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Drug Scheduling: While DEA Decisions Have Aligned with Recent HHS Recommendations, Both Need Comprehensive Policies

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Q&A Report to Congressional Requesters
September 23, 2026

Why This Matters

The use of illicit drugs and misuse of prescription drugs has been a persistent and long-standing public health issue in the United States. The Controlled Substances Act recognized that many drugs controlled by the act have a legitimate medical purpose, but also that the illegal importation, manufacture, distribution, and improper use of controlled substances have a substantial and detrimental effect on public health and welfare. Under the act, a substance that poses a risk of abuse and dependence, such as fentanyl, is to be categorized (or placed in a schedule) based on its relative potential for abuse, whether it has a currently accepted medical use in treatment in the U.S., and other factors.

A substance's schedule and quantity control the extent to which criminal penalties under the Controlled Substances Act may be levied regarding its illegal manufacturing, distribution, or possession. In recent years, members of the public, interest groups, and elected officials have raised questions about how certain substances are scheduled under the act. For example, substances such as marijuana have been legalized in some states for medical use. In April 2026, the Acting Attorney General rescheduled FDA-approved drug products containing marijuana and marijuana subject to a state medical marijuana license, and DEA held a public hearing in summer 2026 regarding the potential rescheduling of all marijuana.

The Controlled Substances Act outlines roles for the Attorney General and the Secretary of Health and Human Services in scheduling substances under certain circumstances. The Attorney General has delegated these responsibilities to the Administrator of the Drug Enforcement Administration (DEA). DEA, in consultation with the Department of Health and Human Services (HHS), may schedule substances through (1) administrative scheduling, (2) new drug application scheduling, (3) temporary scheduling, or (4) international treaty scheduling processes. To carry out certain scheduling actions, DEA must obtain a scheduling recommendation from HHS based on a scientific and medical evaluation of the substance performed by the Food and Drug Administration (FDA), an agency within HHS that oversees the safety and effectiveness of drugs marketed in the U.S. Substances may also be scheduled through legislation.

Members of Congress have raised questions and concerns about how DEA considers scientific and medical evaluations and scheduling recommendations from HHS when making its decisions. We were asked to examine DEA's processes and practices for identifying and requesting evaluations and for implementing recommendations from HHS; we were also asked to study the scheduling actions DEA has taken and not taken in response to HHS recommendations. This report identifies the circumstances under which DEA is required to request and consider HHS scientific and medical evaluations and

scheduling recommendations, the extent to which DEA requested and considered HHS evaluations and recommendations for scheduling actions taken from 2020 through 2025, and the extent to which DEA and HHS have policies and procedures related to evaluating and scheduling substances. We selected this timeframe to assess DEA scheduling actions during the most recent 6 calendar years.

Key Takeaways

- For certain scheduling actions as discussed in detail below, DEA is required to request and consider an HHS scientific and medical evaluation and scheduling recommendation. Substances may also be scheduled through legislation, which does not require a scientific or medical evaluation or recommendation from HHS or DEA.
- We found that DEA was required to consider HHS scientific and medical evaluations and scheduling recommendations for 95 of the 208 substances for which DEA took scheduling actions from 2020 through 2025 and did so for all 95. Of these 95, DEA's final scheduling decision aligned with HHS's recommendation for all 84 substances for which DEA had published a final scheduling decision. The remaining 11 were still under extended temporary scheduling orders as of December 31, 2025 (the end of our study scope).
- We found that DEA and FDA have some policies that address aspects of the scheduling process; however, these policies have gaps. For example, DEA does not have any policies or procedures regarding how its staff are to conduct evaluations or schedule substances. In addition, FDA does not have policies or procedures specifying how its staff are to conduct evaluations or develop scheduling recommendations for substances.
- Additionally, FDA has a memorandum of understanding (MOU) with the National Institutes of Health's (NIH) National Institute on Drug Abuse (NIDA) that describes procedures for FDA to consult NIDA when developing scheduling recommendations, but it is outdated because it does not reflect the current entities involved or procedures.
- As a result, we are recommending that DEA and FDA develop policies and procedures related to evaluating and scheduling substances and that FDA and NIH update their MOU to reflect the current entities involved and procedures. The Department of Justice, including DEA, and HHS, including FDA and NIH, concurred with our recommendations.
- According to DEA and FDA officials, differences of scientific opinion between the two agencies about a substance's schedule are rare, but they have occurred. In such cases, they typically discuss their differences, share data and other information, and resolve any differences before DEA solicits public comments. In one case, Congress passed a law requiring HHS to obtain more information to help inform its scientific and medical evaluation.
- Additionally, in certain instances, legislative scheduling has addressed situations in which the administrative scheduling of certain substances is challenging, such as scheduling certain substances as a class.

What are the five schedules under the Controlled Substances Act?

The Controlled Substances Act, enacted in 1970 and subsequently amended, established a federal legal framework to regulate the manufacturing, distribution, dispensing, importation, and exportation of controlled substances. These include narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and their immediate precursors.[1] The act created five schedules of controlled substances

and initial lists of substances under each schedule.[2] It also identified the scientific and medical findings required to place a substance in each schedule.

Table 1 shows the required findings and examples of substances currently in each schedule.

Table 1. Controlled Substance Schedules, Required Findings, and Examples of Substances

Schedule	Required findings	Examples of substances
Schedule I	Has a high potential for abuse, no currently accepted medical use in treatment in the U.S., and no accepted safety for use under medical supervision	Heroin, lysergic acid diethylamide (LSD), methaqualone, peyote, and 3,4-methylenedioxymethamphetamine (MDMA)
Schedule II	Has a high potential for abuse, a currently accepted medical use in treatment in the U.S. or currently accepted medical use with severe restrictions, and abuse may lead to severe psychological or physical dependence	Cocaine, methamphetamine, methadone, hydromorphone, meperidine, oxycodone
Schedule III	Has a potential for abuse less than the substances in Schedules I and II, a currently accepted medical use in treatment in the U.S., and abuse may lead to moderate or low physical dependence or high psychological dependence	Products containing less than 90 milligrams of codeine per dosage unit (such as acetaminophen with codeine), ketamine, anabolic steroids (such as testosterone)
Schedule IV	Has a low potential for abuse relative to other substances in Schedule III, a currently accepted medical use in treatment in the U.S., and abuse may lead to limited physical or psychological dependence relative to other substances in Schedule III	Many anti-anxiety and sedative medications (such as benzodiazepines), sleep aids
Schedule V	Has a low potential for abuse relative to other substances in schedule IV, a currently accepted medical use in treatment in the U.S., and abuse may lead to limited physical or psychological dependence relative to other substances in Schedule IV	Cough preparations with less than 200 milligrams of codeine per 100 milliliters or per 100 grams

Source: Controlled Substances Act and Drug Enforcement Administration. | GAO-26-108623

What are the ways substances can be scheduled, and when is DEA required to request and consider HHS scientific and medical evaluations and scheduling recommendations?

Substances may be scheduled through (1) administrative scheduling, (2) new drug application scheduling, (3) temporary scheduling, (4) international treaty scheduling through domestic scheduling orders, and (5) legislation.

Administrative scheduling and other administrative scheduling actions: Administrative scheduling occurs when DEA either initiates or responds to a request from HHS or an interested party to add a substance to a schedule, transfer a substance between schedules, or remove a substance from the schedules through administrative rulemaking or other administrative scheduling action.[3] For the purposes of this report, we use terms like, "schedule," for "add;" "reschedule" for "transfer;" and "deschedule" for "remove." We use the term, "administrative scheduling," to refer to administrative scheduling through formal rulemaking pursuant to 21 U.S.C. § 811(a).

For the purposes of this report, we define "other administrative actions" as DEA administrative actions to schedule immediate precursors and positional isomers related to controlled substances.[4] Under the Controlled Substances Act, DEA may administratively schedule some substances, such as immediate precursors and positional isomers related to controlled substances, without regard for certain rulemaking procedures.[5]

Under administrative scheduling, DEA may initiate scheduling or rescheduling if it finds that there is substantial evidence a substance has a potential for abuse and makes the necessary findings to schedule the substance in the schedule in which it is to be placed, or descheduling if it determines there is substantial evidence that the substance should be removed entirely from the schedules.[6] HHS may

also request and any interested party may also submit a petition to schedule, reschedule, or deschedule a substance.[7] Prior to initiating rulemaking on its own or in response to an HHS request or interested party petition, DEA is required to request a scheduling recommendation from the Secretary of Health and Human Services based on an FDA scientific and medical evaluation.[8] The Secretary of Health and Human Services has delegated responsibilities under the Controlled Substances Act to the Assistant Secretary for Health.[9] See figure 1 below for more information about the administrative scheduling process.

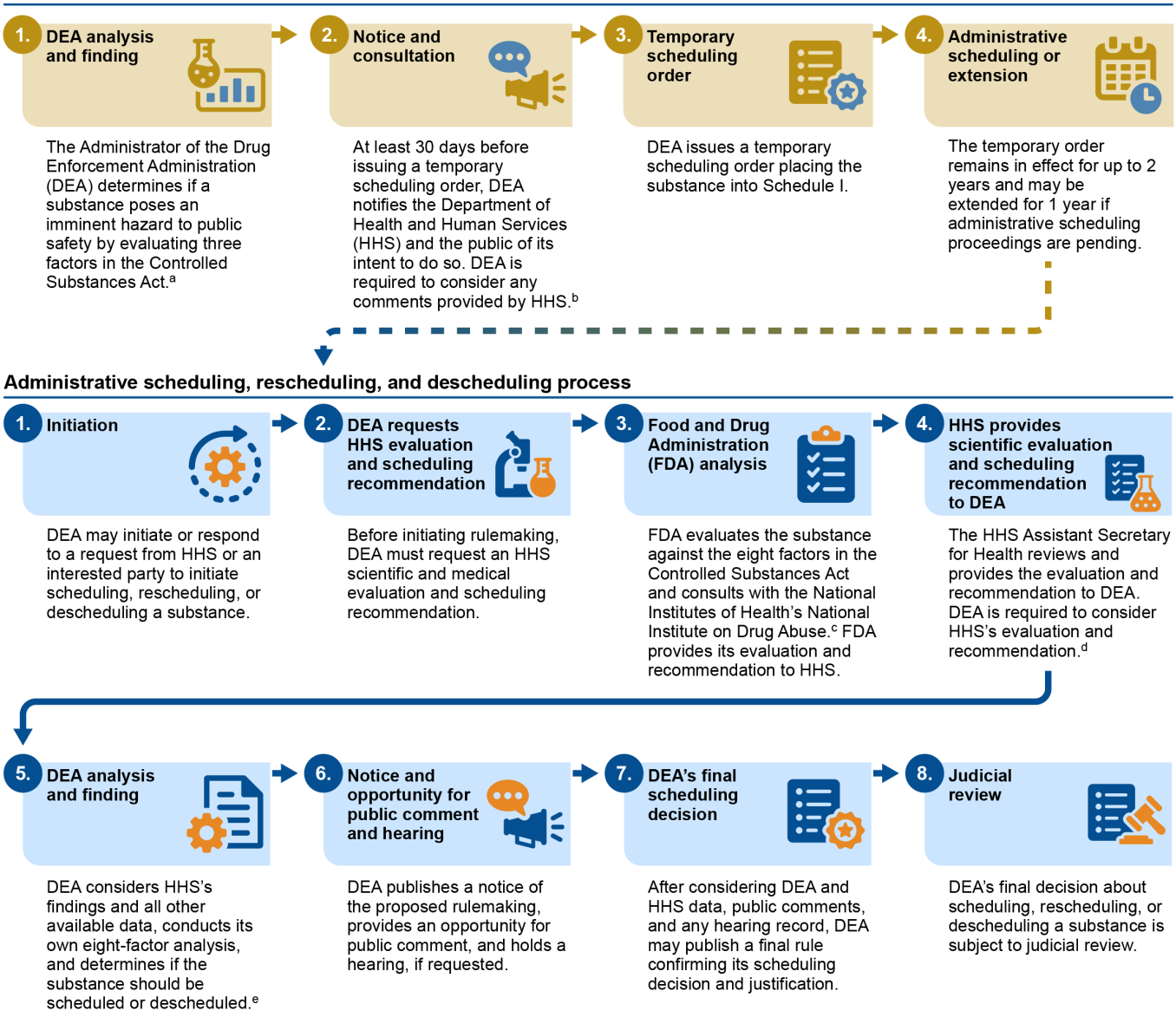
New drug application scheduling: HHS generally requests the scheduling process start in response to a new drug application and risk assessment under the Federal Food, Drug, and Cosmetic Act.[10] If FDA determines that a new drug has the potential for abuse when reviewing a new drug application to market the drug in the U.S., FDA prepares a scientific and medical evaluation and recommended schedule, and HHS sends it to DEA. Under the Improving Regulatory Transparency for New Medical Therapies Act and the Controlled Substances Act, DEA is required to expedite scheduling for certain new drugs approved by the FDA.[11] Specifically, DEA must consider HHS's scientific and medical evaluation and issue an interim final rule scheduling the drug according to HHS's recommendation within 90 days of the date DEA receives HHS's evaluation or FDA's notice of the new drug approval, whichever is later.[12]

