INSTITUTIONAL DESIGN, DRUG POLICY, AND THE LIMITS OF ABSTRACTION

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INTRODUCTION

Professors Matthew Lawrence and David Pozen's *Drug Scheduling as Institutional Design*[1] is an ambitious and welcome intervention in the long-running debate over U.S. drug policy. The authors reconceptualize the Controlled Substances Act[2] (CSA) as a problem of institutional design.[3] This shift in analytic frame is timely and valuable. It invites scholars and policymakers to ask not merely where and how American drug law and policy have failed, but *why* its governing structures have proven persistently unable to successfully manage the complex, recurring tradeoffs inherent in regulating controlled substances.

The Article's core contribution lies in its effort to synthesize public law theory, administrative design, and contemporary drug policy reform into a single account. The authors' identification of three persistent obstacles — the prohibition problem, the pharma problem, and the pluralism problem — offers a useful vocabulary for understanding why drug regulation has resisted durable solutions despite decades of reform efforts.[4] Their call for "democratization without domination" in scheduling decisions[5] and "legalization without laissez faire" in drug markets[6] is an important corrective to reform movements that oscillate between punitive prohibition and unregulated commercialization.

This Response proceeds in a spirit of engagement rather than opposition. Lawrence and Pozen are to be commended for their scholarly framing. We share the authors' view that the CSA's failures cannot be explained solely by moral panics, bad science, punitive intent, or political opportunism, and that institutional design deserves far more sustained attention than it has historically received. At the same time, the

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[1] Matthew B. Lawrence & David E. Pozen, *Drug Scheduling as Institutional Design*, 139 HARV. L. REV. 849 (2026).

[2] Pub. L. No. 91-513, tit. II, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–904).

[3] Lawrence & Pozen, *supra* note 1, at 853.

[4] *See id.* at 853–54.

[5] *See id.* at 882–93.

[6] *See id.* at 893–903.

Article's proposed scheduling interventions invite deeper consideration of multifactorial realities that shape drug regulation and resulting practices on the ground. Workable pragmatic reform, as the authors note, is "problem-oriented [and] context-sensitive."[7] It requires a comprehensive understanding of downstream realities and the experiences of those most affected.

Engagement with existing interdisciplinary scholarship on clinical care under federal drug control regimes is warranted. This includes scholarship on pharmaceutical regulation; practitioner regulation (including prescribing, ordering, dispensing, and administering practitioners and entities); the segregated, triple-regulated federal regime governing opioid use disorder treatment; and clinical care more broadly.[8] So too, engagement with the experiences of people who use drugs, including attention to the harmful effects of stigmatizing language,[9] would enrich any such reform. A more robust exploration of harm reduction and agency authority in these contexts could further sharpen the focus on the institutional dynamics that bear on the persuasiveness of the authors' reform proposals.

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[7] *Id.* at 882.

[8] A thicker examination of clinician decisionmaking processes, pressures, and powers is warranted. So too, are a more precise engagement with current medical criteria for substance use disorders (SUD) (of which "addiction" represents only severe SUD), effective treatments (including those restricted by government intrusion in the clinical space), and the transition from drug use to SUD (for example, first use does not produce "dependence" under any definition of that term). *See, e.g.*, AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 816 (5th ed. 2013) [hereinafter DSM-5] (removing the words "abuse," "dependence," and "addiction" from the criteria); A. Thomas McLellan et al., *Preaddiction — A Missing Concept for Treating Substance Use Disorders*, 79 JAMA PSYCHIATRY 749, 749–51 (2022) ("Among those who initiate alcohol or other drug use, progression to serious SUD is not common. When it does occur, the progression is rarely linear or rapid, usually following years of harmful misuse that by itself is a serious personal and public health threat." *Id.* at 749 (footnote omitted)).

[9] Language shapes attitudes, and the harms of stigmatizing language in the media, scholarly discourse, and the legal system are well documented. *See, e.g.*, Alene Kennedy-Hendricks et al., *Social Stigma Toward Persons with Prescription Opioid Use Disorder: Associations with Public Support for Punitive and Public Health–Oriented Policies*, 68 PSYCHIATRIC SERVS. 462, 467 (2017) (finding positive correlations between stigma and endorsement of punitive and surveilling interventions); Kelly M. Socia et al., *Focus on Prevention: The Public Is More Supportive of "Overdose Prevention Sites" Than They Are of "Safe Injection Facilities,"* 20 CRIMINOLOGY & PUB. POL'Y 729, 732 (2021) (explaining that "certain labels may be more likely to invoke the powerful stigma against people who use drugs, and that strategic communication approaches could increase public support for evidence-based interventions"); Sarah E. Wakeman, *The Language of Stigma and Addiction*, *in* THE STIGMA OF ADDICTION 71, 72–78 (Jonathan D. Avery & Joseph J. Avery eds., 2019) (reviewing the literature connecting patient harm to language use). *See generally* Stacey A. Tovino, *Stigma in the Statute: When the Language of the Law Injures*, 64 WM. & MARY L. REV. 783 (2023) (exploring the expressive function of laws with stigmatizing language about alcohol use disorder). We try to adhere to non-stigmatizing language in our Response. *See generally* Ramez Bathish et al., Editorial, *Guiding Principles for Breaking Down Drug-Related Stigma in Academic Writing*, INT'L J. DRUG POL'Y, Sep. 2024, art. 104515, at 1 (providing principles for and examples of such language).

Our aim here is not to contest the Article's central framework. Rather, we seek to identify several context-dependent areas that bear on the ultimate success of the suggested reforms and the Article's institutional account — especially for readers less familiar with the operational details at the intersection of drug law and health regulation. The Parts that follow elaborate these considerations.

Part I situates the Article's institutional design framework within a broader interdisciplinary literature and examines the demands that a pragmatic institutional approach imposes, emphasizing the need for grounding in the operational complexity of contemporary drug regulation. Part II clarifies the distribution of authority among federal agencies and why those allocations matter for scheduling reform. Part III turns to practitioners and enforcement dynamics, exploring how prescribing regulation and criminal enforcement shape the institutional environment in which reform would operate. Part IV considers opioid treatment programs and harm reduction as institutional case studies, particularly regarding proposed Schedule A, and Part V assesses whether the Article's proposed reforms constitute structural redesign or incremental layering within the CSA framework.

