

Emerging Drug Threats Rapid Scheduling Act of 2026

Anticipated challenges, responses, and probable outcomes

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Adversarial Review: Emerging Drug Threats Rapid Scheduling Act of 2026

October 6, 2026 · Collin B. George, CISSP, National Security Advisor, Sanctir LLC

Method. Each challenge is stated in its strongest form, not its likely form. Where the draft answers it, the answer is identified by section. Where it does not, the gap is marked and a fix proposed. Assessments are against the revision 5 text.

Two findings from this review were applied to the draft, lost when a parallel revision 4 branched from revision 3, and restored in revision 5. Section 230 of the Communications Act barred the marketplace civil penalty in Section 8(c) as drafted through revision 3, and administrative assessment of that penalty was exposed under *SEC v. Jarkesy*. Revision 5 carries both. Neither appeared in the risk table of any prior revision. Three further hardening items identified below — the scienter extension in Section 7, the recast of Section 8(d), and the record-production requirement in Section 4 — are left as options rather than applied, because each involves a scope judgment that belongs to the committee.

Part I. Constitutional challenges

1. Vagueness and fair notice — Sec. 7(a)(11)

The argument. Section 7(a)(11) places in Schedule I, on enactment, every peptide meeting a pharmacological definition, without naming it. A person cannot determine from the statute whether a compound is controlled; that requires a receptor assay. Criminal liability therefore attaches to a status the defendant cannot ascertain by reading the law. *Johnson v. United States*, 576 U.S. 591 (2015), and *Sessions v. Dimaya*, 584 U.S. 148 (2018), struck residual clauses that required courts to imagine an ordinary case; this requires a defendant to predict a laboratory result. The government will say the assay is objective, but objectivity is not notice.

The strongest version adds that the Attorney General’s published list under Section 7(c) is the tell: if the list is what gives notice, then the statute standing alone does not.

Likely outcome. This is the provision that loses, or that forces the government into a narrowing construction. *United States v. Forbes*, 806 F. Supp. 232 (D. Colo. 1992), struck the analogue definition as applied on weaker facts — there the defendant at least had a named comparator substance. Later courts confined *Forbes* to its facts (*United States v. Carlson*, 87 F.3d 440 (11th Cir. 1996)), but they did so by reading a scienter requirement into the Analogue Act, which is the same move available here.

Defense in the draft. Section 7(b) supplies it. The United States must prove the defendant knew or represented that the peptide produces opioid effects. *Village of Hoffman Estates v. Flipside*, 455 U.S. 489, 499 (1982), holds that a scienter requirement mitigates vagueness, and the Analogue Act cases turn on precisely this. The functional-activity requirement in the definition of ‘novel synthetic opioid’ excludes binding affinity without agonist activity, which removes the broadest reading, and the endogenous-peptides exclusion in that definition carves out the human peptides.

Assessment. Survives as to prosecutions, because Section 7(b) converts the question from “did you know the law” to “did you know what you were selling.” Vulnerable as to the regulatory consequences that attach without scienter — registration, importation, forfeiture — where no knowledge element applies.

Recommended hardening. Extend the Section 7(b) knowledge element to any civil or administrative consequence imposed on a person for conduct involving a peptide controlled only under paragraph (11). That removes the strict-liability regulatory exposure, which is the part of the provision with no defense.

2. Nondelegation — Sec. 4

The argument. Congress is handing the Attorney General authority to define criminal classes by pharmacological effect, acting in 15 days or less, on a record that may be classified. That is lawmaking. *Touby* upheld 811(h) but expressly reserved whether criminal delegations require more than an intelligible principle, 500 U.S. at 165–66. This delegation is broader than the one *Touby* approved in every

dimension the Court identified as constraining: it reaches classes rather than substances, it shortens notice, and it defines membership by a functional test the agency itself administers.

Likely outcome. The bill wins, and more comfortably than the memorandum's prior revisions assumed. *FCC v. Consumers' Research*, 606 U.S. 656 (2025), reaffirmed the intelligible-principle test 6–3 and declined to adopt a stricter standard for a delegation involving the power to raise revenue — a context where the argument for heightened scrutiny was stronger than here. *Gundy* produced no majority, and the four-Justice plurality applied the conventional test. A majority has not adopted the Gorsuch position in the six years since.