As such, for approved new drug applications, DEA is not required to request—only consider—HHS's scientific and medical evaluation and scheduling recommendation. The interim final rule is effective on the date it is published and gives any interested person the opportunity to comment and request a hearing before DEA publishes its final rule.[13]

Temporary scheduling: The Controlled Substances Act allows DEA to temporarily place a substance it deems to pose an imminent threat to public safety in Schedule I for up to 2 years.[14] DEA may do so by order and without requesting or considering an HHS scientific and medical evaluation or scheduling recommendation; it may also extend this scheduling decision for an additional year if administrative proceedings are pending.[15] To extend the temporary scheduling order or to permanently schedule the substance, DEA must request and consider an HHS scientific and medical evaluation and scheduling recommendation prior to initiating administrative proceedings.

Figure 1 shows the temporary scheduling process and administrative scheduling process, and how the temporary process may lead to permanent scheduling.

Figure 1: Temporary Scheduling Process to Administrative Scheduling Process for Substances



Source: Controlled Substances Act; Icons-Studio/stock.adobe.com (icons). | GAO-26-108623

Note: Pursuant to 28 C.F.R. § 0.100, the Attorney General has delegated certain responsibilities under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration.

[a]Under 21 U.S.C. § 811(h)(3), DEA is required to evaluate the following three factors for the substance: (1) its history and current pattern of abuse; (2) the scope, duration, and significance of abuse; and (3) any risk to the public health.

[b]DEA may schedule a substance temporarily if the substance is not listed in any other schedule in 21 U.S.C. § 812 or if no exemption or approval is in effect for the substance under 21 U.S.C. § 355.

[c]According to 21 U.S.C. § 811(c), the eight-factor analysis considers the following factors for each drug or other substance proposed to be controlled or removed from the schedules: (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; and (8) whether the substance is an immediate precursor of an existing controlled substance.

[d]According to 21 U.S.C. § 811(b), HHS's recommendation shall be binding on DEA as to such scientific and medical matters. If HHS recommends that a drug or other substance not be controlled, DEA shall not control the drug or other substance. According to the Department of Justice's Office of Legal Counsel, HHS's scientific and medical findings are binding on DEA until DEA issues a notice of proposed rulemaking, and DEA must give "significant deference" to HHS's scientific and medical findings throughout the rulemaking process. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana (Apr. 11, 2024). Upon initiating rulemaking proceedings, DEA provides an opportunity for public comments and hearing. According to FDA officials, new data would have to be presented to DEA from public comments or hearing testimony that DEA can then choose to weigh in addition to HHS findings, while still giving significant deference to HHS findings.

[e]DEA must make findings about the accepted medical use, potential for abuse, and dependence liability of the substance. If DEA determines that HHS's scientific and medical findings and all other available data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substances should be removed entirely from the schedules, the Administrator shall initiate proceedings for control or removal, as the case may be.

International treaty scheduling: When the United States is obligated to control a substance under an international drug control treaty, DEA takes a scheduling action to schedule the substance to meet that obligation according to procedures in the Controlled Substances Act specific to each treaty.[16] For example, DEA must request and consider an HHS scientific and medical evaluation and recommendation for substances scheduled to comply with U.S. treaty obligations under the Convention on Psychotropic Substances. However, DEA is not required to request and consider an HHS scientific and medical evaluation and recommendation for substances scheduled to comply with U.S. treaty obligations under the Single Convention on Narcotic Drugs. The DEA Administrator may issue an order scheduling these substances without an HHS evaluation.

Legislation: Laws can be enacted to schedule, reschedule, or deschedule a substance. Legislative scheduling does not require a scientific and medical evaluation and scheduling recommendation.

What scientific and medical evaluations of substances do HHS and DEA conduct, and how do HHS and DEA determine schedule placement?

Administrative scheduling: For substances scheduled through administrative rulemaking, HHS and DEA each conduct an evaluation of the substance, and DEA is to consider HHS's evaluation and scheduling recommendation. Prior to initiating rulemaking, DEA is to request a scientific and medical evaluation and scheduling recommendation from the HHS Assistant Secretary for Health, who relies on FDA to conduct the evaluation. This evaluation (also known as an eight-factor analysis) considers the following eight factors for each drug or other substance as required by the Controlled Substances Act:

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. the substance's psychic or physiological dependence liability; and
8. whether the substance is an immediate precursor of an existing controlled substance.[17]

When determining scheduling recommendations, FDA must make specific findings related to the substance, according to the Controlled Substances Act:

1. the degree to which it has a potential for abuse;
2. whether the substance has a currently accepted medical use in treatment in the United States; and
3. whether there is an accepted safety for use under medical supervision (for substances contemplated for placement in Schedule I); *or* the degree to which abuse of the substance may lead to psychological or physical dependence (for substances contemplated for placement in Schedules II, II, IV, or V).[18]

The evaluation is conducted by FDA's Center for Drug Evaluation and Research Controlled Substance Staff and incorporates multiple streams of evidence, according to HHS officials. They stated that DEA collects and shares a set of data. For example, according to HHS officials, for emergent illicit drugs, DEA often provides animal studies, which it commissions through contractors, along with law enforcement and drug seizure data and case reports of medical interventions or drug-related deaths.

According to HHS officials, FDA's Controlled Substance Staff also consult with other Center for Drug Evaluation and Research offices for data relevant under

the eight factors. In addition, FDA consults with NIDA to seek concurrence on scientific findings in the drafted drug evaluation. If FDA and NIDA do not fully concur on scientific findings, NIDA may provide separate input to the Assistant Secretary for Health. FDA officials were not aware of any instance in which NIDA had formally issued a nonconcurrence.

According to HHS officials, the Assistant Secretary for Health is to consider the scientific and medical evaluation from FDA, and any separate input provided by NIDA, and determine if they concur with the drafted scheduling recommendation. The Assistant Secretary for Health will then submit the findings and overall recommendation to DEA in writing within a reasonable time (agency definitions of "reasonable time" are addressed later in this report).

Upon receiving HHS's scientific and medical evaluation and scheduling recommendation, DEA evaluates these data and all other relevant data to determine whether to initiate proceedings to control a substance or to remove it entirely from the schedules. To make this determination, DEA's Diversion Control Division conducts its own eight-factor analysis and makes the findings as required by the act.[19] According to DEA officials, when conducting an eight-factor analysis, DEA considers law enforcement data regarding drug encounters reported to DEA's National Forensic Laboratory Information System and other internal DEA data collection systems.[20] In addition, upon initiating rulemaking proceedings, DEA publishes a notice of proposed rulemaking and provides an opportunity for public comments and a hearing. According to DEA officials, once formal rulemaking begins, DEA must continue to give "significant deference" to HHS's findings throughout the rulemaking process when determining schedule placement.

New drug application scheduling: For new drug applications submitted to FDA involving a drug with abuse potential, the applicant will typically provide all necessary animal and human data to enable a drug evaluation under the eight factors. In these situations, FDA staff will usually be able to consider human laboratory studies of abuse potential and adverse events from clinical studies, according to HHS officials. DEA and FDA also consider data from drug treatment admissions, federal surveys on drug use, and other epidemiological databases, as available.[21]

Temporary scheduling: Prior to temporarily scheduling a substance in Schedule I, DEA is required to conduct a three-factor analysis.[22] This is a subset of the eight factors relevant to permanent administrative scheduling—specifically the history and current pattern of abuse of the substance; the scope, duration, and significance of abuse; and the risk to public health.[23] In addition, DEA officials stated that DEA may initiate temporary scheduling actions based on its monitoring of the illicit drug market if it sees substances that have become "prevalent, harmful, and/or persistent." DEA uses data on a substance's harm, trafficking, and abuse to determine if it should be elevated for a potential scheduling action. To extend the temporary scheduling order or to permanently schedule the substance, DEA must request and consider HHS's scientific and medical evaluation and scheduling recommendation prior to initiating administrative proceedings.

How have FDA and DEA scientific and medical evaluations of substances changed?

According to FDA officials, over the past few decades, two main changes have occurred related to substance evaluations. Specifically, for a substance being evaluated that neither has nor is being considered for FDA approval, DEA and HHS have developed and applied new, additional tests to determine whether the substance has a currently accepted medical use in treatment in the United States.

First, in 1992, DEA implemented a five-part test to determine currently accepted medical use for substances that have not been approved by the FDA for medical use and published this test in a notice in the Federal Register that year.[24] Specifically, if the drug meets the following five elements, such a drug may be considered to have a currently accepted medical use: (1) the drug's chemistry is known and reproducible; (2) there are adequate safety studies; (3) there are adequate and well-controlled studies proving efficacy; (4) the drug is accepted by qualified experts; and (5) the scientific evidence is widely available.

Second, in 2023, HHS implemented a two-part test to establish whether a substance unrelated to a new drug application has currently accepted medical use in treatment in the United States. Specifically, a July 2023 memorandum from the Assistant Secretary for Health to the FDA Commissioner stated that, in determining whether a drug could have a currently accepted medical use, HHS considers whether (1) "there exists widespread current experience with medical use of the substance by [licensed health care practitioners] operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine;" and (2) "there exists some credible scientific support for at least one of the medical uses for which Part 1 is met."[25]

For example, in August 2023, based on its application of the two-part test, HHS recommended that DEA reschedule marijuana to Schedule III. In April 2024, the Department of Justice Office of Legal Counsel issued an opinion related to questions on the potential rescheduling of marijuana.[26] Based in part on the Office of Legal Counsel's analysis of the Controlled Substances Act and HHS's analysis, the Office of Legal Counsel found that DEA may satisfy the United States' international treaty obligations by placing marijuana in Schedule III while imposing additional restrictions pursuant to the Controlled Substances Act's regulatory authorities. For additional information about recent federal efforts to reschedule marijuana, see Appendix I.

According to FDA officials, this test has not replaced other methods for determining currently accepted medical use; rather the two-part test is an additional framework. They stated that FDA approval of a new drug application remains the most straightforward way to establish that a drug has a currently accepted medical use in treatment in the U.S., and DEA's five-part test is another method to establish currently accepted medical use.

How, if at all, are HHS's recommendations binding on DEA?