I. Institutional Design as a Frame and the Demands of Pragmatism

The Article's reconceptualization of drug policy as a failure of institutional design is both productive and overdue. By treating the CSA as a governance architecture rather than just a classificatory regime, Lawrence and Pozen help shift the conversation away from substance-specific debates and toward structural questions about authority, accountability, and regulatory capacity. This move is particularly valuable in a policy domain where repeated reform efforts often focus on correcting individual scheduling decisions without interrogating the institutional machinery that produces them.[10] Lawrence and Pozen's approach is admirable. At the same time, additional institutional dynamics complicate their conclusions and deserve sustained attention, including the operational realities in areas such as prescribing regulation, harm reduction, and pharmaceutical oversight. This would clarify how the Article's institutional design proposals would interact with entrenched systems rather than sit alongside them in abstraction.

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[10] *See* Lawrence & Pozen, *supra* note 1, at 851–52, 852 n.8.

The institutional design lens has a longer and broader lineage than the Article's framing sometimes suggests.[11] Scholars in public policy,[12] public health,[13] history,[14] criminology,[15] sociology,[16] and related fields have examined how institutional arrangements shape drug policy outcomes.[17] Along with interdisciplinary legal scholars,[18] this work interrogates the CSA's scheduling framework as an institutional mechanism rather than a neutral scientific taxonomy and the interactions between enforcement dynamics, professional regulation, prescribing law,

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[11] *See id.* at 852 (contending that "[a]ll but absent from the literature . . . is theory in the 'middle range' that interrogates the structure and assumptions of the CSA's governance model" (footnote omitted)).

[12] *See, e.g.*, Kenneth J. Meier & Kevin B. Smith, *Say It Ain't So, Moe: Institutional Design, Policy Effectiveness, and Drug Policy*, 4 J. PUB. ADMIN. RSCH. & THEORY 429, 431 (1994) (discussing the political problem, explaining that "[m]ost federal bureaucracies are generally responsive to political institutions, although the degree of responsiveness varies. Factors that affect responsiveness include expertise, political support, and leadership, among others. Few agencies, however, are as responsive as the Drug Enforcement Administration because the DEA's structure enhances responsiveness." (citations omitted)); Thomas Savidge, *The Concentration of Power in a Single Hand: Administrative Centralization and State and Local Drug Enforcement Policy in the United States, 1995–2016*, 34 J. PRIV. ENTER. 65, 65 (2019).

[13] *See, e.g.*, Joseph Brian Tay Wee Teck & Alexander Baldacchino, *Why Do Different Forms of Knowledge Matter in Evidence-Based Drug Policy?*, 112 AM. J. PUB. HEALTH 140, 141 (2022).

[14] *See, e.g.*, David T. Courtwright, *The Controlled Substances Act: How a "Big Tent" Reform Became a Punitive Drug Law*, 76 DRUG & ALCOHOL DEPENDENCE 9, 10–11, 13–14 (2004) (analyzing the ways institutional forces, including political and administrative actors, influenced the evolution of the CSA and using a historical lens to detail the trajectory of CSA amendments that expanded the criminal reach, including across racial lines, while de-emphasizing and segregating treatment). *See generally* ARTHUR A. DAEMMRICH, PHARMACOPOLITICS: DRUG REGULATION IN THE UNITED STATES AND GERMANY (2004) (using an institutionalist perspective to describe what he refers to as therapeutic cultures in the United States and Germany focusing on political structure, pharmaceutical and insurance industries, and medical practice).

[15] *See, e.g.*, Joseph F. Spillane, *Debating the Controlled Substances Act*, 76 DRUG & ALCOHOL DEPENDENCE 17, 27 (2004) (examining the history of the CSA, including the political, social, and agency dynamics that impacted scheduling decisions and assessments of abuse liability).

[16] *See, e.g.*, Elizabeth Chiarello, *The War on Drugs Comes to the Pharmacy Counter: Frontline Work in the Shadow of Discrepant Institutional Logics*, 40 LAW & SOC. INQUIRY 86, 87 (2015).

[17] *See generally, e.g.*, ALISON RITTER, DRUG POLICY (2021) (examining drug policy formation across public health, sociology, criminology, and political science as a complex, institutionally embedded domain shaped by actors, ideas, and networks of policy advocates).

[18] For an overview of such scholarly work, see generally, for example, Stacey A. Tovino, *Tele-Induction of Buprenorphine for Opioid Use Disorder: Regulatory Flux and Public Confusion*, 93 FORDHAM L. REV. 535 (2024); Jennifer D. Oliva & Taleed El-Sabawi, *The "New" Drug War*, 110 VA. L. REV. 1103 (2024); Jennifer D. Oliva, *Policing Opioid Use Disorder in a Pandemic*, U. CHI. L. REV. ONLINE (2020), https://lawreview.uchicago.edu/online-archive/policing-opioid-use-disorder-pandemic [https://perma.cc/677J-G8TZ]; Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. KAN. L. REV. 961 (2019) [hereinafter Dineen, *Definitions Matter*]; Scott Burris et al., *Toward Healthy Drug Policy in the United States — The Case of Safehouse*, 382 NEJM 4 (2019); Leo Beletsky & Jeremiah Goulka, *The Opioid Crisis: A Failure of Regulatory Design and Action*, 34 CRIM. JUST. 35 (2019); Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7 (2016); and Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 LAW & PSYCH. REV. 1 (2016).

reimbursement structures, and public health interventions. Admittedly, many of these scholars have not used the "institutional design" or institutionalism label, but have nonetheless explored precisely the kinds of questions the Article raises: how regulatory authority is allocated, how agencies interact, and how institutional incentives shape behavior across markets and professions.[19]

Greater engagement with this work would strengthen the Article's claim to offer a "middle range" theory of drug regulation[20] by situating it within an already robust, if fragmented, body of institutional analysis. Recognizing this broader scholarly landscape would not diminish the Article's originality. Instead, it would underscore the distinctive contribution that public law analysis brings to an interdisciplinary conversation that has often proceeded without sustained engagement from constitutional and administrative law scholars.

