drug Control Policy. (2026). *National Drug Control Strategy*. Executive Office of the President of the United States, Office of National Drug Control Policy. <https://www.whitehouse.gov/wp-content/uploads/2026/05/National-Drug-Control-Strategy-2026-1.pdf>

Enhanced Interagency Coordination and Information Collection in Novel Drug Trends and Threats

In 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act was signed into law. A sweeping, bipartisan piece of legislation, it sought to tackle a myriad of issues in the opioid overdose epidemic, including treatment, prevention, recovery, enforcement, Medicaid reform, and government interagency strategy development.

It also required the ONDCP to establish the Evolving and Emerging Threats Committee, which is required to monitor evolving and emerging drug threats to prevent the development of a drug crisis, like the opioid overdose epidemic. The Committee's function supports the ONDCP's efforts to designate and/or terminate a drug or other substance as an evolving or emerging drug threat. It includes representatives from the National Drug Control Program agencies, many other agencies, and state, local, and Tribal Governments.⁹² When making such an emerging threat designation, the ONDCP Director must make publicly available their Emerging Threat Response plan.⁹³ The new law required the Committee to develop and recommend to the Director criteria to be used to identify and/or terminate a drug's status as an emerging drug threat, but did not specify the quality or types of information.

In 2022, President Biden's Drug Czar published a memorandum detailing the criteria for establishing or terminating a threat, metrics, development of the Emerging Threat Response Plan, and their intent to develop a media campaign to address such threat.⁹⁴ The ONDCP Committee developed a four-part framework to guide decision-making on emerging drug trends, based on the HHS framework used to monitor and characterize emerging COVID-19 variants and the potential risks they might pose to public health.^{95,96} Each category builds on the previous in the government's response.

These four categories are, from least to most substantial threat:

1. Drug being monitored

This classification is for drugs or methods of use that have a potential for, or documented risk of harm, though limited data may be available to determine the relative impact of use. This classification indicates further monitoring is warranted to better define the potential risks associated with use, nonmedical use, development of a substance use disorder, or emerging routes of administration.

2. Drug of interest

Compounds within this category are those that are associated with illicit use which may impact overdose risk. Responses to drugs in this category may include enhanced monitoring or research into its clinical or basic pharmacological properties.

⁹² 21 U.S.C. § 1708(b)

⁹³ 21 U.S.C. § 1708(d)

⁹⁴ Office of National Drug Control Policy. (2022). *Criteria For Designating Evolving and Emerging Drug Threats* (Dir. No. 2022-002). Executive Office of the President, Office of National Drug Control Policy.

⁹⁵ National Center for Immunization and Respiratory Diseases (U.S.). Division of Viral Diseases. (2022). *SARS-CoV-2 variant classifications and definitions*. <https://stacks.cdc.gov/view/cdc/116721>

⁹⁶ Ashburn, M. A., Holtgrave, D. R., Baum, R. J., & Gupta, R. (2023). Establishing an Approach for Designation of Evolving and Emerging Drug Threats. *Health security*, 21(3), <https://doi.org/10.1089/hs.2022.0150>

3. Drug of concern

Drugs within this category demonstrate evidence of an increase in prevalence of use, or in the harms associated with such pattern of use, and those harms are observed in a specific subset of the population, or an increasing proportion of the general population. Responses in this category may include the development of detection methods, increasing law enforcement interdiction efforts, advocacy for research into clinical diagnosis and treatment for a substance use disorder, and public health media campaigns. When a substance reaches this designation, the ONDCP Director may formally designate it as an evolving or emerging drug threat.

4. Drug of high consequence

These compounds may have major detrimental impacts on quality of life or have a major impact on fatal and nonfatal overdoses. Substances in this category may require urgent national programming and policymaking efforts.

This bill codifies a multi-tiered response system, enhances intergovernmental agency coordination, and authorizes \$6,000,000 to commission additional studies as needed. This enhanced coordination and collection apparatus will be useful too when HHS seeks to schedule a substance. Information about subnational geographic trends in drug purity and adulterants in the localized supply, routes of administration, and differential harms associated with routes of administration, such as fatal overdose rates or spread of blood-borne pathogens, will be useful in tuning the appropriate level of scheduling control, and public health response. Further, enhancing efforts to identify racial, socioeconomic, age, and other demographic information relating to the spread and use of a particular substance will be helpful in guiding public health responses.

Removal of Language Opposing Preventing the Funding of any Study Relating to the Legalization of a Schedule I Substance

Current law requires the Drug Czar to ensure that the ONDCP's funding is not used for any study relating to the legalization of a Schedule I substance, and to oppose any efforts to legalize any substance that the FDA has not approved for medical uses.⁹⁷ This bill alters the Schedules, and Schedule I would now include FDA-approved drugs or substances. As such, this language is no longer necessary.

Changes to Emergency Scheduling Provisions

Changed "Imminent Hazard to the Public Safety" to "Imminent Significant Threat to Public Health" under Emergency Scheduling

Emergency scheduling permits the AG to place a drug or other substance under control in Schedule I for a two-year period, to avoid "an imminent hazard to the public safety".⁹⁸ Current law and regulation do not define what might constitute an "imminent hazard to the public safety," giving the agency substantial discretion. This bill changes that threat to a "threat to the public health," a phrase the bill also defines and uses in the updated scheduling framework. This change links the "threat to public

⁹⁷ 21 U.S.C. § 1703(b)(12)

⁹⁸ 21 U.S.C. § 811(h)

health” definition used to determine the numerical schedule to the type of threat warranting immediate action.