According to the Controlled Substances Act and a 2024 Department of Justice Office of Legal Counsel opinion, HHS's recommendations to DEA are binding on DEA until the issuance of the notice of proposed rulemaking, and DEA must give "significant deference" to HHS's recommendations throughout the rulemaking process. According to the Controlled Substances Act, HHS's recommendations to DEA shall be binding on DEA as to such scientific and medical matters, and if HHS recommends that a substance not be controlled, DEA shall not control it.[27] According to the Department of Justice Office of Legal Counsel, its core function is to provide controlling advice to Executive Branch officials on questions of law that are centrally important to the functioning of the federal government. In 2024, the Office of Legal Counsel issued an opinion that stated, among other things:

"Under 21 U.S.C. § 811(b), a recommendation by HHS that a drug has or lacks a 'currently accepted medical use' does not bind DEA. In contrast, the scientific and medical determinations that underlie HHS's 'currently accepted medical use' recommendation are binding on DEA, but only until the initiation of formal rulemaking proceedings to schedule a drug. Once DEA initiates a formal rulemaking, HHS's determinations no longer bind DEA, but DEA must continue to

accord HHS's scientific and medical determinations significant deference, and the [Controlled Substances Act] does not allow DEA to undertake a *de novo* assessment of HHS's findings at any point in the process."[28]

DEA and FDA interpretations of this statutory provision are largely based on the Office of Legal Counsel opinion. Specifically, according to DEA officials, HHS's scientific and medical determinations are binding on DEA only until DEA publishes a notice of proposed rulemaking. However, they stated that once formal rulemaking begins, DEA must continue to give "significant deference" to HHS's determinations. Under the act, after DEA considers HHS's scientific and medical findings and scheduling recommendation and all other relevant data and evaluates this information against the eight factors in the act, DEA may initiate proceedings for control or removal of the substance in accordance with rulemaking procedures. Upon initiating proceedings, DEA publishes a notice of proposed rulemaking to allow for comments from the public with the opportunity for a hearing, after which DEA has the authority to make the final scheduling decision for a substance.[29]

FDA officials also generally agreed with the Office of Legal Counsel—that is, HHS's findings are binding on DEA regarding medical and scientific matters in that DEA cannot control a drug that HHS has found to have no potential for abuse and control is not warranted. Additionally, if HHS finds that a substance has a currently accepted medical use in treatment in the U.S, DEA must take that into account. According to FDA officials, while HHS's specific schedule placement recommendation is not binding, HHS is the leading scientific and medical authority under the Controlled Substances Act, and its findings should preempt scientific and medical findings made by others. However, FDA officials acknowledged that DEA has the discretion to, for example, prioritize its own law enforcement data, or may change its mind based on information received during public comments or hearings (which FDA may support, if, for example, DEA is presented at a hearing with new information that FDA did not consider).

FDA officials stated that DEA usually agreed with HHS's recommendations. They noted that differences of opinion with DEA about a substance's schedule are uncommon, and a memorandum of understanding between the two agencies helps to address areas of potential dispute and guide resolution (discussed further below). FDA officials added that they believed this provision in the Controlled Substances Act regarding HHS's recommendations was primarily meant to prevent substances from being controlled unless there was scientific and medical evidence to support control.

For how many substances did DEA take scheduling actions from 2020 to 2025, and did DEA request and consider HHS scientific and medical evaluations and scheduling recommendations when required?

From 2020 through 2025, DEA took scheduling actions related to 208 substances, and DEA consistently requested and considered HHS scientific and medical evaluations and scheduling recommendations when required. We found that, of the 208 substances, DEA was required to request and consider HHS evaluations and recommendations for 86 substances and did so for all 86. DEA was required to consider HHS evaluations and recommendations for 95 substances (including the 86 substances) and did so for all 95.[30]

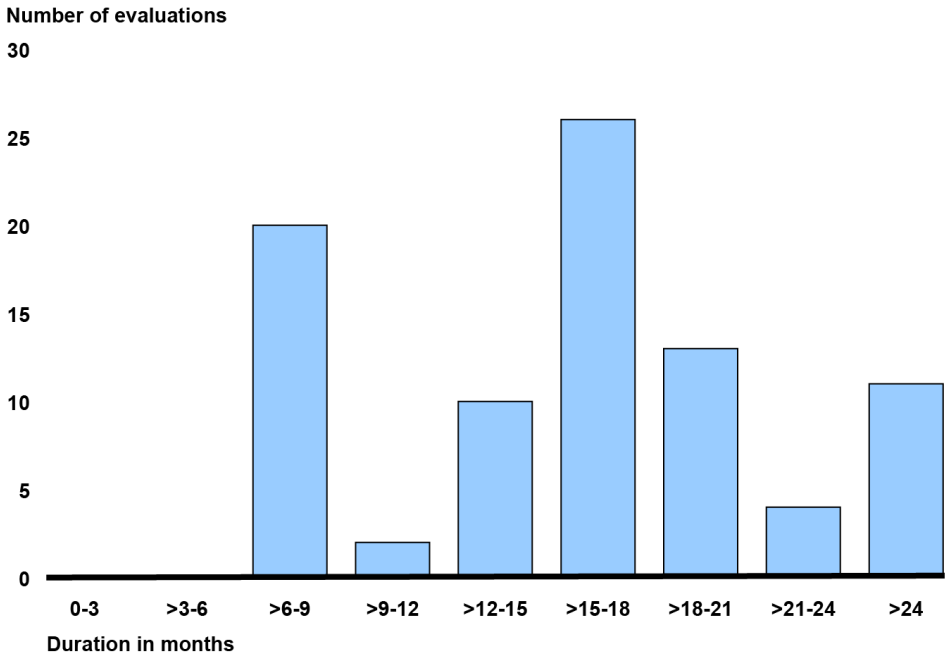
In addition, according to our analysis of DEA data, of the 208 substances, DEA took scheduling actions related to 86 substances scheduled legislatively, 74 substances scheduled administratively (including 4 substances that were descheduled), 9 substances scheduled according to the new drug application process, and 19 substances to comply with international treaty obligations. Additionally, DEA took scheduling actions to schedule 20 substances temporarily or to extend their temporary status.[31]

Of the 95 substances for which DEA was required to consider HHS scientific and medical evaluations and scheduling recommendations, DEA's final scheduling decision aligned with HHS's recommendation for all 84 substances for which DEA had published a final scheduling decision. The remaining 11 were still under extended temporary scheduling orders as of December 31, 2025 (the end of our study scope).[32] So, while DEA had requested and received HHS evaluations and recommendations for those 11 (as was required to extend their temporary scheduling orders), it had not yet made a final scheduling decision on those substances as of December 31, 2025. See Appendix II for more information about DEA's scheduling actions taken from 2020 through 2025.

How long did HHS scientific and medical evaluations and recommendations requested by DEA take for substances for which DEA took scheduling actions from 2020 through 2025, and what factors affected those time frames?

DEA requested and considered HHS scientific and medical evaluations and scheduling recommendations for 86 substances from 2020 through 2025 (as described above). For these 86 substances, according to our analysis of DEA and FDA data, HHS evaluations and recommendations took an average of 1.5 years and a median of about 1.3 years to complete. For 75 of the 86 substances (87 percent), HHS evaluations and recommendations were completed within 2 years. Eleven HHS evaluations and recommendations took more than 2 years to complete; of those, one took almost 8. See Figure 2 below.

Figure 2: HHS Evaluations and Recommendations Prepared at DEA's Request for Substances Scheduled 2020-2025, Grouped by Duration



Source: GAO analysis of DEA and FDA data. | GAO-26-108623

The Controlled Substances Act requires that HHS provide requested scientific and medical evaluations and scheduling recommendations to DEA "within a reasonable time."[33] DEA officials told us that they did not have a definition of reasonable time and explained that they understood that a range of factors could affect the time FDA needed to complete evaluations. They could not recall any examples where they believe HHS had failed to deliver evaluations and recommendations within what they felt to be a reasonable time. FDA officials explained that they also did not have specific, written definitions of reasonable time, and that what seems to be a "reasonable time" can depend on factors such as the type of scheduling being pursued.

For example, FDA officials told us that a reasonable time to complete an evaluation and recommendation for a temporarily scheduled substance might be 12 to 14 months, as they estimated this to be about the window of time between when DEA requests the evaluation and recommendation and when DEA must begin preparing regulatory filings to extend the temporary scheduling for another year. In contrast, according to FDA officials, substances whose scheduling is based on a petition filed by a member of the public may require years to evaluate, as the petitioner may not have included comprehensive data or information to support their request.

FDA officials also described other factors, such as distinguishing between similar substances with and without currently accepted medical uses, that influence the time required to prepare scientific and medical evaluations and scheduling recommendations. For example, more complex consideration of data is required for substances without currently accepted medical use than a substance that has FDA approval. Such cases require additional discussion between FDA and DEA to assess whether the substance meets the statutory criteria for accepted medical use, which can add delays. For instance, according to FDA officials, when DEA temporarily placed five benzodiazepines in Schedule I in 2023, DEA and FDA officials had to work within the criteria for each of the possible schedules to recommend an appropriate schedule for the benzodiazepines without an accepted medical use (sometimes called “designer” benzodiazepines) because they had similar pharmacology to the medical benzodiazepines in Schedule IV.[34]

How long did DEA final scheduling decisions take after receiving HHS evaluations and recommendations for substances for which DEA took scheduling actions from 2020 through 2025, and what factors affected those timeframes?

Of the 95 substances for which DEA considered HHS scientific and medical evaluations and scheduling recommendations from 2020 through 2025 (as described above), DEA considered HHS evaluations and recommendations and published its final scheduling decision for 84 substances. (This number excludes the 11 substances still under extended temporary scheduling orders.)

For these 84 substances, according to our analysis of DEA data, it took DEA on average 1.4 years and a median 11 months to finalize the rulemaking process and publish final scheduling decisions after receiving HHS’s evaluations and recommendations. DEA officials told us that the time required to complete a scheduling action can vary depending on the type of scheduling action, as DEA prioritizes actions based on factors such as statutory deadlines or risk to public harm. For example, for approved new drugs for which FDA determines scheduling is warranted, DEA is required to publish interim final rules for those substances within 90 days of receiving HHS’s evaluation and recommendation, or FDA drug approval notification – whichever comes later.[35] Therefore, according to DEA officials, they prioritize scheduling these substances to ensure they meet the statutory deadline.[36]

How long was the total scheduling process for substances for which DEA requested an HHS evaluation and recommendation and took scheduling actions from 2020 through 2025?

Of the 86 substances for which DEA requested and considered HHS scientific and medical evaluations and scheduling recommendations from 2020 through 2025 (as described above), DEA requested HHS evaluations and recommendations and published its final scheduling decision for 75 substances as of December 31, 2025. (This number excludes the 9 substances scheduled according to the new drug application process, which does not require that DEA request an HHS evaluation or recommendation, and which has a statutory deadline; and the 11 substances still under extended temporary scheduling orders.[37])

For these 75 substances, according to our analysis of DEA data, an average of 3 years and a median of 2.3 years passed between the date DEA sent its request to HHS and the date DEA published its final scheduling decision. Scheduling durations varied; one substance was scheduled in about 1.6 years, while another substance took over 14 years to schedule. As discussed above, both FDA and DEA officials explained various factors that may affect the time required to schedule substances.

To what extent do DEA and HHS have policies and procedures related to evaluating and scheduling substances?

DEA and HHS have some policies that address aspects of the scheduling process, including a memorandum of understanding (MOU) between FDA and DEA for sharing information with each other; however, these policies have gaps that may pose a risk to the consistency of DEA's and FDA's future operations in the event of staff turnover or any other disruption that could lead to a loss of institutional knowledge.