Additionally, the authors describe their approach as pragmatic, emphasizing practicality, pluralism, and empirically informed experimentation over abstract principles.[21] This orientation is especially appealing in the drug policy context, where moral absolutism and technocratic overconfidence have produced significant harms.[22] The Article's resistance to both prohibitionist idealism and deregulatory fatalism is among its most important contributions.

Pragmatism, however, imposes demanding obligations on institutional analysis. It demands attention not only to normative coherence but also to implementation pathways, bureaucratic incentives, and political durability. Reform proposals must be evaluated not only for conceptual coherence, but also for how they would operate within the existing legal, clinical, and political landscape. That landscape spans

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[19] *See, e.g.*, LEO BELETSKY, ARIZ. STATE UNIV. ACAD. FOR JUST. & OHIO STATE UNIV. DRUG ENF'T & POL'Y CTR., CONTROLLED SUBSTANCES ACT AT 50: A BLUEPRINT FOR REFORM 1 (2020), https://law.asu.edu/sites/g/files/litvpz156/files/pdf/academy_for_justice/csa_at_50_blueprint.pdf [https://perma.cc/K7AA-BGCY] (pointing out that "[v]igorous critiques of the CSA's structure and function are as old as the Act itself").

[20] Lawrence & Pozen, *supra* note 1, at 852.

[21] *Id.* at 853, 855, 879, 881–84, 887, 890, 893–94, 897, 899, 903–04, 906–07, 913 (all mentions of the word "pragmatic" or its variants in the Article).

[22] *See, e.g.*, Aliza Cohen et al., *How the War on Drugs Impacts Social Determinants of Health Beyond the Criminal Legal System*, 54 ANNALS MED. 2024, 2025 (2022) (arguing that drug-war "logic" embedded in institutions exacerbates social and health harms); Julia Dickson-Gomez et al., *The Effects of Opioid Policy Changes on Transitions from Prescription Opioids to Heroin, Fentanyl and Injection Drug Use: A Qualitative Analysis*, SUBSTANCE ABUSE TREATMENT, PREVENTION & POL'Y, Dec. 2022, art. 55, at 10 (reporting "unintended harms" from policy changes limiting prescribing and diversion, including accelerated transitions to heroin/fentanyl); Mark C. Bicket et al., *Unintended Consequences from the 2016 US Centers for Disease Control and Prevention Guideline for Prescribing Opioids — Accelerating Change in Postoperative Prescribing*, JAMA NETWORK OPEN, June 2021, art. e211997, at 1 (describing concern about misapplication of evidence-based prescribing guidance and resulting patient harms); Andrew D. Hathaway, *Shortcomings of Harm Reduction: Toward a Morally Invested Drug Reform Strategy*, 12 INT'L J. DRUG POL'Y 125, 125 (2001).

federal, state, and even local law;[23] deploys criminal, administrative, and civil enforcement mechanisms;[24] and encompasses pharmaceutical regulation, health care delivery,[25] professional oversight, consumer protection, and public health promotion. These overlapping domains are further shaped by market incentives, enforcement cultures, and social norms that vary widely across substances and settings.[26]

Because the Article seeks to address these domains simultaneously, it necessarily moves quickly across them, at times leaving key institutional dynamics underdeveloped. This is not a critique of ambition — indeed, the project's breadth is one of its strengths. But some of the proposed reforms would be more persuasive if the analysis more precisely drew on existing research and practice to demonstrate concretely how existing and proposed regulatory structures function.

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[23] *See, e.g.*, Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 849 (2017); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1844 (1996).

[24] *See, e.g.*, Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801–971); Gonzales v. Raich, 545 U.S. 1, 5 (2005); Robert A. Mikos, *On the Limits of Supremacy: Medical Marijuana and the States' Overlooked Power to Legalize Federal Crime*, 62 VAND. L. REV. 1421, 1438–40 (2009).

[25] Some of the discussions of clinical and public health information would benefit from additional nuance. For example, the language of physiologic and psychological dependence is not consistent with current medical criteria — at least not for the last thirteen years. *See, e.g.*, Deborah S. Hasin et al., *DSM-5 Criteria for Substance Use Disorders: Recommendations and Rationale*, 170 AM. J. PSYCHIATRY 834, 835–36 (2013) (explaining the removal of dependence from the DSM-5 criteria for substance use disorder); Elizabeth Pendo & Jennifer D. Oliva, *Disability Discrimination by Clinical Algorithm*, 103 N.C. L. REV. 187, 194 (2024) (describing the harms of failing to "appropriately distinguish between drug dependence, which is a normal physiological response, and SUD"); Maia Szalavitz et al., *Drug Dependence Is Not Addiction — And It Matters*, 53 ANNALS MED. 1989, 1990 (2021) (explaining that "physical dependence is an ordinary biological consequence of taking certain medications for weeks or years — while addiction is continued drug use that persists in the face of negative experience"). Similarly, the idea that the "first use" of a controlled substance alone can be "habit-forming" is inaccurate. *See, e.g.*, Nora D. Volkow & Carlos Blanco, *Substance Use Disorders: A Comprehensive Update of Classification, Epidemiology, Neurobiology, Clinical Aspects, Treatment and Prevention*, 22 WORLD PSYCHIATRY 203, 204 (2023) (reviewing the complex factors that contribute to repeated and escalating use and development of SUD). Likewise, treating "dependence" on non-controlled substances — such as antidepressants and anticonvulsants — as de facto problematic lacks necessary context (including the medical criteria for use and the many non-economically motivated reasons for shifts in prescribing trends). Similarly, describing the "opioid crisis" as primarily triggered by pharmaceutical companies ignores the many converging forces that contributed to what was always multiple, overlapping public health and polysubstance use crises. *See, e.g.*, Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 183–84 (2018).

[26] *See* Jonathan P. Caulkins & Peter Reuter, *How Drug Enforcement Affects Drug Prices*, 39 CRIME & JUST. 213, 215 (2010) (analyzing how enforcement intensity and market incentives interact differently across substances); DAVID T. COURTWRIGHT, FORCES OF HABIT: DRUGS AND THE MAKING OF THE MODERN WORLD 2–3 (2001) (providing a well-regarded social history showing how social and cultural norms shape drug policy and regulatory approaches across different substances and eras).