Changed the Primary Authority for Initiating Emergency Scheduling Action to the Director of the Office of National Drug Control Policy (ONDCP) from the Attorney General

This change was two-fold: (1) non-emergency scheduling actions are now initiated by the Secretary of HHS, and thus to leave this authority with the Attorney General would have been inconsistent with the policy; (2) the ONDCP takes a more central role in coordinating action to emerging drug trends and threats in this bill, thus they are central to receiving information from the multitude of drug surveillance networks, and would be best equipped to initiate the request for emergency scheduling.

Updated the Factors Used in Considering Emergency Scheduling Action

When the AG places a drug under temporary control via Emergency Scheduling actions, they make findings *only* with respect to factors 4, 5, 6.⁹⁹ As this bill updates the factors, new factors 3, 4, 6, 11, and 12 are to be considered.¹⁰⁰

Removal of Marijuana from the CSA

I have long believed that marijuana does not belong on the CSA, and the penalties involving it have rendered irreparable harm to tens of millions of Americans by stripping them of civil liberties such as voting rights. Nearly 9 in 10 Americans believe it should be legal for medicinal or recreational purposes.¹⁰¹ Reportedly, Richard Nixon’s former White House Counsel, John Ehrlichman, said of President Nixon’s drug policy, “We knew we couldn’t make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities...”¹⁰²

The legislative history of the CSA indicates there was substantial debate over how to deal with marijuana – whether it should be scheduled, and if so, in which schedule. Scientific studies were lacking at the time; for that era, Congress largely believed it should be included. The Assistant Secretary for Health and Scientific Affairs recommended “that marihuana be retained within schedule

⁹⁹ (4) Its history and current pattern of abuse; (5) The scope, duration, and significance of abuse; and (6) What, if any, risk there is to the public health.

¹⁰⁰ (3) Its history and current trends of non-medical use, dependence, and developments of substance use disorders, including subnational geographical trends. (4) The nature of, and actual (or, if unknown, the potential) magnitude of, threats to public health related to misuse, nonmedical use, and developments of substance use disorders, including drug-specific mortality, drug-related mortality, drug-specific damage, and drug-related damage. (6) Prevalence of medical conditions or disease that the drug or substance is used in or has the potential for treatment for a currently met or unmet therapeutic utility. (11) What threat to public health, if any, from scheduling the drug or other substance, including replacement by alternative drugs or substances. (12) The extent to which the drug or other substance is used to reduce the severity of an individual’s substance use disorder with respect to the use of another scheduled drug or substance, along with harms to the individual and society associated with use of that other scheduled drug or substance.

¹⁰¹ McCarthy, J. (2025, November 5). Americans Much More Positive About Progress on Drugs. *Gallup*.

<https://news.gallup.com/poll/697445/americans-positive-progress-drugs.aspx>

¹⁰² LoBlanco, T. (2016, March 24). Report: Aide says Nixon’s war on drugs targeted blacks, hippies. *CNN*.

<https://www.cnn.com/2016/03/23/politics/john-ehrichman-richard-nixon-drug-war-blacks-hippie/index.html>

I at least until the completion of certain studies now underway.”¹⁰³ Additionally, the CSA mandated that a “Commission on Marihuana and Drug Abuse” be established to study the “causes of drug abuse and their relative significance.”¹⁰⁴ President Nixon appointed its members, and it was chaired by former Pennsylvania Governor Raymond Shafer. This commission has since been known as the “Shafer Commission”, and it issued its findings in 1972, which called for the decriminalization of marijuana possession.¹⁰⁵ President Nixon ignored his own appointed commission’s recommendations.

It has been 54 years since the Commission issued its recommendations, and the data indicate that marijuana carries less harm to oneself or to society than alcohol.^{106,107} It is past time to remove it from the CSA and step into a new era of drug policy.

¹⁰³ August 14, 1970 letter from Roer O. Egeberg, MD, Assistant Secretary for Health and Scientific Affairs to Congressman Harley O. Staggers, Chairman, Committee on Interstate and Foreign Commerce

¹⁰⁴ Section 601 of P.L. 91-513

¹⁰⁵ National Commission on Marihuana and Drug Abuse. (1972). *Marihuana: A Signal of Misunderstanding*. <https://babel.hathitrust.org/cgi/pt?id=mdp.39015015647558&seq=5>

¹⁰⁶ Broman, M., Davis, A. K., Armstrong, S., Levin, A., Ahmed, K., Angarita, G. A., Arterberry, B. J., Bergeria, C., Earleywine, M., Gex, K. S., Gregoire, T., Lister, J. J., Mathai, D. S., Mehtani, N. J., Menke, N., Nichols, C. D., Shaub, H., Tackett, A. P., Weiss, B., ... Phillips, L. D. (2026). US drug policy does not align with experts’ rankings of drug harms: A multi-criteria decision analysis. *Harm Reduction Journal*, 23(17). <https://doi.org/10.1186/s12954-025-01390-x>

¹⁰⁷ *Drug Abuse Warning Network National Estimates from Drug-Related Emergency Department Visits*, 2023 (Nos. PEP24-07–033). (2024). Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. <https://www.samhsa.gov/data/sites/default/files/reports/rpt53161/dawn-national-estimates-2023.pdf>