According to federal internal control standards, management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objectives.[38] Management also establishes control activities by documenting in policies what is expected and in procedures specified actions that implement policies, to mitigate risks to achieving the entity's objectives to acceptable levels.[39] Documentation also provides a means to retain organizational knowledge and mitigate the risk of having that knowledge limited to a few personnel. In addition, management reviews policies, procedures, and related control activities on a periodic and ongoing basis for continued relevance and effectiveness in achieving the entity's objectives or mitigating related risks.[40]

DEA Policy Gaps: Aside from the MOU, DEA does not have any policies related to how its staff are to conduct evaluations or schedule substances through administrative scheduling, new drug application scheduling, temporary scheduling, or international treaty scheduling processes. DEA officials told us that they have no other guidance related to scheduling substances, besides the MOU and applicable laws and regulations. According to DEA and FDA officials, the MOU between FDA and DEA governs information-sharing between the two agencies throughout the scheduling process. Specifically, the MOU provides procedures for the agencies to exchange information through quarterly or biannual interagency meetings and other verbal and written communications, including information related to scientific and medical evaluations and scheduling recommendations. The MOU also requires the agencies to protect sensitive exchanged information from unauthorized disclosure.[41]

However, based on our review of the MOU, it does not include policies and procedures specifically outlining DEA's responsibilities and procedures related to drug scheduling under the Controlled Substances Act or Federal Food, Drug, and Cosmetic Act. For example, DEA does not have policies or procedures in the MOU or any other document that identify roles, responsibilities, and procedures within the Diversion Control Division (or any other relevant DEA units) for:

- collecting and analyzing data prior to initiating administrative rulemaking;
- carrying out responsibilities related to new drug application scheduling;
- conducting a three-factor analysis and making findings to issue a temporary scheduling order;
- conducting an eight-factor analysis and making findings to determine schedule placement; or

- considering HHS scientific and medical evaluations and scheduling recommendations and making final scheduling decisions.

According to DEA officials, the Controlled Substances Act establishes clear and strict legal procedures DEA must follow. DEA officials deemed developing policies unnecessary, saying the requirements are clearly outlined in the Controlled Substances Act and related regulations. However, based on our review of the act, it does not provide this level of specificity (e.g., roles, responsibilities, and procedures) regarding how DEA is to carry out these responsibilities.

They also stated that DEA scientific staff hired to conduct the research outlined in the act and related regulations are scientists who are considered subject matter experts in their field and have decades of research experience—not only through their academic backgrounds (all have advanced degrees), but also through their professional backgrounds and specialized training. According to the statute and regulations, decisions must be based on scientifically verified and legally defensible data. According to DEA officials, the DEA scientific staff responsible for making scheduling recommendations are vetted throughout the hiring process to ensure that they can understand scientific data that satisfy that requirement.

However, by developing policies and procedures that identify DEA's roles, responsibilities, and procedures for evaluating and scheduling substances through administrative scheduling, new drug application scheduling, temporary scheduling, and international treaty scheduling under relevant statutes (including collecting and evaluating data, conducting three-factor and eight-factor analyses, and determining scheduling decisions), DEA would be able to better ensure its staff can clearly and consistently carry out their various responsibilities in the drug scheduling process. In addition, developing such policies and procedures could help ensure consistency of DEA's future operations in the event of staff turnover or any other disruption that could lead to a loss of institutional knowledge.

FDA Policy Gaps: FDA has some policies and procedures related to drug evaluations and scheduling, but they have gaps. Specifically, FDA has issued:

- a policy document that establishes responsibilities and procedures in the FDA Center for Drug Evaluation and Research for consulting the Controlled Substance Staff regarding the evaluation of drug abuse potential and labeling, drug scheduling, dependence risk, and drug abuse risks to the public health for certain substances submitted under new drug applications and other submissions for FDA approval;[42]
- guidance to assist new drug applicants and sponsors of investigational new drugs in evaluating whether their new drug product has abuse potential;[43] and
- standard operating procedures related to the approval process for new drug applications; the processing and clearance of eight-factor analyses for new drug approvals and unapproved drugs; determining currently accepted medical use for drug scheduling requests from DEA; and for responding to a DEA notice of intent to temporarily schedule a substance.

FDA officials told us that they believed these policies were necessary to preserve institutional knowledge due to the number of staff and volume of staff turnover involved with these processes. However, FDA does not have policies or procedures that:

- outline how its staff are to conduct an eight-factor analysis or make scheduling recommendations; or
- clearly define the criteria and process for determining a substance's "potential for abuse," including its abuse potential relative to other substances. A substance's "actual or relative potential for abuse" is the first factor in the eight-factor analysis and related to the first finding required to determine schedule placement under the Controlled Substances Act. However, the Controlled Substances Act does not include a statutory definition of "potential for abuse." 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. As a result, FDA officials stated they use their professional judgment to apply aspects of the eight factors to determine a substance's potential for abuse. FDA officials cited this lack of legal and policy definition as a challenge in determining the abuse potential of xylazine, an animal sedative that is often mixed with illicit drugs (discussed further below).

Instead of having policies and procedures for how staff are to conduct eight-factor analyses and develop recommendations, according to FDA officials, FDA's Controlled Substance Staff rely on person-to-person training of staff members who contribute to eight-factor analyses. According to the officials, because each analysis and scheduling recommendation is an individualized determination based on substance-specific information that requires case-by-case analysis, a single policy for conducting an eight-factor analysis may not provide adequate flexibility. In addition, FDA officials told us that they did not believe such policies were necessary, as the number of scientific and medical staff involved in these activities is well-suited to ensuring continuity of institutional knowledge.

By developing policies and procedures that FDA staff can use to complete eight-factor evaluations and develop scheduling recommendations—including the criteria and process for determining a substance's "potential for abuse," as well as relative potential for abuse—FDA would be able to better ensure that Center for Drug Evaluation and Research staff can clearly and consistently carry out their various responsibilities in the drug evaluation and scheduling process. In doing this, FDA would not necessarily need to develop a single policy for conducting an eight-factor analysis but could develop policies and procedures that provide the appropriate level of clarity and standardization of its terms and procedures, with guidance regarding case-by-case analysis that would allow adequate flexibility. FDA officials stated that they understood these documents could be useful in the event of future challenges, such as staff turnover, and that FDA was open to preparing policies on these topics.

Outdated MOU Between FDA and NIDA: FDA has a separate MOU with NIDA that describes procedures for FDA to consult NIDA when developing scheduling recommendations, but the MOU is over 40 years old and no longer accurately reflects those agencies' organizational structures or procedures. Specifically, the FDA-NIDA MOU includes outdated FDA offices and entities that no longer exist, outdated procedures, and no term clause to ensure that the MOU is regularly reviewed. For example, the FDA Center for Drugs and Biologics and Division of Neuropharmacological Drug Products in the MOU no longer exist. FDA and NIDA officials agreed that the MOU is out-of-date and warrants revising to reflect their more streamlined process.

By updating the MOU between FDA and NIDA to reflect current agency entities and procedures for coordination, including adding a term clause to ensure the MOU is regularly reviewed, staff within both FDA and NIDA would have clarity on

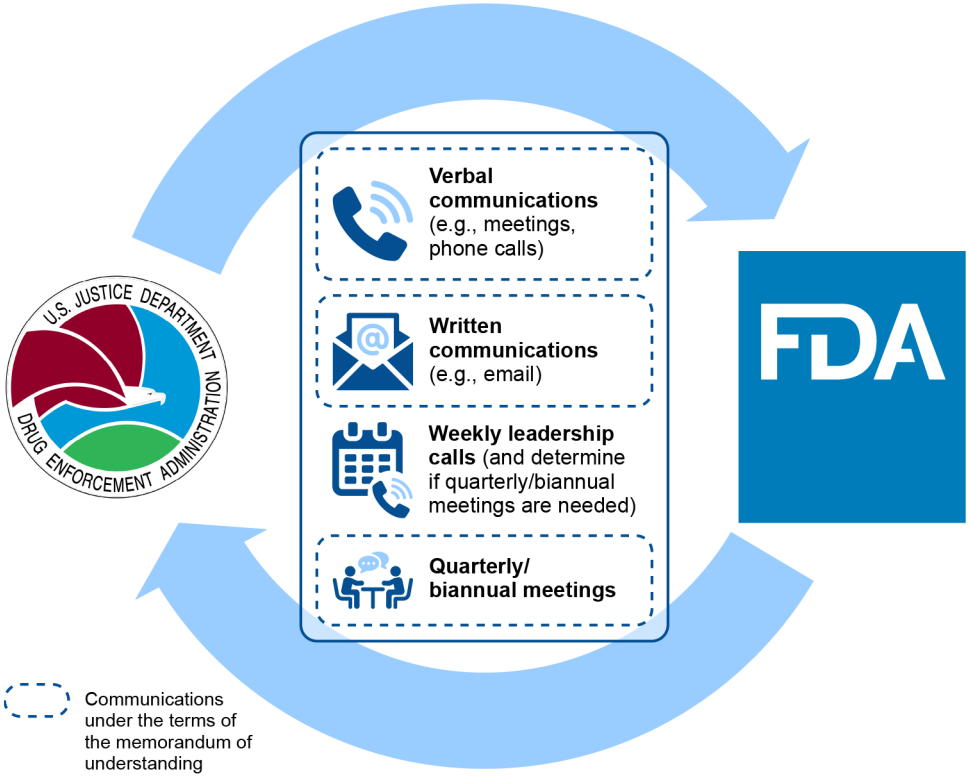
the correct entities and procedures to follow to ensure that NIDA's expertise about drug abuse informs these scheduling recommendations.

How do DEA and FDA coordinate regarding scientific and medical evaluations and scheduling recommendations, including navigating any differences of opinion?

DEA and FDA coordinate while preparing scientific and medical evaluations and scheduling recommendations in accordance with the MOU. Specifically, the MOU establishes quarterly or biannual meetings and verbal and written communication methods through which DEA and FDA can share information or concerns. DEA officials told us that senior DEA and FDA officials have weekly calls and determine if they need to hold the formal quarterly or biannual meetings. In addition, DEA and FDA officials stated that DEA and FDA staff may have informal telephone or other discussions to clarify scientific points. FDA officials stated these discussions could involve sharing new information or concerns, rather than characterizing the discussions as "disagreements." DEA officials emphasized that DEA and FDA maintain constant informal contact throughout the process of preparing their evaluations. FDA officials emphasized that any differences of opinion that arise are generally resolved through conversation under the terms of the MOU. Officials from both agencies stated that they usually resolve any differences of opinion or analyses prior to DEA issuing a notice of proposed rulemaking to schedule a substance.

Figure 3 shows the different methods DEA and FDA use to coordinate when preparing scientific and medical evaluations of substances and determining scheduling recommendations.

Figure 3: DEA and FDA Methods for Coordinating Regarding Evaluations and Recommendations for Substances



Source: DEA and FDA documentation and interviews, and agency seals; Icons-Studio/stock.adobe.com. | GAO-26-108623

According to DEA and FDA officials, differences of opinion about appropriate schedule placement not resolved through the coordination described above are rare, but they have taken place. For example, both DEA and FDA officials recalled a difference of scheduling opinion over the scheduling of hydrocodone

combination products. In 1999, DEA received a petition from a member of the public proposing that DEA reschedule hydrocodone combination products from Schedule III to Schedule II. In 2004, following a 5-year data collection period, DEA requested a scientific and medical evaluation and scheduling recommendation from HHS. In 2008, HHS provided DEA with its evaluation, which included a recommendation that hydrocodone combination products remain in Schedule III. In response, in 2009, DEA provided additional data and analysis to HHS and requested that HHS re-evaluate the data on hydrocodone combination products and provide another evaluation and recommendation based on the additional data and analysis. Additionally, the Food and Drug Administration Safety and Innovation Act required that, if practicable, HHS hold a public meeting to solicit stakeholder input to help inform its evaluation and recommendation for hydrocodone combination products.[44] Following this additional review and the hearing (held in January 2013), based on its re-evaluation of the data and additional information collected at the hearing, HHS recommended to DEA that the hydrocodone products be moved to Schedule II in December 2013. DEA published a final rule rescheduling the products to Schedule II in August 2014.[45]

How can legislative scheduling address certain challenges?