II. Agency Roles and the Architecture of Drug Regulation

"Effective institutional design requires an understanding of how bureaucracies operate and why they act,"[27] and additional specificity in several interagency dynamics is useful in considering Lawrence and Pozen's institutional design lens. First, drug regulation reaches beyond scheduling, and substantial regulatory authority over both scheduled and unscheduled substances resides outside the Drug Enforcement Agency (DEA). Additional attention to the respective roles of the DEA, the DOJ, Health and Human Services (HHS), the FDA, and the FTC would significantly bolster the Article's institutional analysis. Second, while the Article appropriately centers the CSA's scheduling regime and the DEA's authority within it, the degree and scope of the DEA's expertise is overstated, and the extent to which scheduling criteria diverge from established scientific standards is understated. Third, greater precision is warranted in describing the joint DEA–HHS scheduling process, which bears directly on the Article's claims about democratization, expertise, and political accountability. Clarifying how authority is allocated — and contested — across agencies would not weaken the Article's critique. Instead, it would sharpen the institutional account by situating reform proposals within the actual architecture of interagency power.

A. Overlapping Federal Authority and the Centrality of the FDA

The FDA plays the primary regulatory role in drug approval, labeling, marketing, and post-market surveillance in enforcing the Federal Food, Drug, and Cosmetic Act[28] (FDCA). Its authority extends to many (if not most) of the market practices that the Article seeks to regulate more aggressively, including advertising and detailing by pharmaceutical manufacturers. In that area, the FDA shares authority with the FTC, which exercises consumer protection and competition authority relevant to drug markets, including deceptive marketing and unfair trade practices.[29] Subject to evolving First Amendment constraints on commercial speech,[30] the FDA — together with the FTC — are institutionally better

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[27] Meier & Smith, *supra* note 12, at 431.

[28] 21 U.S.C. §§ 301–399. The FDCA governs manufacture and distribution of medications in the United States. *See id.* §§ 351–360.

[29] *See, e.g.*, FTC, Health Products Compliance Guidance 3 (2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf [https://perma.cc/P34V-5SY4]; FTC, MOU 225-71-8003, Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration (1971), https://www.ftc.gov/legal-library/browse/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug-administration [https://perma.cc/N7AC-694S].

[30] *See, e.g.*, Coleen Klasmeier, *FDA, Medical Communications, and Intended Use — A New Challenge to First and Fifth Amendment Constraints on Government Power*, 78 Food & Drug L.J. 263, 264 (2023); Jennifer L. Pomeranz et al., *Regulating Direct-to-Consumer Prescription Drug Advertising in the United States*, 104 Milbank Q. 13, 17 (2026).

positioned to address the pharmaceutical marketing dynamics at the core of the pharma problem. A more sustained engagement with these agencies' existing powers — and with the administrative and constitutional law governing their actions[31] — would clarify the promise and the limits of the Article's proposed reforms, especially in addressing the pharma problem.

The FDA likewise shares authority with the DEA over pharmaceutical products that are controlled substances.[32] The FDA determines — subject to established safety and effectiveness standards and ongoing post-market review — whether such products enter or remain on the market and under what conditions.[33] In exercising that authority, the FDA establishes the scientific criteria for and conditions of continued approval. These include whether a drug is limited to "prescription only" status;[34] the content and form of the drug's label and labeling;[35] required warnings;[36] and the imposition of risk evaluation and mitigation strategies (REMS).[37] Many controlled substances are subject to REMS,[38] which require additional assessments of potential risks and benefits and impose additional conditions, such as practitioner and pharmacy

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[31] *See, e.g.*, United States v. Caronia, 703 F.3d 149, 162 (2d Cir. 2012); Nat'l Inst. of Fam. & Life Advocs. v. James, 160 F.4th 360, 375 (2d Cir. 2025); Thompson v. W. States Med. Ctr., 535 U.S. 357, 377 (2002).

[32] States have individual versions of the CSA and FDCA, as well as other laws that impact controlled substances access and use. The treatment of SUD involves additional layers of federal regulation with state counterparts. *See infra* Part IV, pp. 256–61. Despite the benefits of relaxing federal law to improve access to care, doing so instigates a cascade of confusion at the state level where laws are rarely subject to preemption. *See* Robert A. Mikos, *Preemption Under the Controlled Substances Act*, 16 J. HEALTH CARE L. & POL'Y 5, 8 (2013). For examples, see Stacey A. Tovino, *Dialing In or Dialing Out? The Relationship Between State Telemedicine Law and Access to Buprenorphine*, 12 TEX. A&M L. REV. 1595, 1615–53 (2025), and Jennifer D. Oliva, *Decriminalizing Cannabis*, 134 YALE L.J.F. 942, 948–49 (2025).

[33] For an excellent explanation of the process, see Patricia J. Zettler et al., *Implementing a Public Health Perspective in FDA Drug Regulation*, 73 FOOD & DRUG L.J. 221, 230–35 (2018).

[34] 21 U.S.C. § 353(b)(1) (a drug may require prescription only status "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use").

[35] *Id.* § 321(k), (m) (defining "label" and "labeling"); *id.* § 825 (describing labeling requirements for controlled substances).

[36] *Id.* § 352(a), (f) (requiring adequate warnings and directions for use as a condition of lawful marketing); 21 C.F.R. § 201.57 (2023) (establishing FDA requirements for prescription drug labeling, including warnings and precautions).

[37] 21 U.S.C. § 355-1.

[38] *See, e.g.*, FDA, *Approved Risk Evaluation and Mitigation Strategies (REMS): Opioid Analgesic REMS* (May 20, 2025), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm [https://perma.cc/3JHH-HLM4].

certification and training,[39] manufacturer obligations,[40] restricted dispensing settings,[41] and patient monitoring and tracking.[42]

Although not without shortcomings, the FDA's legal requirements and regulatory standards are generally grounded in data-driven scientific criteria.[43] The agency is staffed by highly credentialed scientific and medical experts — which the Article may be too quick to characterize as too insulated from practical experience to address the pluralism problem.[44] Particularly in the context of controlled substances policy, some isolation from the effects of entrenched structural discrimination against people who use drugs might be beneficial — especially when combined with expertise in considering many kinds of evidence.[45]

In fact, the FDA (along with other entities within HHS) has the capacity to address the authors' concerns around rigid empiricism.[46] Unlike the DEA, the FDA already considers less easily quantifiable data — in other words, "real world evidence."[47] The agency has done so under complex conditions, including its consideration of controlled substances.[48] Similarly, the FDA and other HHS entities have specifically considered evidence beyond what is required for drug approval,

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[39] 21 U.S.C. § 355-1(f)(3)(A), (B) (authorizing FDA to require additional practitioner training and certification for pharmacies, practitioners, or health care settings).

