

# The Opportunity to be Heard: Post-Loper Bright Analysis of Controlled Substances Act Rulemaking Procedures<sup>1</sup>

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## ABSTRACT

Reasonable minds can disagree as to the exact administrative process required to schedule and reschedule drugs and substances under the Controlled Substances Act. The current consensus and position of the Drug Enforcement Agency is that the process follows formal rulemaking. This note argues that post-Loper Bright de novo review better supports a hybrid rulemaking process due to the ambiguous language of 21 U.S.C. § 811(a)(2).

**Keywords:** Controlled Substances Act; Administrative Procedures Act; Drug Enforcement Agency; rescheduling; formal rulemaking; hybrid rulemaking; informal rulemaking; notice and comment; section 811; section 553; section 556; section 557; marijuana; ALJ hearing; due process; enabling statutes; oral hearing

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<sup>1</sup> Anthony Deiningner, *The Opportunity to be Heard: Post-Loper Bright Analysis of Controlled Substances Act Procedures* (May 2026) (unpublished manuscript) [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=6855698](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=6855698)

The primary scheduling pathway for drugs and substances under the Controlled Substances Act is codified at 21 U.S.C. 811(a)(2) and the language there is genuinely ambiguous.<sup>2</sup> The current position of the Drug Enforcement Agency is that the statutory language triggers formal rulemaking.<sup>3</sup> This note argues that a post-*Loper Bright* de novo reading of 21 U.S.C. § 811(a)(2) better supports a hybrid rulemaking process that incorporates elements of both informal and formal rulemaking procedures.

For statutes to be ambiguous, it must be capable of more than one plausible interpretation. Before the Supreme Court ruling in *Loper Bright Enterprises v. Raimondo*, agency interpretations of ambiguous statutes were reviewed under Chevron deference. If the statute could be read two different ways, courts would defer to the agency's interpretation in deciding which of the two controlled. In June of 2024, the Court in *Loper Bright* struck down this method and held that only Article III courts can issue binding interpretations of statutes.

When Congress writes statutes that delegate to an executive agency the power to issue regulations that carry the force of law, they are known as “enabling statutes.” These enabling statutes will be the first deciding factor in determining what process the agency must follow in order to issue said binding regulation. This process can either follow informal rulemaking under section 553, formal rulemaking under

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<sup>2</sup> 21 U.S.C. 811(a)(2)

<sup>3</sup> *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994) (reflecting DEA's adoption of formal rulemaking procedures under § 811(a)); *see also* 21 C.F.R. § 1308.43 (codifying DEA's formal hearing procedures for scheduling actions).

sections 556 and 557, or a **hybrid mixture of both informal and formal rulemaking procedural elements**.

Section 811(a)(2) governs the rulemaking procedures under the Controlled Substances Act and states that “[r]ules of the Attorney General under this subsection shall be made *on the record after opportunity for a hearing pursuant to* the rulemaking procedures prescribed by *subchapter II* of chapter 5 of title 5.<sup>4</sup> This is problematic for two independent reasons.

First, subchapter II of chapter 5 of title 5 contains the **entire Administrative Procedures Act (sections 551 through 559)**. This is a problem because the statute does not state the specific hearing procedures that must be followed: informal section 553 procedures or formal section 556 and 557 procedures? The statute points to both.

Under *Chevron* deference, this ambiguity afforded deference towards the Drug Enforcement Agency interpretation between the two. This is significant because formal rulemaking requires trial-like oral hearings before an Administrative Law Judge (ALJ), while informal rulemaking encourages but does not require such a hearing. Because *Chevron* deference no longer applies, the DEA cannot unilaterally interpret ambiguity in section 811(a)(2) to require formal rulemaking.

Second, “on the record after opportunity for a hearing” is not the same language that the Court in *United States v. Florida East Coast Railway* held to trigger formal rulemaking.<sup>5</sup> The triggering language is “on the record after the

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<sup>4</sup> 21 U.S.C. 811(a)(2) (emphasis added).

<sup>5</sup> *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224 (1973).

opportunity for an *agency hearing*.”<sup>6</sup> These are not the same words. Each operative term must be identical unless a superseding canon of statutory construction has been given force and expressly allows for interpretive breadth in order to effectuate clearly stated Congressional purpose.<sup>7</sup>

Because the triggering language does not match the language in Florida East Coast Railway, the process is not automatically formal. As the court explained in *Chemical Waste Management*, “it is not [for the court] to presume that a statutory references to a ‘hearing,’ without more specific guidance from Congress, evinces an intention to require formal adjudicatory procedures.”<sup>8</sup> Furthermore, the Court stated in *Vermont Yankee Nuclear Power Corp.*, “courts may not impose procedural requirements beyond the minimum required by the APA.”<sup>9</sup> Therefore, the process required under the Controlled Substances Act is properly interpreted as a *hybrid* rulemaking process that includes some elements of informal rulemaking and some elements of formal rulemaking.