Since the enactment of the Controlled Substances Act in 1970, Congress has passed laws to legislatively schedule additional substances. For example, legislative scheduling has addressed situations in which administrative scheduling is challenging, such as (1) scheduling an entire class of substances at the same time, and (2) scheduling substances intended for animal use that have also been used by humans.[46] As we and the Congressional Research Service have reported, legislative scheduling can address certain challenges with administrative scheduling.[47] However, as we have also reported, some stakeholder groups have expressed concerns that substances may be legislatively scheduled without a scientific and medical evaluation of the substance and regardless of whether the substance meets the statutory criteria in the Controlled Substances Act.[48]

Substances may be scheduled legislatively to address challenges posed by administratively scheduling them, such as class-wide scheduling. In 2021, we identified possible considerations and options for the class-wide scheduling of fentanyl-related substances.[49] Under the Controlled Substances Act, administrative scheduling requires an individualized scientific and medical evaluation for each substance. We reported that HHS officials told us that they were not sure a class-wide evaluation of fentanyl-related substances could be completed due to the large number of potential substances in the class, including those yet to be identified. During our current review, FDA officials told us that when DEA temporarily scheduled fentanyl-related substances as a class in February 2018, this class-wide definition could encompass millions of individual fentanyl-related substances.[50] FDA officials stated that this would have been too many substances to evaluate individually within required timeframes to administratively schedule them and that FDA worked with Congress on this issue. According to DEA officials, DEA communicated to Congress that legislative action would be required because its temporary class-wide scheduling of fentanyl-related substances would expire and worked with HHS on proposed legislation. In July 2025, the Halt All Lethal Trafficking (HALT) of Fentanyl Act was enacted, which legislatively scheduled all fentanyl-related substances as a class under Schedule I, unless specifically exempted or listed in another schedule (see sidebar).[51]

Fentanyl-related substances

In February 2018, DEA issued a temporary scheduling order to control fentanyl-related substances, defined as those substances not otherwise controlled that are structurally related to fentanyl by one or more of five chemical structural modifications. DEA began requesting evaluations for these substances from HHS in April 2019, which HHS began providing to DEA in July 2020. The original temporary scheduling order was due to expire in February 2020, and federal law extended it several times until September 30, 2025. The HALT Fentanyl Act ultimately legislatively scheduled these substances as Schedule I in July 2025. Since then, FDA officials told us they had not received new requests to evaluate additional fentanyl-related substances, including whether any of them may have a medical use. FDA officials stated that they may still receive requests from DEA to evaluate certain substances, such as for authorizing research into a specific substance. As of May 2026, they stated that FDA had evaluated 46 fentanyl-related substances at DEA's request and had recommended

Source: GAO. | GAO-26-108623

Legislative scheduling of substances allows for tailored provisions for regulatory controls and criminal penalties, which DEA may not be able to do under the administrative scheduling process. For example, according to DEA officials, DEA requested in 2021 an HHS scientific and medical evaluation and scheduling recommendation for xylazine—an animal tranquilizer found in illicit street drugs—because DEA had noticed that law enforcement data began showing increased abuse of xylazine and its growing impact on public health and safety since 2019.[52] According to DEA and FDA officials, FDA provided its evaluation and recommendation to DEA in 2024 and recommended placing xylazine in Schedule V. As of May 2026, DEA had not completed its own evaluation, according to DEA officials.

However, according to DEA officials, DEA identified multiple challenges related to scheduling xylazine administratively. For example, DEA officials identified challenges related to ensuring continued access to xylazine for legitimate users, such as for agriculture and veterinary medicine, and to including those users in DEA's controlled substance reporting system. For instance, they stated that the Controlled Substances Act does not permit individuals who do not own a given animal, are not a member of the owner's household, or are not registered with DEA to handle controlled substances to possess a controlled substance. Officials stated that this often excludes individuals such as ranch hands or slaughterhouse attendants who might have legitimate reasons to handle xylazine, and that legislative scheduling could allow for tailored provisions to address these issues. DEA officials also said that DEA believes Schedule III to be a more appropriate placement for xylazine, based on relevant law enforcement data and abuse potential. Given these concerns, DEA ultimately requested that Congress schedule xylazine legislatively, as DEA officials believed these challenges could be more effectively addressed through legislation.

According to FDA officials, while FDA previously recommended placement of xylazine in Schedule V, it now also supports a legislative solution, including its placement in Schedule III. FDA officials told us the eight-factor analysis in the Controlled Substances Act requires that drugs be studied with respect to their own individual properties and drug effects, including their potential for abuse. However, they stated that some substances may show up in the illicit drug supply that on their own may not have a significant potential for abuse but are an additive or adulterant in other illicit drugs being abused. They stated that this creates a problem for scheduling such substances. FDA officials stated that some sedatives, like xylazine, that are designed to make large animals sleep are not typically sought by individuals for abuse purposes (e.g., do not produce feelings of euphoria).

According to FDA officials, their abuse potential is low, based on FDA's interpretations of the Controlled Substances Act's concept of abuse potential. However, according to FDA officials, Congress is not bound by any specific framework regarding scientific or medical findings before controlling substances and can do so freely based on its own concerns. According to FDA officials, HHS has not objected to helping when Congress has asked FDA for technical assistance related to scheduling xylazine. FDA accepts the Schedule III placement that Congress is pursuing, given the harms to public health due to the presence of the substance in illicit drugs that people are using.

Conclusions

DEA, in coordination with HHS and its component agencies, FDA and NIH, is responsible for scheduling substances in accordance with relevant laws and regulations. DEA's scheduling decisions affect the extent to which criminal penalties under the Controlled Substances Act may be levied regarding the

illegal manufacturing, distribution, and possession of substances. For scheduling actions taken from 2020 through 2025, we found that DEA requested and considered HHS scientific and medical evaluations and scheduling recommendations for all substances for which they were required. FDA has established some policies describing how FDA officials are to follow these requirements, and DEA and FDA have established an MOU related to sharing information. These actions and officials we interviewed at both agencies indicated that DEA routinely seeks and considers HHS's scientific and medical expertise about substances to inform scheduling decisions.

However, DEA does not have policies that assign roles and responsibilities related to scheduling substances, and neither DEA nor FDA have policies that describe the specific procedures staff should follow for fulfilling their responsibilities related to preparing scheduling evaluations and recommendations. Formally describing their policies and procedures for evaluating and scheduling substances and assigning roles and responsibilities would help ensure consistency of operations in the event of staff turnover or other disruptions that could lead to a loss of institutional knowledge.

Additionally, FDA's MOU with NIDA is over 40 years old and no longer accurately reflects those agencies' organizational structures. Updating the FDA-NIDA MOU would help ensure that staff know the correct entities and proper procedures for coordinating to develop scheduling recommendations, as well as help ensure that NIDA's expertise about drug abuse is incorporated into the scheduling recommendations that FDA provides to HHS.

Recommendations for Executive Action

We are making a total of three recommendations, including one to DEA and two to HHS component agencies:

The Administrator of DEA should develop policies and procedures that identify DEA's roles, responsibilities, and procedures for evaluating and scheduling substances through administrative scheduling, new drug application scheduling, temporary scheduling, and international treaty scheduling under relevant statutes (including collecting and evaluating data, conducting three-factor and eight-factor analyses, and determining scheduling decisions). (Recommendation 1)

The Commissioner of FDA should develop policies and procedures that Center for Drug Evaluation and Research staff are to use to when completing eight-factor evaluations and developing scheduling recommendations, including the criteria and process for determining a substance's "potential for abuse," including abuse potential relative to other substances. (Recommendation 2)

The Commissioner of FDA and the Director of NIH should update their memorandum of understanding (MOU) concerning developing drug scheduling recommendations. The updated MOU should reflect the current entities involved and procedures and include a term clause to ensure the MOU is regularly reviewed. (Recommendation 3)

Agency Comments

We provided a draft of this report to the Department of Justice and the Department of Health and Human Services for review and comment. Both the Departments of Justice and Health and Human Services agreed with our recommendations. In its written comments, which are reprinted in appendix III, HHS stated that FDA will develop a new policy describing how to conduct eight-factor evaluations that support drug scheduling recommendations to DEA issued by HHS, and FDA and NIH have begun to update their MOU. Additionally, the

Departments of Justice and Health and Human Services provided technical comments, which we incorporated as appropriate.

How GAO Did This Study

To identify the circumstances under which DEA is required to request and consider HHS scientific and medical evaluations and scheduling recommendations prepared by FDA, we analyzed statutory and regulatory requirements related to (1) adding a substance to a schedule, transferring a substance between schedules, or removing a substance from the schedules through administrative rulemaking or other administrative action; (2) scheduling substances according to the new drug application process; (3) temporarily scheduling substances; and (4) scheduling substances to comply with certain international treaties. For the purposes of this report, we use the terms such as, "schedule," for the term, "add;" "reschedule" for the term, "transfer;" and "deschedule" for the term, "remove." We use the term "administrative scheduling" to refer to administrative scheduling through formal rulemaking pursuant to 21 U.S.C. § 811(a).

For the purposes of this report, we define "other administrative actions" as DEA administrative actions to schedule immediate precursors and positional isomers related to controlled substances.[53] Under the Controlled Substances Act, DEA may administratively schedule some substances, such as immediate precursors and positional isomers related to controlled substances, without regard for certain rulemaking procedures.[54]

To assess the extent to which DEA has requested and considered HHS scientific and medical evaluations and scheduling recommendations, we analyzed DEA and FDA data and documents regarding substances for which DEA took scheduling actions from 2020 through 2025. We selected this timeframe to assess DEA scheduling actions during the most recent 6 calendar years. These documents included DEA's List of Scheduling Actions (also known as the Orange Book) and rulemaking dockets for each of the approximately 208 individual substances for which DEA took scheduling actions from 2020 through 2025. We identified the 208 substances by analyzing data DEA provided to us regarding its scheduling actions taken from 2020 to 2025 and comparing these against the List of Scheduling Actions, as well as similar data from FDA, for the same time period to ensure that we had an accurate count of individual substances for which DEA took scheduling actions. DEA's data also sorted these substances by the type of scheduling action taken, including substances scheduled:

- through administrative rulemaking,
- following new drug application approvals,
- as precursors or positional isomers of other substances already scheduled,
- to comply with international treaties, and
- through temporary scheduling orders, including those whose temporary scheduling orders had been extended.

DEA's data on scheduling actions also included an action taken for 86 substances that had been legislatively scheduled in 2014, but DEA took action to reorganize its schedules in regulation regarding those substances in 2023, during our scoped period.[55]

Of these 208 substances, we identified the 95 substances that required HHS evaluations and recommendations by excluding those that did not.[56] We identified and analyzed key data points related to requirements for requesting

HHS evaluations (including the date DEA requested the evaluation and the date HHS provided it) and for considering HHS's scheduling recommendations (including HHS's recommended placement and DEA's final decision). To validate and supplement DEA and FDA data, we used a large language model to extract the same key data points from the rulemaking dockets. We compared the results to the DEA and FDA data and manually verified the results where the model extracted information that was different from what DEA and FDA provided to us.

In addition, we measured the durations between steps in the processes (including time between the dates DEA requested and HHS provided the evaluation, and time between the dates DEA received the evaluation and DEA issued the final scheduling decision) to assess how HHS provided evaluations within a reasonable time and to identify any abnormalities in the processes. We also assessed whether DEA scheduled approved new drugs within the required 90-day timeframe.