Defense in the draft. Imminent-hazard standard carried over from 811(h), which *Touby* upheld. Enumerated evidentiary categories in Sec. 4(2). HHS consultation in Sec. 4(4). Substantial-evidence review in Sec. 4(7)(B) — a constraint 811(h) lacks entirely. Duration cap, transfer obligation under 202A(f), and a six-year sunset.

Assessment. Likely survives a facial challenge. The substantial-evidence review is the strongest single feature, because it distinguishes this delegation favorably from the one already upheld.

Watch item. *Learning Resources* is a statutory-interpretation holding, but Gorsuch's concurrence presses nondelegation themes, and the major-questions discussion drew three votes. A litigant will cite it for atmosphere. The response is that major questions governs claims of *implied* authority from ambiguous text; here Congress delegates expressly and bounds the grant. That distinction is clean and should be made in the findings, not left to counsel.

3. Due process — the permissive inference in Sec. 6

The argument. The inference tells the jury it may find the human-consumption element from the fact of research chemical marketing. Juries treat statutory inferences as judicial endorsement. *Francis v. Franklin*, 471 U.S. 307 (1985), and *Sandstrom v. Montana*, 442 U.S. 510 (1979), bar shifting any element; a statutory inference on a contested element invites exactly that error.

Likely outcome. Survives. *County Court of Ulster County v. Allen*, 442 U.S. 140 (1979), permits a permissive inference where the inferred fact flows more likely than not from the proved fact, judged as applied. Marketing a dosed, injectable-presentation product with a “not for human consumption” label makes human-consumption intent more likely than not by a wide margin — that is the whole commercial point of the labeling practice.

Defense in the draft. Sec. 6(a), new 813(b)(1) is framed permissively. New 813(b)(3) expressly disclaims burden shifting. The inference is unavailable where the article is FDA-approved, licensed, or distributed to a registrant for legitimate purposes.

Assessment. Low. The *Ulster County* analysis is as-applied, so the exposure is to a bad fact pattern rather than to the provision.

4. Due process — classified evidence, Sec. 4(7)(C)

The argument. A petitioner challenging a scheduling order cannot contest evidence it is not shown. *Al Haramain Islamic Found. v. U.S. Dep't of the Treasury*, 686 F.3d 965 (9th Cir. 2012), held that OFAC violated due process by failing to mitigate reliance on classified evidence through unclassified summaries or cleared counsel.

Likely outcome. Survives, and the objection is weaker than it looks because of a category difference the memorandum should state. The IEEPA designation cases involve deprivation of identified parties' specific property. A scheduling order is a rule of general applicability that deprives no identified person of anything; procedural due process attaches thinly to quasi-legislative action. *Holy Land Found. v. Ashcroft*, 333 F.3d 156 (D.C. Cir. 2003), and *Global Relief Found. v. O'Neill*, 315 F.3d 748 (7th Cir. 2002), uphold ex parte review even in the harder designation posture.

Defense in the draft. Sec. 4(7)(C) requires an unclassified statement of the substance of the evidence relied on — the mitigation *Al Haramain* said was missing.

Assessment. Low. Consider adding that the court may appoint cleared counsel, which costs nothing and forecloses the remaining *Al Haramain* argument.

5. Fourth Amendment — Sec. 10(b) subpoenas

The argument. *Carpenter v. United States*, 585 U.S. 296 (2018), limits the third-party doctrine. Aggregated purchase, payment, and shipping records from marketplaces and registrars reveal as much about a person as cell-site location.

Likely outcome. Fails. *Carpenter* was expressly narrow and did not disturb the subpoena doctrine of *Oklahoma Press Publishing Co. v. Walling*, 327 U.S. 186 (1946), and *See v. City of Seattle*, 387 U.S. 541 (1967), which require only reasonable relevance. 21 U.S.C. 876 has been sustained for decades.

Defense in the draft. Sec. 10(b)(3) excludes communications content. Sec. 10(b)(2) — added in revision 3 — supplies the jurisdictional nexus. Sec. 10(e)(4) requires annual reporting of subpoena counts and categories.