[40] *Id.* § 355-1(f)(3), (g)(4) (authorizing FDA to require implementation systems to monitor and evaluate compliance with elements to assure safe use (ETASU), including manufacturer responsibilities). For example, manufacturers of opioid analgesics are now required to provide pre-paid mail back packages for safe disposal. *See* Opioid Analgesic REMS Program Cos., Dear Professional Society/Licensing Board Letter #1: FDA-Required REMS for Serious Drug Risks, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2025_05_30_Professional_Society_Licensing_Board_Letter_1.pdf [https://perma.cc/R3MV-FQRJ].

[41] 21 U.S.C. § 355-1(f)(3)(C) (authorizing FDA to require that a drug "be dispensed to patients only in certain health care settings, such as hospitals").

[42] *Id.* § 355-1(f)(3)(E) (authorizing FDA to require that "each patient using the drug be subject to certain monitoring").

[43] *See, e.g.*, Zettler et al., *supra* note 33, at 234–35.

[44] Lawrence & Pozen, *supra* note 1, at 874.

[45] *See infra* section II.B, pp. 247–51.

[46] Lawrence & Pozen, *supra* note 1, at 874–77.

[47] *See, e.g.*, 21st Century Cures Act, Pub. L. No. 114-255, § 2022, 130 Stat. 1096 (codified at 21 U.S.C. § 355g) ("'real world evidence' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources *other than randomized clinical trials*" and includes, but is not limited to, "ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities" (emphasis added)).

[48] For example, in 2019, the FDA issued safety warnings and required label changes after receiving multiple case reports of harm ranging from withdrawal symptoms to suicide after abrupt or too rapid discontinuation of prescription opioids. *See FDA Identifies Harm Reported from Sudden Discontinuation of Opioid Pain Medicines and Requires Label Changes to Guide Prescribers on Gradual, Individualized Tapering*, FDA (Apr. 9, 2019), https://web.archive.org/web/20260118050243/https:/www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes [https://perma.cc/MY4F-Z4C5]; *see also* Zettler et al., *supra* note 33, at 236–39 (describing the agency's capacity to weigh public health data, including harms that extend beyond individual patients).

including in scheduling decisions.[49] By contrast, the DOJ and the DEA possess comparatively limited scientific and health-focused infrastructure[50] — understandably so for institutions designed for law enforcement narrowly focused on market controls, often at the expense of population health and other benefits.[51] Yet, despite the breadth of the FDA's scientific expertise and public health mandate,[52] the DEA controls ultimate scheduling determinations.[53] This is the principal exception to the FDA's regulatory authority over drug products,[54] and it is consequential, in part, because unlike the DEA, the FDA considers both benefits and harms of drugs[55] — including many kinds of evidence that the authors worry go unaddressed and contribute to the pluralism problem.[56]

We also question whether the health risks of controlled substances are uniquely difficult to evaluate[57] or whether such a suggestion is merely another form of drug exceptionalism. While some drugs, especially botanicals and drugs not legally manufactured, have variable effects,[58] this does not render them insusceptible to systematic

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[49] *See, e.g.*, Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597, 44616–17 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

[50] *See* Taleed El-Sabawi, *Why the DEA, Not the FDA? Revisiting the Regulation of Potentially-Addictive Substances*, 16 N.Y.U. J.L. & BUS. 317, 342 (2020).

[51] *See, e.g.*, Mason Marks, *Separation of Drug Scheduling Powers*, 134 Yale L.J.F. 976, 981–82 (2025); Dineen & DuBois, *supra* note 18, at 26–27; Bridget C.E. Dooling & Laura E. Stanley, *Methadone's Regulatory Thicket*, 32 ANNALS HEALTH L. & LIFE SCI. 191, 215 (2023) (describing the DEA's "evaluation process [a]s inherently subjective" and explaining that, regarding the DEA's use of data, "[t]here is no bright line . . . to delineate what counts as 'abuse' such that a substance must be controlled in a particular manner").

[52] *See* Oliva & El-Sabawi, *supra* note 18, at 1143 (explaining that "one of the hallmarks of the Nixonian War on Drugs was its delegation of final determinations about a drug's risk-benefit profile to a law enforcement agency — the DEA, whose primary mission is policing — and not to a scientific health agency staffed with pharmacological and toxicological experts").

[53] *See* 21 U.S.C. § 811(b); Oliva, *supra* note 32, at 958–59; Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. (Apr. 11, 2024) (slip op. at 4), https://www.regulations.gov/document/DEA-2024-0059-0004 [https://perma.cc/3PAF-SQRT] [hereinafter OLC Opinion]; *see also* Grinspoon v. DEA, 828 F.2d 881, 897 (1st Cir. 1987) (stating that the HHS Secretary's recommendations do not bind the DEA). And the DEA has been critical of health agencies' use of more "real world evidence." *See, e.g.*, Schedules of Controlled Substances: Rescheduling of Marijuana, *supra* note 49, at 44601, 44603, 44613 (criticizing at multiple points HHS's reliance, with admitted reservations, on descriptive studies).

[54] HASSAN Z. SHEIKH, CONG. RSCH. SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 1 (2018).

[55] *See* 21 U.S.C. § 355(d); United States v. Rutherford, 442 U.S. 544, 555 (1979); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 621–22 (1973). By contrast, DEA scheduling decisions under the Controlled Substances Act focus on abuse potential and related public health risks rather than therapeutic risk–benefit balancing. *See* 21 U.S.C. § 811(c).

[56] *See supra* note 18 and accompanying text.

[57] *See* Lawrence & Pozen, *supra* note 1, at 875.