To assess the extent to which DEA and HHS have policies and procedures related to evaluating and scheduling substances, we examined available agency policies and procedures from 2020 through 2025. We selected this timeframe to examine how, if at all, DEA and FDA policies and actions may have changed during the most recent 6 calendar years. We analyzed the extent to which these policies and procedures were sufficient in assigning roles and responsibilities and describing procedures for evaluating and scheduling substances such that the agencies could ensure consistency and continuity in the scheduling of substances. We assessed these policies against Standards for Internal Control in the Federal Government related to documentation and control activities. In addition, we conducted interviews with DEA and HHS officials, including officials from FDA and NIH, to clarify roles and responsibilities, requirements, policies and how they have changed over time, and scheduling actions as needed.

We conducted this performance audit from July 2025 to September 2026 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

List of Addressees

The Honorable Richard J. Durbin
Ranking Member
Committee on the Judiciary
United States Senate

The Honorable Cory Booker
United States Senate

We are sending copies of this report to the appropriate congressional committees, the Attorney General, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

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Appendix I: Recent Federal Efforts to Reschedule Marijuana

Marijuana has been a Schedule I controlled substance since the enactment of the Controlled Substances Act in 1970.[57] This is the classification reserved for drugs that have been found by the Federal Government to have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.[58] However, an increasing number of states have legalized using marijuana under state law for medical purposes. In October 2022, the President requested the Secretary of Health and Human Services (HHS) and the Attorney General to initiate an administrative process to review the scheduling of marijuana under federal law. In 2023, based on the Food and Drug Administration's (FDA) application of the two-part test (discussed earlier in this report), HHS recommended that the Drug Enforcement Administration (DEA) reschedule marijuana to Schedule III. HHS concluded that, regardless of whether a substance was approved by the FDA or satisfied DEA's five-part test, the substance could have a currently accepted medical use in treatment in the United States if it satisfied the new, two-part inquiry.

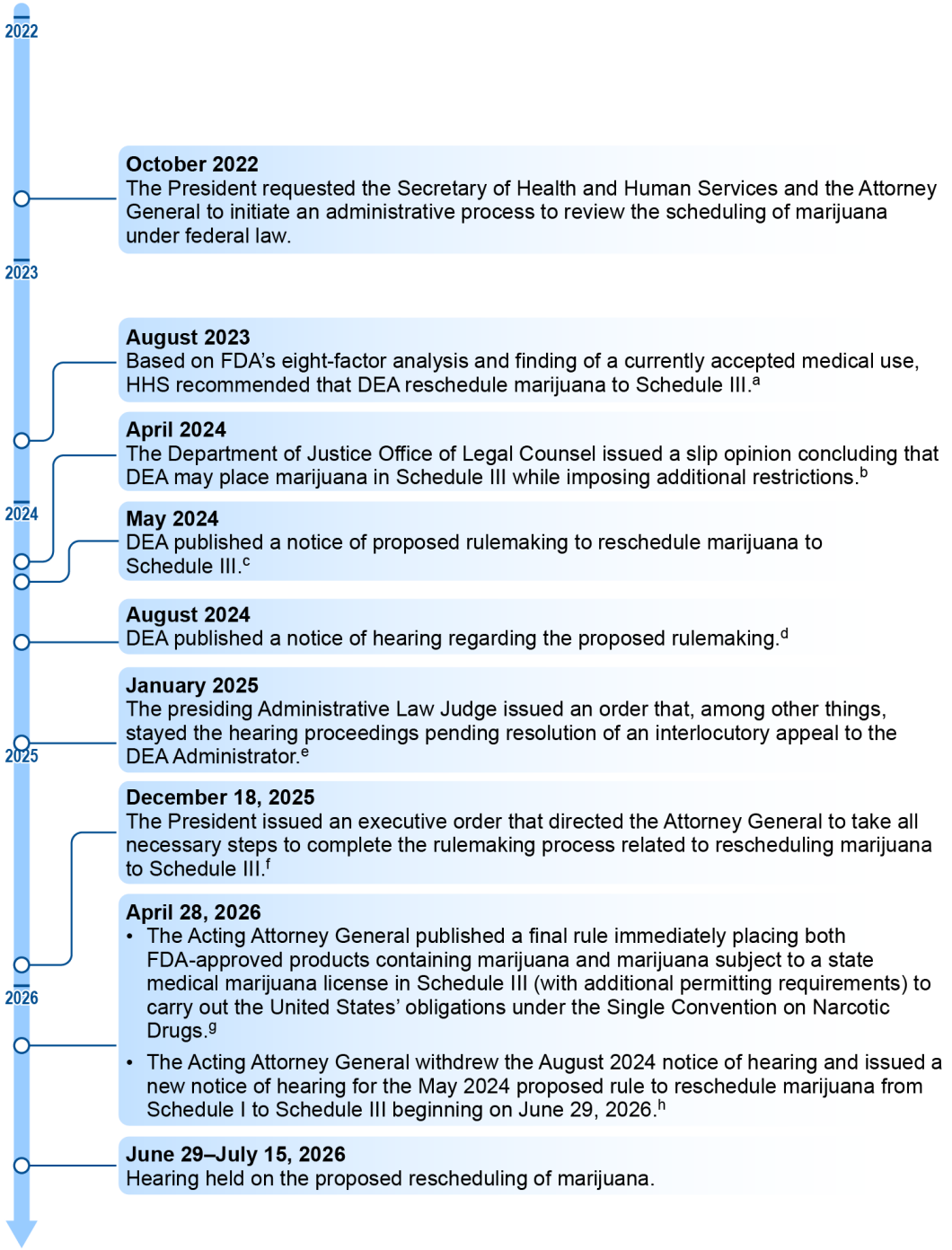
In April 2024, the Department of Justice Office of Legal Counsel issued an opinion related to questions on the potential rescheduling of marijuana.[59] One issue addressed by the Office of Legal Counsel was whether a substance that satisfies HHS's two-part inquiry was sufficient to establish a currently accepted medical use under the statute,[60] even if the substance has not been approved by the FDA and does not satisfy DEA's five-part test. According to the Office of Legal Counsel, DEA's approach to determining whether a substance had a currently accepted medical use was an impermissibly narrow interpretation of the Controlled Substances Act and that satisfying HHS's two-part inquiry was sufficient to establish a substance had a currently accepted medical use.[61] This was still the case, even if the substance had not been approved by the FDA and did not satisfy DEA's test.

In addition, the Office of Legal Counsel stated that DEA may satisfy its obligations related to the Single Convention on Narcotic Drugs by placing marijuana in Schedule III while imposing additional restrictions according to the Controlled Substances Act.[62]

In April 2026, the Acting Attorney General issued a final rule,[63] which constituted a final order, placing drug products containing marijuana that have been approved by the FDA and marijuana subject to a state medical marijuana license

into Schedule III of the Controlled Substances Act under the authority to reschedule drugs to carry out international treaty obligations.[64] The Acting Attorney General also scheduled a public hearing regarding the potential rescheduling of all marijuana,[65] and DEA held the hearing in June-July 2026, as shown in Figure 4.

Figure 4: Timeline of Recent Federal Efforts to Reschedule Marijuana



Source: GAO presentation of regulations and DEA documentation. | GAO-26-108623

[a]Food and Drug Administration, Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act (Washington, D.C.: Aug. 29, 2023).

[b]Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana (Apr. 11, 2024).

[c]Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (proposed May 21, 2024).

[d]Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 70,148 (proposed Aug. 29, 2024).

[e]In the matter of Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, No. 24-44 (DEA A.L.J., Jan. 13, 2025) (Administrative Law Judge Mulrooney).

[f]"Increasing Medical Marijuana and Cannabidiol Research," Exec. Order No. 14,570, 90 Fed. Reg. 60,541 (Dec. 18, 2025).

[g]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, 91 Fed. Reg. 22,714 (Apr. 28, 2026) (to be codified at 21 C.F.R. pts. 1300, 1301, 1308, and 1312).

[h]Schedules of Controlled Substances: Rescheduling of Marijuana; Withdrawal, 91 Fed. Reg. 22,778 (Apr. 28, 2026). Schedules of Controlled Substances: Rescheduling of Marijuana, 91 Fed. Reg. 22,777 (Apr. 28, 2026).

Appendix II: Table of Substances for which DEA Took Scheduling Actions, 2020-2025

We reviewed all scheduling actions taken by DEA from 2020 through 2025, categorized them by scheduling type, and identified the requirements for DEA to request and consider HHS scientific and medical evaluations and scheduling recommendations for each type. We assessed whether and how DEA met those requirements for all substances for which it took scheduling actions from 2020 through 2025. See table 2.

Table 2: Number of Substances for which DEA Took Scheduling Actions by Scheduling Type and DEA Scheduling Actions Related to HHS Evaluations and Recommendations, 2020-2025

Scheduling type		Number of substances for which DEA took scheduling actions	Number of substances for which DEA was required to consider an HHS evaluation and scheduling recommendation	Did DEA request and consider an HHS evaluation and recommendation as required?	Did DEA's scheduling decision align with HHS's recommendation?
Legislative scheduling	Actions related to legislative scheduling[a]	86	0	Not applicable	Not applicable
Administrative scheduling through rulemaking or other administrative actions	Regular process (scheduled)[b]	62	62	Yes	Yes
	Regular process (descheduled)	4	4	Yes	Yes
	Immediate precursors and positional isomers[c]	8	0	Not applicable	Not applicable
New drug application scheduling	Actions related to new drug application approvals	9	9[d]	Yes	Yes
International treaty scheduling[e]	Single Convention on Narcotic Drugs, 1961	10	0	Not applicable[f]	Not applicable
	Convention on Psychotropic Substances (1971)	9	9	Yes	Yes
Temporary scheduling	Temporary placement[g]	9	0	Not applicable	Not applicable
	Extended temporary placement[h]	11	11	Yes	Not applicable[i]
Totals		**208**	**95**	-	-

Source: GAO analysis of DEA data. | GAO-26-108623

[a]In December 2014, the Designer Anabolic Steroid Control Act (DASCA) of 2014, Pub. L. No. 113-260, 128 Stat. 2929, amended the Controlled Substances Act to revise and add specified substances to the definition of "anabolic steroid" under 21 U.S.C. § 802(41). In August 2023, DEA published a final rule, Implementation of the Designer Anabolic Steroid Control Act of 2014, 88 Fed. Reg. 50,036 (Aug. 1, 2023) (codified at 21 C.F.R. pt. 1300, 1302, and 1308), to amend and reorganize its regulations to make them consistent with DASCA regarding the updated definition of anabolic steroid and specific substances, among other things. According to the final rule, DASCA amended the Controlled Substances Act definition of "anabolic steroid" by adding 22 new substances to the prior statutory list of anabolic steroids. While DASCA listed 25 substances, two of the listed substances were duplicates of substances previously listed in the regulatory definition of anabolic steroid, and one substance was included twice in DASCA. The final rule indicated that in addition to incorporating the language of the statutory amendments of DASCA into DEA's regulations, the rule relocated and made a number of organizational and typographical changes to the regulatory list of anabolic steroids to improve the list's clarity. These changes did not add or remove any substances from the list beyond the 22 new substances added by DASCA. This resulted in the revision of 21 C.F.R. § 1308.13(f) and the listing of 86 substances as anabolic steroids in schedule III.