Assessment. Low as a constitutional matter. The political exposure is higher than the legal exposure, which is the argument for keeping the nexus and the reporting.

6. First Amendment — the marketing definition

The argument. This is the most underrated challenge in the package. "Research chemical marketing" is defined at 102(63) by the content of the seller's statements. Section 8(d) makes distribution accompanied by those statements an FDCA prohibited act. *Sorrell v. IMS Health*, 564 U.S. 552 (2011), applies heightened scrutiny to content- and speaker-based burdens on commercial speech, and the FDA intended-use litigation has made the use of a manufacturer's speech to establish regulatory status genuinely contested.

Likely outcome. Survives, but the draft should not meet it by accident. The prohibition runs to distribution, not to speech; the statements are evidence of intended use, and *Wisconsin v. Mitchell*, 508 U.S. 476 (1993), permits speech as evidence of intent. Speech proposing an unlawful transaction has no protection at all under *Central Hudson*'s threshold inquiry.

Gap. Section 8(d) as drafted makes the *speech* an element of the prohibited act rather than evidence of it: the offense is introducing a drug into commerce "through research chemical marketing." That phrasing invites the argument that the statement is the violation.

Recommended fix. Recast Sec. 8(d) so the prohibited act is introducing an unapproved drug intended for human consumption into interstate commerce, with research chemical marketing identified as evidence from which that intent may be found. The enforcement reach is identical and the constitutional question largely disappears.

Part II. Statutory and structural challenges

7. Section 230 barred the marketplace penalty — cured in Sec. 8(c)(4)

The problem. Section 8(c) imposes a federal *civil* penalty on a marketplace for third-party listings. 47 U.S.C. 230(c)(1) treats the provider as not the publisher of third-party content, and the carve-out at 230(e)(1) covers federal *criminal* statutes only. A civil penalty is not a criminal prosecution. Absent an override a marketplace moves to dismiss on Section 230 and should win unless it materially contributed to the listing's unlawfulness.

This was dispositive, not a risk. The provision did not work. The safe harbor in Sec. 8(c)(3) is irrelevant if the claim never reaches the merits.

Applied. Sec. 8(c)(4) provides that nothing in Section 230 limits liability under the subsection, following the model of 47 U.S.C. 230(e)(5), added by FOSTA (Pub. L. 115–164).

Residual exposure, and it is political rather than legal. Expect this to be the most contested line in the bill. NetChoice and CCIA will characterize it as FOSTA precedent being extended to a new subject matter, and the FOSTA experience — collateral effects on lawful speech, contested evidence of enforcement benefit — is the argument they will make. The distinguishing feature is the knowledge element in Sec. 8(c)(1): liability requires knowing the substance is controlled, not merely hosting a listing. Brief the two provisions together; the override is not defensible without the scienter.

Alternative if the override cannot hold. Make the provision criminal, which 230(e)(1) already excepts. That trades a Section 230 fight for a mens rea fight and raises the political cost, but it is a real fallback rather than a rhetorical one.

8. Jarkesy exposure on administrative assessment — cured in Sec. 8(c)(2)

The problem. As drafted before this review, Sec. 8(c)(2) had the Attorney General assess the civil penalty. *SEC v. Jarkesy*, 603 U.S. 109 (2024), held that a civil penalty action seeking to punish is legal in nature and triggers the Seventh Amendment jury right unless the public-rights exception applies. Agency adjudication of punitive monetary penalties against private parties is contested ground.

Assessment had the provision stood. The government had a workable public-rights argument — a regulatory scheme with no common-law analogue to facilitating drug distribution. But the argument was no longer free, and it was not worth preserving for a mechanism the government does not use.

Applied. Sec. 8(c)(2) provides that the penalty is recovered in a civil action brought by the United States in district court. That is how 21 U.S.C. 842(c) penalties are collected in practice, and it removes the question rather than litigating it.

9. The 15-day order and arbitrary-and-capricious review

The argument. Substantial-evidence review of a record assembled in 15 days, or none where the order issues on publication, is review in name only. The agency will characterize every order as emergent and the court will have nothing to examine.