[58] *See generally* CARL HART, DRUG USE FOR GROWN-UPS: CHASING LIBERTY IN THE LAND OF FEAR (2021) (drawing on neuropsychopharmacological research to argue that the variable and dangerous effects of unregulated drugs derive primarily from inconsistent potency, adulteration, and unknown composition rather than inherent pharmacological properties).

evaluation.[59] All drugs, controlled and uncontrolled, have effects that vary by person, place, and setting.[60] That psychedelics, for example, have a broad range of variability, does not make their effects impenetrable by the FDA — in fact, the FDA has provided express guidance on this issue.[61] And the idea that some drugs currently in use are too dangerous to evaluate is unpersuasive as well.[62] Of the available options, a health agency is better suited than a law enforcement agency to supervise scheduling. As other scholars have noted,[63] there are compelling reasons to consider expanding — rather than diminishing — the FDA's role in this domain, including its institutional orientation toward comprehensive evaluations and health-risk assessments.

B. Irrational Scheduling System and Processes

While health agencies are well equipped to evaluate drug benefits and risks, the scheduling criteria themselves are so problematic that any scheduling authority may struggle to make sense of them without institutional reform to those criteria.[64] While the authors note that scheduling criteria are "specifie[d] in some detail,"[65] they do not fully engage

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[59] In fact, HHS's recommendation to reschedule marijuana relies on the agency's broadening of the type of evidence it is willing to consider. *See* HHS, Basis for the Recommendation to Reschedule Marijuana into Schedule III of the Controlled Substances Act 2 (Aug. 29, 2023), https://www.regulations.gov/document/DEA-2024-0059-0006 [https://perma.cc/S4W8-7SM3].

[60] *See generally* HART, *supra* note 58.

[61] *See, e.g.*, Mason Marks & I. Glenn Cohen, *How Should the FDA Evaluate Psychedelic Medicine?*, 389 NEJM 1733, 1733 (2023).

[62] The authors use the fact that "[s]ome people have died of overdose the first time they tried heroin" to advance their point, Lawrence & Pozen, *supra* note 1, at 875, but that is true of most drugs on the illegal market because their strength and ingredients are unregulated and toxicity is common. *See* Leo Beletsky & Corey S. Davis, *Today's Fentanyl Crisis: Prohibition's Iron Law, Revisited*, 46 INT'L J. DRUG POL'Y 156, 156 (2017). In fact, pharmaceutical heroin is extremely effective for both pain control and SUD treatment, where it is used across Europe and Canada, among other countries. *See, e.g.*, Riley McNair et al., *Heroin Assisted Treatment for Key Health Outcomes in People with Chronic Heroin Addictions: A Context-Focused Systematic Review*, DRUG & ALCOHOL DEPENDENCE REPS., June 2023, art. 109869, at 2 (explaining that heroin assisted therapy "administered in supervised, clinical settings can be an effective treatment for long-term, refractory heroin addiction for people who have been unresponsive to standard forms of opioid substitution treatment"). Moreover, no drug is risk free, and many pharmaceutical drugs can cause death in some people. *See, e.g.*, Diane K. Wysowski, *Surveillance of Prescription Drug-Related Mortality Using Death Certificate Data*, 30 DRUG SAFETY 533, 539 (2007) (finding that drugs such as anticoagulants and antibacterials are among top causes of deaths involving pharmaceuticals).

[63] El-Sabawi, *supra* note 50, at 320–21; Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55, 60 (2003).

[64] *See* Kimani Paul-Emile, *Making Sense of Drug Regulation: A Theory of Law for Drug Control Policy*, 19 CORN. J.L. & PUB. POL'Y 691, 694–95 (2009) (describing drug regulation within particular analytic frames as unrelated to "whether the drug poses a threat to health or safety and *even if the regime placement decision flouts empirical evidence grounded in medicine or science*," *id.* at 695 (emphasis added)).

[65] Lawrence & Pozen, *supra* note 1, at 875.

with the system's irrationality.[66] In fact, the current distribution of scheduling authority consistently "produces . . . unscientific scheduling actions that contradict the CSA text, purpose, and history."[67]

The process is also self-reinforcing.[68] For example, in large part, scheduling decisions depend on the concept of "abuse,"[69] but abuse is not defined in the statute or regulations, and its meaning and the weight afforded to it vary widely in practice.[70] Two "indicators that a drug . . . has a potential for abuse," according to the DEA, are (1) "significant diversion . . . from legitimate drug channels" and (2) that "[i]ndividuals are taking the drug . . . on their own initiative rather than on the basis of medical advice."[71] Both are *created* by scheduling, which constricts access and predictably increases reliance on informal or "illicit" markets, including for therapeutic use. The foreseeable result — that individuals obtain substances without prescriptions or outside regulated supply chains — indicates "abuse" is a self-reinforcing loop justifying continued control, even when use is beneficial.[72] Because scheduling incentivizes behavior the DEA considers "abuse," a scheduled drug is rarely downscheduled or

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[66] *See id.* at 863 n.78 (quoting Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALBANY GOV'T L. REV. 332, 345 (2013); United States v. Pastor, 419 F. Supp. 1318, 1339 n.6 (S.D.N.Y. 1975)).

[67] Marks, *supra* note 51, at 980; *see also* Trevor Burrus, *The War on Drugs*, *in* CATO INST., CATO HANDBOOK FOR POLICYMAKERS 133, 135 (9th ed. 2022), https://www.cato.org/cato-handbook-policymakers/cato-handbook-policymakers-9th-edition-2022/war-drugs [https://perma.cc/XXW5-K46S] ("The scheduling system is irrational and unscientific. Marijuana unquestionably has medical uses, yet it is in Schedule I. Heroin is used as a painkiller in dozens of countries, as well as in addiction treatment, yet it is Schedule I . . . .").

[68] The CSA requires consideration of eight factors for each drug: (1) "[i]ts actual or relative potential for abuse"; (2) "[s]cientific evidence of its pharmacological effect"; (3) "[t]he state of current scientific knowledge regarding the drug"; (4) "[i]ts history and current pattern of abuse"; (5) "[t]he scope, duration, and significance of abuse"; (6) "[w]hat, if any, risk there is to the public health"; (7) "[i]ts psychic or physiological dependence liability"; and (8) "[w]hether the substance is an immediate precursor of a substance already controlled under this subchapter." 21 U.S.C. § 811(c).