The government’s own statements reinforce this position. The order rescheduling FDA-approved and qualifying state-licensed medical marijuana states multiple times that informal notice-and-comment hearing standards apply.

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<sup>6</sup> *Id.* at 238.

<sup>7</sup> Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 170 (2012) (“If the legislature used certain language in one part of an act and different language in another, the court will assume the difference was intentional.”); see also *Russello v. United States*, 464 U.S. 16, 23 (1983) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”).

<sup>8</sup> *Chemical Waste Management, Inc. v. EPA*, 873 F.2d 1477, 1482 (D.C. Cir. 1989); see also *City of West Chicago v. NRC*, 701 F.2d 632, 644 (7th Cir. 1983) (“Formal rulemaking is the exception rather than the rule. Unless Congress has clearly required formal rulemaking procedures, an agency may proceed under the less burdensome notice-and-comment procedures of section 553.”).

<sup>9</sup> *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524 (1978).

Page 22 of the order states:

In accordance with 21 U.S.C. 811(d)(1), scheduling actions . . . shall be issued by order, as opposed to scheduling by rule pursuant to 21 U.S.C. 811(a)(2). Therefore, DEA believes that the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action.<sup>10</sup>

Page 23 of the order states:

The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment under the APA or any other law. As explained above, this final rule is not subject to the notice-and-comment procedures of the APA. Consequently, the RFA does not apply to this action [because 811(a)(2) is not invoked].<sup>11</sup>

Additionally, the DEA's website misstates the law and further speaks to section 553 hearing standards. "The [rescheduling] process is being carried out through the formal rulemaking process which includes public input, administrative review, and *potential* hearings."<sup>12</sup> The label of formal rulemaking coupled with an admission that hearings are only potential and not required is an incoherent statement of law. The combination of public input, administrative review, but only potential hearings instead speaks to a hybrid procedure.

**How is the language "after a hearing pursuant to the rulemaking procedures prescribed by *subchapter II of chapter 5 of title 5*" interpreted under this hybrid approach?**

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<sup>10</sup> 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, 22,735 (Apr. 28, 2026) (AG Order No. 6754-2026).

<sup>11</sup> *Id.* at 22,736.

<sup>12</sup> DEA Website: "Marijuana Rescheduling Regulatory Actions" (<https://www.dea.gov/marijuana-rescheduling-regulatory-actions>) (<https://perma.cc/77R2-ZTRK>)

By examining the first principles counseling hearing standards across the Administrative Procedures Act and applying grammatical tools of textual construction. “[A]fter the opportunity for a hearing” is a subordinate prepositional phrase that modifies and delimits the operative legal standard of “on the record” and gives it procedural meaning. It serves as the antecedent condition that instantiates the record to give it legal effect. The phrase “on the record after the opportunity for a hearing” thus functions as a unitary trigger, not two independent conditions that must be satisfied separately. The result is that the opportunity to be heard could be satisfied by contextual indicia including the nature of the proceeding, object of regulation, and attached due process interests.

*Board of Regents v. Roth* establishes that Constitutional due process protections attach where agency action threatens cognizable liberty or property interests.<sup>13</sup> *Mathews v. Eldridge* supplies the content of that process through a three-factor inquiry balancing the private interests affected, the risk of erroneous deprivation, and countervailing government interests.<sup>14</sup> The Court reasoned that oral hearings advance due process protections only where the inquiry involves contested factual narratives, credibility of expert witnesses, or normative judgments that could not be adequately captured in the record without an oral hearing.<sup>15</sup> Thus, agency

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<sup>13</sup> *Bd. of Regents v. Roth*, 408 U.S. 564, 569–70 (1972) (“To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have a legitimate claim of entitlement to it.”).

<sup>14</sup> *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

<sup>15</sup> *Id.* at 345 n. 28 (“The statistical information relevant to this judgment is more amenable to written than to oral presentation.”).

determinations of empirical questions based solely on objective data are not conducive to trial-like oral hearings and are better decided on the paper record alone.

Applied to the Controlled Substances Act, the rescheduling of drugs and substances follows an empirical inquiry based on eight objective factors listed in section 811(c) and includes (1) the actual or relative potential for abuse; (2) scientific evidence of pharmacological effect; (3) state of current scientific knowledge regarding the drug or substance; (4) history and current pattern of abuse; (5) scope, duration, and significance of abuse; (6) risk to public health; (7) psychic or physiological dependence liability; and (8) immediate precursor status of a substance already controlled.<sup>16</sup> These empirical questions are fully resolvable on the paper record. They only require determinations of objective scientific and medical data and Constitutional due process does not attach to the rescheduling from schedule I to schedule III because no cognizable property or liberty interests are affected.<sup>17</sup>

As applied to the ongoing rescheduling of marijuana, the hybrid-incorporative rulemaking structure of the Controlled Substances Act and the first principles of due process counsel that the hearing standard governing the “opportunity for a hearing pursuant to [the Administrative Procedures Act]” is properly satisfied through the informal rulemaking standards of section 553 notice-and-comment procedures, which state that “the agency shall give interested persons an opportunity to participate in

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<sup>16</sup> 21 U.S.C. 811(c).