Likely outcome. Partial success, on an as-applied basis, against a thin record. This is the provision most likely to produce an adverse published opinion even though the statute survives.

Defense in the draft. Sec. 4(2) enumerates the evidentiary categories, which gives a reviewing court a checklist. Sec. 4(3) requires the Attorney General to state the basis for any shortened period. Sec. 12(d) requires annual reporting of the evidence relied on for each order.

Recommended hardening. Require that an order taking effect on publication be accompanied by the administrative record within 30 days. That is an administrative obligation, not a constraint on the emergency, and it removes the “review in name only” argument cleanly.

10. Two mechanical failures found on third-pass verification

Neither is a constitutional challenge; both would have defeated provisions the bill depends on, and both are recorded here because the pattern matters more than either instance.

18 U.S.C. 2516 does not incorporate the CSA definitions. Section 2516(1)(e) describes drug offenses with the freestanding phrase “narcotic drugs, marihuana, or other dangerous drugs, punishable under any law of the United States.” Congress conformed the racketeering predicate in 1961(1) to CSA section 102 but made no corresponding change to 2516. The 802(6) amendment therefore does not reach wiretap authority, and neither did the deeming provision that preceded it. Sec. 5(f) now amends 2516(1)(e) expressly. Confirmed against the GovInfo 2024 Code edition.

The schedule-number rule defeated the research pathway. Sec. 202A(d) treats provisional substances as Schedule III wherever a provision distinguishes among schedules by number. But 823(n)(1) authorizes the expedited procedure for research “with 1 or more schedule I substances,” and 822(h) applies to a substance “newly added to schedule I.” The rule intended to make incorporated provisions work prevented the most important of them from attaching. Sec. 11(b) now deems provisional substances Schedule I for research purposes, and Sec. 202A(d) opens with an express exception.

Why this is in an adversarial review. The research pathway has now failed twice on mechanics across revisions, each time in a way that left the operative text looking correct. It is the provision whose failure would be least visible in markup and most damaging in practice, because the research community’s support is what distinguishes this bill from SITSA. Re-verify Sec. 11 against codified text before introduction rather than against any prior draft.

11. Conflict with the HALT Fentanyl Act

This is resolved by applying 823(n) rather than amending it. Worth noting for the briefing: the bill as drafted adds no new limits to HALT and touches no fentanyl-related-substance provision. If asked whether this reopens HALT, the answer is no, and Section 11(b) is the provision that demonstrates it.

Part III. Legislative opposition

Research community

Objection. Scheduling by pharmacological class captures compounds nobody has studied, and registration burdens fall on the laboratories best positioned to characterize them. This is what stalled SITSA in the 115th and 116th Congresses.

Response. Section 11 is the answer and should be briefed first, not last. The bill applies HALT's registration procedures and then extends the 30-day expedited procedure past HALT's own IND and HHS/DoD/VA limits to universities, forensic laboratories, public health laboratories, medical examiners, and federally funded researchers. SITSA had nothing comparable. The reference-standard and reagent exemptions in Sec. 11(d) cover the transactions that actually generate laboratory complaints.

Residual exposure. The reagent quantity limit in Sec. 11(d)(3) is blank. Until it is filled, the exemption is unquantified and the objection stays live. Fill it before transmittal.

Harm reduction and public health

Objection. Class-wide prohibition displaces supply toward compounds that are less characterized and more lethal. The UK experience under the Psychoactive Substances Act 2016 is the cited evidence, and the bill itself asks GAO to make that comparison in Sec. 13(a).

Response. The bill does not criminalize possession (Sec. 401A(c), Sec. 14(a)(1)), sets Schedule III penalty levels with no mandatory minimums, and funds the forensic and toxicology capacity that detects displacement when it happens (Sec. 12). The displacement concern is an argument for the early-warning system, not against the control authority.

Honest concession. The displacement evidence is real and the bill does not refute it. Asking GAO to study it is the right posture, and claiming more invites a fight with the literature that the bill will lose.

Civil liberties organizations

Objection. Section 10 builds a domestic intelligence function around a public health problem, with administrative subpoenas to platforms and a three-year retention floor for irrelevant U.S.-person information.