[69] Abuse determinations are explicitly required under three of the eight factors. *See id.* The DEA further uses four factors to evaluate abuse. *See* DEA, DRUGS OF ABUSE: A DEA RESOURCE GUIDE 8 (2020), https://sites.rutgers.edu/mat-coe/wp-content/uploads/sites/473/2021/11/DEA-Drugs-of-Abuse-Report-2020_Part1.pdf [https://perma.cc/5RGM-Q48M] [hereinafter DRUGS OF ABUSE].

[70] It was poorly conceptualized from the start and has been afforded disproportionate weight in decisions. *See* Spillane, *supra* note 15, at 23–24; Marks, *supra* note 51, at 993–94; Robert A. Mikos, *Marijuana and the Tyrannies of Scheduling*, 93 FORDHAM L. REV. 473, 480–81 (2024); Dooling & Stanley, *supra* note 51, at 215.

[71] DRUGS OF ABUSE, *supra* note 69, at 8. The other two factors are evidence of drug use "in amounts sufficient to create a hazard to their health or to the safety of other[s]" and, for new drugs, comparison to other drugs with "potential for abuse." *Id.*

[72] *See, e.g.*, Expansion of Buprenorphine Treatment via Telemedicine Encounter, 90 Fed. Reg. 6504, 6512 (Jan. 17, 2025) (to be codified at 21 C.F.R. pt. 1306, 42 C.F.R. pt. 12) (reaffirming its "mandate and commitment to detect and prevent the diversion of controlled substances, *regardless of the reason for diversion*" (emphasis added)); DRUGS OF ABUSE, *supra* note 69, at 8 (acknowledging that "[o]f course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse").

descheduled.[73] Upscheduling is far more common and usually privileges law enforcement goals of more control and less access to substances[74] — even those with proven benefits.[75]

And, as the authors note,[76] the scheduling framework excludes explicit consideration of benefits, much less any balancing of benefits against harms that might disrupt the cycle. Although there is potential to afford more weight to benefits, that potential is unrealized. Given the irrationality and one-sidedness of scheduling criteria and practices under the final control of the DEA, the idea of adding *additional schedules* gives us pause — especially in the absence of other significant reforms.

Relatedly, the Article's account of the joint DEA–HHS scheduling process[77] would be strengthened by greater institutional specificity. Although HHS's scientific and medical recommendations play a critical role,[78] they are binding on the DOJ only prior to the *initiation* of formal rulemaking.[79] Thereafter, those recommendations are entitled only to deference.[80] This distinction has proved consequential in recent rescheduling debates involving cannabis[81] and bears directly on the Article's claims regarding democratization, expertise, and political accountability. Clarifying these institutional relationships would not dilute the Article's critique of the current system. Rather, it would sharpen the analysis by demonstrating how authority is distributed — and

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[73] *See* Marks, *supra* note 51, at 996. There are limited exceptions. *See, e.g.*, Schedules of Controlled Substances: Removal of Fenfluramine from Control, 87 Fed. Reg. 78857, 78857–58 (Dec. 23, 2022) (to be codified at 21 C.F.R. pt. 1308) (moving the drug from Schedule IV to unscheduled). On the other hand, the DEA finds it easier to move drugs up on the schedule. For example, buprenorphine, in all its forms, was moved from Schedule V to Schedule III in 2002. *See* Oliva & El-Sabawi, *supra* note 18, at 1144 (noting that nothing notable had changed about the drug's toxicology between 1970 and 2002); *see also* Jonathan P. Caulkins et al., *Outcomes Associated with Scheduling or Up-Scheduling Controlled Substances*, INT'L J. DRUG POL'Y, May 2021, art. 103110, at 3 (charting several of the drugs that the DEA either newly scheduled or upscheduled between 1974 and 2014).

[74] *See* Marks, *supra* note 51, at 996.

[75] *See, e.g.*, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 11037, 11039 (Feb. 27, 2014) (to be codified at 21 C.F.R. pt. 1308) ("This proposed action was initiated by a petition to reschedule hydrocodone combination products (HCPs) from schedule III to schedule II of the CSA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of the HHS." (footnote omitted)).

[76] *See* Lawrence & Pozen, *supra* note 1, at 877, 892.

[77] *See id.* at 862–63.

[78] *See* 21 U.S.C. § 811(b). It is also worth noting that while the FDA plays a primary role, HHS's recommendations are formulated in consultation with several sub-agencies and divisions. *See, e.g.*, Memorandum of Understanding with the National Institute on Drug Abuse, 50 Fed. Reg. 9518, 9518–20 (Mar. 8, 1985).

[79] *See* Oliva, *supra* note 32, at 959; Grinspoon v. DEA, 828 F.2d 881, 897 (1st Cir. 1987); OLC Opinion, *supra* note 53, at 24.

[80] This has been DEA's interpretation of the statute since its inception. *See Grinspoon*, 828 F.2d at 897; OLC Opinion, *supra* note 53, at 24. Others have argued that, while the DEA dominates scheduling, HHS is more empowered to intervene in scheduling than it has done in practice. *See, e.g.*, Marks, *supra* note 51, at 980.

[81] *See, e.g.*, OLC Opinion, *supra* note 53, at 4.

contested — across agencies, and why institutional design reform must account for that distribution.

The authors propose shifting scheduling authority from the DEA back to the Attorney General.[82] In practical terms, this would relocate technical classification decisions from policing personnel to prosecutorial leadership — shifting authority within law enforcement rather than outside it.[83] They further characterize the relative political insulation of health agencies as a liability.[84] We are unpersuaded.

That argument insufficiently accounts for the long-standing structural project of stigmatizing certain drugs and the people who use — or are perceived to use — them,[85] and the degree to which this stigmatization continues to influence public perceptions and political motivations.[86] The Attorney General has historically been a central power broker in that project, and the DOJ and DEA occupy leadership roles within the institutional architecture of criminalization that not only establishes a self-justifying feedback loop for the agency,[87] but further constructs drugs and drug users as dangerous and deviant, often leveraging existing racial, disability, and other biases in framing and enforcing the CSA.[88] In turn, this structure reinforces discriminatory preferences that infect public attitudes and political will.[89] These attitudes shape decisionmaking across individual, institutional, and structural domains, fueling harmful — and at times deadly — laws, policies,

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[82] *See* Lawrence & Pozen, *supra* note 1, at 889.