[b]All of the substances in this data set that were administratively scheduled for the first time through the regular process were previously temporarily scheduled. Temporary scheduling is not required to administratively schedule a substance, including substances being scheduled for the first time. Unless specifically addressed by another subsection of 21 U.S.C. § 811, all substance scheduling actions follow the procedures in 21 U.S.C. § 811(a) and (b), including actions to administratively schedule a substance for the first time (whether previously temporarily scheduled or not), move substances between schedules (rescheduling), or remove a substance from scheduling (descheduling). According to DEA's List of Scheduling Actions published online, no substances were rescheduled from January 2020 through December 2025.

[c]Under 21 U.S.C. § 802(23), "immediate precursors" means "a substance which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance; which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and the control of which is necessary to prevent, curtail, or limit

the manufacture of such controlled substance." Under 21 C.F.R. § 1300.01(b), "positional isomer" means "any substance possessing the same molecular formula and core structure and having the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen." Under 21 U.S.C. § 811(e), the Attorney General may, without regard to the findings required by 21 U.S.C. § 811(a) or 21 U.S.C. § 812(b) and without regard to the procedures prescribed by 21 U.S.C. § 811(a), which generally requires notice and comment rulemaking procedures, and 21 U.S.C. § 811(b), which generally requires the Attorney General to request from the Secretary of HHS a scientific and medical evaluation and recommendation as to whether the substance should be controlled or removed as a controlled substance, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. Under 28 C.F.R. § 0.100, the Attorney General has delegated functions vested in the Attorney General by the Controlled Substances Act to the Administrator of the Drug Enforcement Administration. Under 21 U.S.C. § 812, Schedule I, (c), unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the scheduled hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are classified as Schedule I controlled substances.

[d]For substances scheduled related to approval of a new drug application, DEA does not request an evaluation or recommendation; HHS instead provides them to DEA as part of its process for reviewing these applications. When HHS notifies DEA of the approval of a new drug and provides DEA a scientific and medical evaluation and scheduling recommendation, DEA is required to issue an interim final rule controlling the drug within a specified 90-day timeframe and to subsequently issue a final rule. Improving Regulatory Transparency for New Medical Therapies Act, Pub. L. No. 114-89, § 2, 129 Stat. 698, 698-701 (codified, in part, at 21 U.S.C. § 811) (2015).

[e]Generally, under 21 U.S.C. § 811(d)(1), if control is required by United States obligations under certain international treaties, conventions, or protocols, the Attorney General is required to issue an order controlling such drug under the schedule the Attorney General deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. § 811(a) or 21 U.S.C. § 812(b) and without regard to the procedures prescribed by 21 U.S.C. § 811(a), which generally requires notice and comment rulemaking procedures, and 21 U.S.C. § 811(b), which generally requires the Attorney General to request from the Secretary of HHS a scientific and medical evaluation and recommendation as to whether the substance should be controlled or removed as a controlled substance. Under 28 C.F.R. § 0.100, the Attorney General has delegated functions vested in the Attorney General by the Controlled Substances Act to the Administrator of the Drug Enforcement Administration. Under certain circumstances, with respect to certain international treaties, conventions, or protocols, scheduling procedures are governed by 21 U.S.C. § 811(d)(2)-(4).

[f]For substances scheduled to comply with the Single Convention on Narcotic Drugs, 1961, DEA told us that they requested HHS evaluations and recommendations for substances that were previously scheduled temporarily; DEA requested five and received four of these. For one previously temporarily scheduled substance that was then scheduled to comply with the Single Convention on Narcotic Drugs, 1961 (brorphine), DEA scheduled it after requesting an evaluation and recommendation from HHS but before receiving them. Ultimately, DEA was not required to consider these evaluations because they were scheduled according to the 1961 Convention.

[g]The nine substances that were under temporary scheduling and did not have their temporary scheduling extended for an additional year as of December 31, 2025 were temporarily scheduled between August and October 2025. Under 21 U.S.C. § 811(h)(2), temporary scheduling orders lapse after 2 years. To extend temporary scheduling for an additional year or administratively schedule a given substance, DEA must initiate administrative scheduling proceedings under the procedures laid out in 21 U.S.C. § 811(a) and (b). Two of these substances were ultimately instead scheduled according to the Single Convention on Narcotic Drugs, 1961 in January 2026, while DEA officials told us that HHS evaluations and recommendations were requested for the remaining seven in December 2025.

[h]The 11 substances that were under temporary scheduling and did have their temporary scheduling extended for an additional year as of December 31, 2025 were temporarily scheduled between July and December 2023, with their temporary scheduling extended between July and December 2025 for an additional year. Under 21 U.S.C. § 811(h), the extended temporary scheduling orders will lapse after the additional year. All 11 of these substances were ultimately placed in Schedule I, with seven scheduled to meet U.S. obligations under the Convention on Psychotropic Substances (1971) in March, April, and May 2026 and the other four scheduled administratively in May 2026.

[i]As DEA had not yet administratively scheduled these substances as of December 31, 2025, it had not yet made a final scheduling decision for these substances as of the end of our study's scope. DEA ultimately aligned with HHS's recommendations for all 11 substances and placed all in Schedule I in March, April, and May 2026.

Appendix III: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

September 3, 2026

Triana McNeil
Director
Homeland Security and Justice Issues
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. McNeil:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"DRUG SCHEDULING: While DEA Decisions Are Consistent with Recent HHS Recommendations, Both Need Comprehensive Policies"** (GAO-26-108623).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Gary Andres
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - DRUG SCHEDULING: WHILE DEA DECISIONS ARE CONSISTENT WITH RECENT HHS RECOMMENDATIONS, BOTH NEED COMPREHENSIVE POLICIES (GAO-26-108623)

The Department appreciates the opportunity to review and comment on this draft report. FDA acknowledges our several meetings with GAO staff during their fact-finding efforts to produce this report on drug scheduling processes, agency roles, and processes.

GAO Recommendation 2
The Commissioner of FDA should develop policies and procedures that Center for Drug Evaluation and Research staff are to use to when completing eight-factor evaluations and developing scheduling recommendations, including the criteria and process for determining a substance's "potential for abuse," including abuse potential relative to other substances.

HHS Response
HHS concurs with this recommendation.

FDA, through the Center for Drug Evaluation and Research's Controlled Substance Staff, will initiate a process to draft a new MaPP that would describe how an Eight Factor Analysis is conducted, including discussion of the roles, responsibilities, processes, and potential data sources involved in these CDER drug evaluations (led by the Controlled Substance Staff) that support drug scheduling recommendations to DEA issued by HHS/OASH. The new MaPP would be consistent with the statutory role of the Secretary of HHS in advising DEA for certain drug scheduling actions for which "a scientific and medical evaluation" (Eight Factor Analysis) and drug scheduling recommendations by HHS to DEA are required.

GAO Recommendation 3
The Commissioner of FDA and the Director of NIH should update their memorandum of understanding (MOU) concerning developing drug scheduling recommendations. The updated MOU should reflect the current entities involved and procedures and include a term clause to ensure the MOU is regularly reviewed.

HHS Response
HHS concurs with this recommendation.

FDA acknowledges that the long-existing MOU with NIDA on processes between the agencies for drug evaluations supporting HHS drug scheduling recommendations does not reflect current practices and is worthy of updating. Toward that end, FDA and NIDA have already begun communicating on this matter and drafting a revised MOU that we hope to finalize within the current calendar year.

Endnotes

[1]According to 21 U.S.C. § 802(23), "immediate precursors" means "a substance which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance; which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance."

[2]21 U.S.C. § 812. The Controlled Substances Act also regulates chemicals used in the manufacture of controlled substances. These chemicals are placed by law or regulation into two Lists – I and II – based on their importance to the manufacturing of a given controlled substance. We excluded these chemicals from our review because DEA may list these chemicals by regulation without any HHS evaluations or recommendations and because they are defined separately from controlled substances, which were the focus of our review.

[3]21 U.S.C. § 811(a).

[4]21 U.S.C. § 811(e). Under 21 U.S.C. § 802(23), "immediate precursors" means "a substance which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance; which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance." Under 21 C.F.R. § 1300.01(b), "positional isomer" means "any substance possessing the same molecular formula and core structure and having the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen." Under 21 U.S.C. § 811(e), the Attorney General may, without regard to the findings required by 21 U.S.C. § 811(a) or 21 U.S.C. § 812(b) and without regard to the procedures prescribed by 21 U.S.C. § 811(a), which generally requires notice and comment rulemaking procedures, and 21 U.S.C. § 811(b), which generally requires the Attorney General to request from the Secretary of HHS a scientific and medical evaluation and recommendation as to whether the substance should be controlled or removed as a controlled substance, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. Under 21 U.S.C. § 812, Schedule I, (c), unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the scheduled hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are classified as schedule I controlled substances. Under 28 C.F.R. § 0.100, the Attorney General has delegated functions vested in the Attorney General by the Controlled Substances Act to the Administrator of the Drug Enforcement Administration.

[5]21 U.S.C. § 811(e) and 21 U.S.C. §§ 802(14), 812, Schedule I, (c). See Appendix II for more information about immediate precursors and positional isomers. DEA may also administratively schedule substances pursuant to international treaty obligations, but we categorized those scheduling actions under "international treaty scheduling" for the purposes of this report.

[6]21 U.S.C. § 811(a)(1)-(2).

[7]21 U.S.C. § 811(a) and 21 C.F.R. § 1308.43(a). For example, any interested party could include the manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a state or local government agency, or an individual citizen.

[8]21 U.S.C. § 811(b).

[9]Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, As Amended; Delegation of Authority, 58 Fed. Reg. 35,460 (July 1, 1993).

[10]21 U.S.C. § 355(c).

[11]Improving Regulatory Transparency for New Medical Therapies Act, Pub. L. No. 114-89, § 2, 129 Stat. 698, 698-701 (2015) (codified, in part, at 21 U.S.C. § 811(j)).

[12]21 U.S.C. § 811(j).

[13]21 U.S.C. § 811(j)(3).

[14]21 U.S.C. § 811(h).

[15]21 U.S.C. § 811(h)(2).

[16]21 U.S.C. § 811(d). The United States is a signatory to the Single Convention on Narcotic Drugs (1961, amended 1972), Convention on Psychotropic Substances (1971), and Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988). DEA is required to request and consider an HHS evaluation and scheduling recommendation for substances scheduled under the Convention on Psychotropic Substances, but not the other two treaties.

[17]21 U.S.C. § 811(b), (c).

[18]21 U.S.C. § 812(b). Under 21 U.S.C. § 812(b)(1), Schedule I controlled substances are drugs or substances that have been found to have (1) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use of the drug or substance under medical supervision. 21 U.S.C. § 812(b)(2)-(5) for Schedules II, III, IV, and V controlled substances.

[19]21 U.S.C. §§ 811(a), (c) and 812(b).

[20]According to DEA officials, DEA's National Forensic Laboratory Information System (NFLIS) collects scientifically verified data on drug items and cases submitted to and analyzed by

participating federal, state, and local forensic drug laboratories within the United States (including DEA laboratories). The system is available to the public, including FDA, at https://www.nflis.deadiversion.usdoj.gov. Furthermore, they stated that the data maintained within the internal DEA data collection system contains law enforcement data that is integrated into the comprehensive NFLIS database.

[21]According to HHS officials, epidemiological data sources include, and are not limited to, DEA's National Forensic Laboratory Information System, NIDA's Monitoring the Future survey, poison control center reports, Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health and its Treatment Episode Data Set, and adverse event reporting systems, such as the FDA Adverse Event Reporting System.

[22]21 U.S.C. § 811(h)(3).

[23]Under 21 U.S.C. § 811(h)(3), when issuing a temporary scheduling order pursuant to 21 U.S.C. § 811(h)(1), the Attorney General is required to consider, with respect to the finding of an imminent hazard to the public safety, three factors which is a subset of the eight factors relevant to permanent administrative scheduling, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, and distribution.

[24]Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499 (March 26, 1992).