Response. Sec. 10(e)(1) grants no collection authority and expressly disclaims FISA and E.O. 12333 expansion. Subpoenas reach non-content records only, now with a jurisdictional nexus. The Privacy Act applies. Revision 3 reduced the retention ceiling for irrelevant U.S.-person information to one year, which is the single cheapest concession in the bill and should be offered early rather than extracted.

Sentencing reform caucus

Objection. A new criminal category is a new criminal category, whatever the penalty level.

Response. No mandatory minimum, no possession offense, Schedule III exposure, and a knowledge element codified in Sec. 401A(d). The bill moves in the opposite direction from the last two decades of synthetic-drug legislation, which reached for Schedule I by default. That framing is accurate and should be used.

Online marketplaces and platforms

Objection. Section 8(c), and especially the Section 230 override it now needs, is FOSTA by another name.

Response. The knowledge element added in revision 3 is the distinction: liability requires knowing the substance is controlled, not merely hosting a listing. The ten-business-day safe harbor is longer than most takedown regimes. Expect this to be the hardest-fought provision once the override is added, and plan to trade on penalty amount rather than on the knowledge element.

FDA and HHS equities

Objection. A ten-day comment window under Sec. 4(4) is not consultation, and the bill routes a scientific judgment through the Attorney General.

Response. The structure mirrors existing 811(h), where HHS consultation is also non-blocking. The bill adds nothing to the Attorney General's primacy that current law does not already provide.

Residual exposure. This is a genuine interagency friction point and HHS may seek a longer window or a concurrence requirement. A fifteen-day window is a reasonable fallback and does not meaningfully slow the authority.

Cost

No appropriations figures are filled (Secs. 10(f), 12(e)), so CBO cannot score it. Grants under Sec. 12(a), published reference spectra under Sec. 12(c), and the fusion function are all new spending. Supply figures before transmittal or expect the score to be the first question.

Part IV. What to concede, what to hold

Concede early. The retention period in Sec. 10(e)(2). The HHS comment window. The marketplace penalty amount. Narrowing Sec. 7(a)(11) to the published list — the authority is recoverable through 811(k) orders, so the loss is procedural rather than substantive, and conceding it removes the bill's highest-risk provision.

Hold. Judicial review in Sec. 4(7), which is what makes the delegation defensible. The knowledge elements in Sec. 401A(d) and Sec. 7(b). The no-possession-offense rule, which is the bill's principal distinction from prior synthetic-drug legislation. Section 11 in full — trading away the research pathway recreates the condition that killed SITSA.

Do not trade. The 802(6) amendment in Sec. 5(e) and the 2516 amendment in Sec. 5(f). Both look technical and together carry every title 18 predicate in the bill. Likewise the Schedule I treatment in Sec. 11(b): without it the research pathway does not operate.

Part V. Questions to expect in a staff briefing

Why not just use 811(h)? Because it reaches one substance at a time with 30 days' notice, and because it denies judicial review. The bill's class authority is the point, and the review provision is what makes the class authority survivable.

Does this reopen HALT? No. Section 11 applies HALT's procedures without amending them.

What happens to an existing researcher when a substance is controlled? 21 U.S.C. 822(h), incorporated by Sec. 11(a)(4), lets the research continue if an application is filed within 90 days.

Who decides whether a compound is in the class? The Attorney General, on a record subject to substantial-evidence review in the D.C. Circuit, with the determination published within 30 days under Sec. 201(k)(6)(C).

Is simple possession a crime? No. Sec. 401A(c) and Sec. 14(a)(1).

What is the Section 230 answer? Sec. 8(c)(4) overrides it expressly, on the FOSTA model. Do not brief that provision without the knowledge element in 8(c)(1); the override is not defensible on its own.

Why three years rather than two? Because Sec. 202A(f) requires a transfer proceeding that 811(h) does not. If the committee prefers 2 plus 1, the bill still functions.

Has anything like the class authority been used? Once — the 2018 fentanyl-related substances order under 811(h), later made permanent by HALT. That precedent is the strongest practical argument that the authority is administrable and the strongest argument that it is rarely needed. Expect both.

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