<sup>17</sup> *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 675 (1999) (property interests subject to due process protection must be rooted in existing rules or understandings that stem from an independent source such as state law); *See Bd. of Regents v. Roth*, 408 U.S. 564, 569; *see also Mathews v. Eldridge*, 424 U.S. 319, 332 (1976).

the rule making through submission of written data, views, or arguments *with or without opportunity for oral presentation.*”<sup>18</sup>

Even if the process required by 811(a)(2) demands formal rulemaking under sections 556 and 557, an oral hearing is not strictly required.<sup>19</sup> Section 556(d) states that “[a] party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination *as may be required* for a full and true disclosure of the facts.”<sup>20</sup> The Court in *Kingdomware Technologies* explains that “[u]nlike the word ‘may,’ which implies discretions, the word ‘shall’ usually connotes a requirement.”<sup>21</sup>

The eight objective factors of section 811(c) read through *Mathews v. Eldridge* counsel against an oral hearing being required to advance factual determinations relevant to the inquiry regardless of which hearing standard applies. Prior to promulgating notices of proposed rulemaking for scheduling actions, the Drug Enforcement Agency receives a comprehensive recommendation from the Department of Health and Human Services on the appropriate scheduling classification for a particular drug or substance based on factual determinations of the eight objective scheduling factors.<sup>22</sup> This report is then instantiated by public

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<sup>18</sup> 5 U.S.C. 553(c).

<sup>19</sup> 5 U.S.C. 556(d).

<sup>20</sup> *Id.* (emphasis added).

<sup>21</sup> *Kingdomware Technologies, Inc. v. United States*, 579 U.S. 162, 171 (2016).

<sup>22</sup> 21 U.S.C. § 811(b) (“The Attorney General shall, before initiating proceedings under subsection (a)(1) of this section to control a drug or other substance . . . request from the Secretary a scientific and medical evaluation.”); Letter from Rachel L. Levine, M.D., Assistant Secretary for Health, HHS, to Anne Milgram, Administrator, DEA (Aug. 29, 2023) (HHS scheduling recommendation for marijuana to Schedule III).

comment.<sup>23</sup> Together they constitute the universe of material fact relevant to the inquiry and satisfy the opportunity for a hearing. Any remaining scientific or medical data is better found not in a trial-like hearing, but in the laboratories of democracy that have examined these questions in practice for over a decade.

Alternatively, if marijuana is rescheduled from schedule III to schedule I, fifth amendment regulatory takings may implicate cognizable property interests and trigger heightened Constitutional due process protections. Under *Regents v. Roth*, a section 556(d) oral hearing with cross-examination is likely required for the full disclosure of individualized determination of reliance facts. The Court in *Motor Vehicle Manufacturers Association v. State Farm* explained that “[n]ormally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem.”<sup>24</sup> Applying the three-factor *Mathews* balancing test, the calculation of adequate compensation owed to affected parties may require attestations not otherwise accessible if not for a formal hearing and that are required for a prudential determination of fair market value.<sup>25</sup>

More examination is needed into whether the scheduled expedited oral hearings beginning in June 2026 would actually satisfy the opportunity to be heard if Constitutional due process does attach and section 556 and 557 formal hearings are

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<sup>23</sup> Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (May 21, 2024) (Docket No. DEA-1362) (receiving approximately 43,000 public comments by the July 22, 2024 close of the comment period).

<sup>24</sup> *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

<sup>25</sup> See *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976); see also *Monongahela Navigation Co. v. United States*, 148 U.S. 312, 326 (1893) (just compensation under the Fifth Amendment requires individualized factual determination of fair market value).

required.<sup>26</sup> Additionally, meetings between OIRA and affected parties in the ALJ proceedings warrant further analyzing into ex parte communication concerns and resulting potential detachment of due process according to sections 556(d) and 557(d).<sup>27</sup>

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<sup>26</sup> Cite to DEA ALJ hearing schedule once participant list and schedule are finalized and publicly available.

<sup>27</sup> 5 U.S.C. §§ 556(d), 557(d); *Prof'l Air Traffic Controllers Org. v. Fed. Labor Relations Auth.*, 685 F.2d 547, 564–65 (D.C. Cir. 1982) (ex parte communications during formal APA proceedings violate the statutory prohibition and may require supplementation of the record or other remedial measures); *see also Sierra Club v. Costle*, 657 F.2d 298, 400–01 (D.C. Cir. 1981) (discussing scope of permissible executive branch communications in formal rulemaking proceedings).