[25]Memorandum for the Commissioner, Food and Drug Administration, from the Assistant Secretary for Health, HHS, *Re: Part 1 Analysis* (July 17, 2023).

[26]Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana (Apr. 11, 2024).

[27]21 U.S.C. § 811(b).

[28]Office of Legal Counsel, Memorandum.

[29]21 U.S.C. § 811(b).

[30]These 95 substances include the 9 additional substances scheduled according to the new drug application process, which requires DEA to consider, and not request, HHS evaluations and recommendations. Of the 208 substances for which DEA took scheduling actions from 2020 through 2025, HHS scientific and medical evaluations and scheduling recommendations were not required for 86 substances scheduled legislatively, 8 precursors and positional isomers scheduled administratively, 10 substances scheduled to comply with the Single Convention on Narcotic Drugs, and 9 substances scheduled temporarily whose temporary scheduling orders had not been extended. For more information about the substances for which DEA took scheduling actions from 2020 through 2025, see Appendix II.

[31]For more information about our scope and methodology, see the "How GAO Did This Study" section of this report. For more information about DEA's scheduling actions from 2020 through 2025, see Appendix II.

[32]The 11 substances that were under temporary scheduling and did have their temporary scheduling extended for an additional year as of December 31, 2025 were temporarily scheduled between July and December 2023, with their temporary scheduling extended between July and December 2025 for an additional year. Under 21 U.S.C. § 811(h), the extended temporary scheduling orders will lapse after the additional year. All 11 of these substances were ultimately placed in Schedule I, with seven scheduled to meet U.S. obligations under the Convention on Psychotropic Substances (1971) in March, April, and May 2026 and the other four scheduled administratively in May 2026.

[33]21 U.S.C. § 811(b).

[34]FDA officials told us that this required additional consideration and FDA concluded that, since the designer benzodiazepines did not have safe established dosage, the potential for abuse could be far higher than for those that have a currently accepted medical use, so Schedule I placement was appropriate even aside from the currently accepted medical use issue. DEA permanently scheduled the five "designer" benzodiazepines as Schedule I in March 2026. Schedules of Controlled Substances: Placement of Clonazolam, Diclazepam, Etizolam, Flualprazolam, and Flubromazolam in Schedule I of the Controlled Substances Act, 91 Fed. Reg. 9985 (Mar. 2, 2026) (codified at 21 C.F.R. § 1308.11). 21 C.F.R. § 1308.11(e)(1)-(5).

[35]21 U.S.C. § 811(j).

[36]According to our analysis of DEA data and regulatory dockets, all 9 substances scheduled according to the new drug application process from 2020 through 2025 were scheduled within 90 days of DEA receiving the later of either HHS's scientific and medical evaluation and scheduling recommendation or notice of FDA's approval of the new drug application.

[37]According to our analysis of DEA data and regulatory dockets, all 9 substances scheduled according to the new drug application approval process from 2020 through 2025 were scheduled within 90 days of DEA receiving the later of either HHS's scientific and medical evaluation and scheduling recommendation or notice of FDA's approval of the new drug application.

[38]GAO, *Standards for Internal Control in the Federal Government*, GAO-25-107721 (Washington, D.C.: May 15, 2025).

[39]According to Standards for Internal Control in the Federal Government, management documents in policies and procedures for each unit within the entity's organizational structure its responsibility for a business process's objectives and related risks and control activity design, implementation, and operating effectiveness. Each unit, with guidance from management, determines the policies necessary to operate the business process based on the objectives and related risks. Each unit also documents policies and procedures in the appropriate level of detail to allow management to effectively monitor the control activity. The documentation may appear in various forms, such as management directives, administrative policies, or operating manuals. See GAO-25-107721, 80.

[40]See GAO-25-107721, 81.

[41]This information includes commercially confidential, personally identifiable, law enforcement sensitive, and any other information otherwise prohibited by disclosure under laws and regulations (e.g., trade secret information). See, 5 U.S.C. §§ 552a, 552(b), 18 U.S.C. § 1905, and 21 U.S.C. § 331(j), and Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

[42]U.S. Food and Drug Administration, Manual of Policies and Procedures (MaPP) 4200.3, Rev. 2, *Consulting the Controlled Substances Staff on Drug Abuse Potential and Labeling, Dependence Liability, and Drug Abuse Risks to the Public Health* (effective Oct. 26, 2022).

[43]U.S. Food and Drug Administration, *Assessment of Abuse Potential of Drugs: Guidance for Industry* (Silver Spring, Md.: Jan. 2017).

[44]Pub. L. No. 112-144, § 1139, 126 Stat. 993, 1126 (2012).

[45]Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 79 Fed. Reg. 49,661 (Aug. 22, 2014).

[46]For example, see Congressional Research Service, *In Focus: Legislative Scheduling of Controlled Substances*, IF12709 (Washington, D.C.: June 9, 2025). This report surveys instances in which Congress has scheduled a controlled substance or changed the status of a controlled substance under the Controlled Substances Act via legislation, as of June 9, 2025.

[47]See GAO-21-499, *Synthetic Opioids: Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances* (Washington, D.C.: Apr. 12, 2021) and Congressional Research Service, 2. For example, as the Congressional Research Service reported, the Controlled Substances Act (CSA) established Schedules I through V, with each schedule carrying a defined set of regulatory controls and penalties for unauthorized activities. If DEA decides to control a substance under the CSA, it must place the substance in one of the existing schedules. The agency has asserted some authority to tailor controls to specific substances, but it cannot create new schedules or implement regulations or exceptions from control that are not authorized under the CSA. If Congress wishes to regulate a controlled substance in a way that does not fit within the existing CSA framework, or allow DEA to do so, it must enact legislation.

[48]For example, in 2021, we reported that representatives of six of the 11 research organizations we interviewed emphasized the importance of considering the scientific evidence, including pharmacological activity, in any scheduling decision. For example, a stakeholder told us that a scheduling decision made without the eight-factor analysis would be based on insufficient evidence. Another representative of a research organization told us that the scientific expertise of HHS, FDA, and NIDA should be used in making scheduling decisions. In addition, we reported that civil rights and criminal justice stakeholders cited concerns that the class-wide scheduling of fentanyl-related substances as Schedule I could result in convictions for substances that may not be harmful and lengthy sentences for trace amounts of fentanyl-related substances and exacerbate racial disparities in federal sentencing. See GAO-21-499.

[49]For example, we reported about considerations for scheduling decisions when the temporary classification of fentanyl-related substances expired, including (a) allowing the temporary order to expire and individually scheduling substances through the administrative process, (b) legislative scheduling as a class without modifications, and (c) legislative scheduling as a class with modifications. For instance, we reported that potential modifications included those recommended by an interagency workgroup convened by the Office of National Drug Control Policy, such as removing barriers to research and streamlining the process for removing substances from

Schedule I if they are discovered to have no abuse potential. See GAO-21-499 for more information.

[50]FDA officials told us that the exact number of fentanyl-related substances depended on assumptions made about the number of different ways these substances can vary chemically, and that the total number of fentanyl-related substances could be close to 24 million.

[51]Pub. L. No. 119-26, 139 Stat. 410 (2025).

[52]We previously reported about the emergence of xylazine and medetomidine—another even more potent veterinary tranquilizer with the street name "dex" for dexmedetomidine—that may be competing with or even replacing xylazine in street drugs. See GAO-26-107763, *Factors Affecting the Detection and Identification of Emerging Substances* (Washington, D.C.: Feb. 3, 2026).

[53]21 U.S.C. § 811(e). Under 21 U.S.C. § 802(23), "immediate precursors" means "a substance which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance; which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance." Under 21 C.F.R. § 1300.01(b), "positional isomer" means "any substance possessing the same molecular formula and core structure and having the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen." Under 21 U.S.C. § 811(e), the Attorney General may, without regard to the findings required by 21 U.S.C. § 811(a) or 21 U.S.C. § 812(b) and without regard to the procedures prescribed by 21 U.S.C. § 811(a), which generally requires notice and comment rulemaking procedures, and 21 U.S.C. § 811(b), which generally requires the Attorney General to request from the Secretary of HHS a scientific and medical evaluation and recommendation as to whether the substance should be controlled or removed as a controlled substance, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. Under 21 U.S.C. § 812, Schedule I, (c), unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the scheduled hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are classified as schedule I controlled substances. Under 28 C.F.R. § 0.100, the Attorney General has delegated functions vested in the Attorney General by the Controlled Substances Act to the Administrator of the Drug Enforcement Administration.

[54]21 U.S.C. § 811(e) and 21 U.S.C. §§ 802(14), 812, Schedule I, (c). See Appendix II for more information about immediate precursors and positional isomers. DEA may also administratively schedule substances pursuant to international treaty obligations, but we categorized those scheduling actions under "international treaty scheduling" for the purposes of this report.

[55]In December 2014, the Designer Anabolic Steroid Control Act (DASCA) of 2014, Pub. L. No. 113-260, 128 Stat. 2929, amended the Controlled Substances Act to revise and add specified substances to the definition of "anabolic steroid" under 21 U.S.C. § 802(41). In August 2023, DEA published a final rule, Implementation of the Designer Anabolic Steroid Control Act of 2014, 88 Fed. Reg. 50,036 (Aug. 1, 2023) (codified at 21 C.F.R. pt. 1300, 1302, and 1308), to amend and reorganize its regulations to make them consistent with DASCA regarding the updated definition of anabolic steroid and specific substances, among other things. According to the final rule, DASCA amended the Controlled Substances Act definition of "anabolic steroid" by adding 22 new substances to the prior statutory list of anabolic steroids. While DASCA listed 25 substances, two of the listed substances were duplicates of substances previously listed in the regulatory definition of anabolic steroid, and one substance was included twice in DASCA. The final rule indicated that in addition to incorporating the language of the statutory amendments of DASCA into DEA's regulations, the rule relocated and made a number of organizational and typographical changes to the regulatory list of anabolic steroids to improve the list's clarity. These changes did not add or remove any substances from the list beyond the 22 new substances added by DASCA. This resulted in the revision of 21 C.F.R. § 1308.13(f) and the listing of 86 substances as anabolic steroids in schedule III.

[56]Of the 208 substances for which DEA took scheduling actions from 2020 through 2025, HHS scientific and medical evaluations and scheduling recommendations were not required for 86 substances scheduled legislatively, 8 precursors and positional isomers scheduled administratively, 10 substances scheduled to comply with the Single Convention on Narcotic Drugs, and 9 substances scheduled temporarily whose temporary scheduling orders had not been extended. For more information about the substances for which DEA took scheduling actions from 2020 through 2025, see Appendix II.

[57]Controlled Substances Act, Pub. L. No. 91-513, § 202, 84 Stat. 1242, 1247-52 (1970) (codified as amended at 21 U.S.C. § 812).

[58]21 U.S.C. §§ 811(b)(1) and 812, sch. I, (c)(10).

[59]Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana (Apr. 11, 2024).

[60]Generally, to place substances in Schedule II-V, there must be a finding that the drug or other substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. § 812(b)(2)(B), (b)(3)(B), (b)(4)(B), and (b)(5)(B).

[61]21 U.S.C. § 812(b).

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

[63]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, 91 Fed. Reg. 22,714 (Apr. 28, 2026) (to be codified at 21 C.F.R. pts. 1300, 1301, 1308, and 1312).

[64]21 U.S.C. § 811(d)(1).

[65]Schedules of Controlled Substances: Rescheduling of Marijuana; Withdrawal, 91 Fed. Reg. 22,778 (Apr. 28, 2026). Schedules of Controlled Substances: Rescheduling of Marijuana, 91 Fed. Reg. 22,777 (Apr. 28, 2026). The hearing is to conclude not later than July 15, 2026.