[83] In other contexts, scholars have explored the problems in institutional design considering the disproportionate powers afforded federal prosecutors. *See, e.g.*, Rachel E. Barkow, *Institutional Design and the Policing of Prosecutors*, 61 STAN. L. REV. 869, 874 (2009) (in part exploring the vast powers and dual roles of prosecutors as a flawed institutional design).

[84] *See* Lawrence & Pozen, *supra* note 1, at 889.

[85] *See, e.g.*, Oliva & El-Sabawi, *supra* note 18, at 1126; Kelly K. Dineen & Elizabeth Pendo, *Engaging Disability Rights Law to Address the Distinct Harms at the Intersection of Race and Disability for People with Substance Use Disorder*, 50 J.L. MED. & ETHICS 38, 38 (2022).

[86] *See, e.g.*, Saba Rouhani et al., *Racial Resentment and Support for Decriminalization of Drug Possession in the United States*, PREVENTIVE MED., Oct. 2022, art. 107189, at 3 (finding positive correlations between racial resentment and opposition to drug decriminalization and identifying it as a political barrier to policy reform); Adam Dunbar, *Arguing for Criminal Justice Reform: Examining the Effects of Message Framing on Policy Preferences*, 39 JUST. Q. 1524, 1537 (2022).

[87] Many scholars have explored the self-reinforcing and self-justifying nature of criminal drug enforcement. *See, e.g.*, Oliva & El-Sabawi, *supra* note 18, at 1128.

[88] *See, e.g.*, *id.* at 1117–22; Khiara M. Bridges, *Race, Pregnancy, and the Opioid Epidemic: White Privilege and the Criminalization of Opioid Use During Pregnancy*, 133 HARV. L. REV. 770, 777 (2020); Kelly K. Dineen & Elizabeth Pendo, *Ending the War on People with Substance Use Disorders in Health Care*, AM. J. BIOETHICS, Apr. 2021, at 20, 21; Lawrence D. Bobo & Victor Thompson, *Unfair by Design: The War on Drugs, Race, and the Legitimacy of the Criminal Justice System*, 73 SOC. RSCH., 445, 460–62 (2006).

[89] *See, e.g.*, Oliva & El-Sabawi, *supra* note 18, at 1117–22; Kristin E. Schneider et al., *Political Partisanship and Stigma Against People Who Use Drugs in Opinions About Allocating COVID-19 Prevention Resources to Vulnerable Populations*, INT'L J. DRUG POL'Y, Sep. 2021, art. 103301, at 5; Lisa A. Kort-Butler et al., *Drug Use Stigma and Public Preferences for Public Health Versus Legal System Responses,* 55 J. DRUG ISSUES 611, 618 (2024); Kennedy-Hendricks et al., *supra* note 9, at 465.

and practices not only within the criminal legal system but also in health care, housing, employment, and other settings.[90] For the foreseeable future, political actors most responsive to public pressure are therefore more likely to reinforce, rather than dismantle, these dynamics. The DEA, in particular, has a pattern and practice of repeating and endorsing many long-standing punitive and stigmatizing approaches.[91] For these reasons, we do not believe reallocating authority to the Attorney General offers a meaningful corrective.

Of course, the status quo is likewise unsatisfactory, as the authors persuasively demonstrate. We commend them for looking beyond the binary of DEA versus FDA control.[92] Additional institutional configurations warrant consideration, including those suggested by other scholars.[93] As one illustration, recent rulemakings jointly issued by the DEA and HHS — or by divisions such as the Substance Abuse and Mental Health Services Administration — have resulted in final regulations reflecting greater attention to benefits and harm reduction than rules promulgated by the DEA alone.[94] These processes have also generated substantial public engagement and, in some instances, delayed implementation of enforcement-leaning regulations in ways that have benefited patients who rely on controlled substances for medical care.[95] The causal dynamics are complex and extend beyond dual-agency involvement. We offer this example simply as a starting point for the broader institutional inquiry that Lawrence and Pozen have helpfully initiated.

III. PRACTITIONERS, PRESCRIBING, AND ENFORCEMENT DYNAMICS

The Article's discussion of practitioners as gatekeepers within the CSA's regulatory scheme raises related issues where deeper engagement would strengthen the institutional account. Controlled substance prescribing is governed by a dense web of federal and state law, professional regulation, and enforcement practices. There is also a substantial

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[90] *See, e.g.*, Dineen, *Definitions Matter*, *supra* note 18, at 969–77; Oliva & El-Sabawi, *supra* note 18, at 1123–26.

[91] *See, e.g.*, Ifetayo Harvey, *Time to Abolish the DEA: Evaluating the Agency's Failures and Calling for Community Investments*, 93 FORDHAM L. REV. 423, 428–32 (2024).

[92] *See* Lawrence & Pozen, *supra* note 1, at 888–89.

[93] *See* Marks, *supra* note 51, at 980; Mikos, *supra* note 70, at 496.

[94] *See, e.g.*, Expansion of Buprenorphine Treatment via Telemedicine Encounter, 90 Fed. Reg. 6504, 6508 (Jan. 17, 2025) (to be codified at 21 C.F.R. pt. 1306, 42 C.F.R. pt. 12); *DEA and HHS Issue Final Telemedicine Rules for Buprenorphine Access*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Jan. 17, 2025), https://www.samhsa.gov/about/news-announcements/statements/2025/dea-and-hhs-issue-final-telemedicine-rule-for-buprenorphine-access [https://perma.cc/REB7-YAZU].

[95] *See, e.g.*, *DEA, HHS Delay Implementation of Buprenorphine Final Rule Until Dec. 31*, AM. HOSP. ASS'N (Mar. 21, 2025, at 14:52 ET), https://www.aha.org/news/headline/2025-03-21-dea-hhs-delay-implementation-buprenorphine-final-rule-until-dec-31 [https://perma.cc/UYP3-E5QS].

interdisciplinary literature examining how these legal structures shape clinician behavior, patient access, and public health outcomes.

Several points about practitioners merit particular attention. Centering physicians as the primary gatekeepers of the "flow of potentially addictive drugs"[96] both overstates their role and lacks important specificity for evaluating institutional design in this context. First, it underestimates the role of the DEA,[97] state law enforcement actors,[98] and an ecosystem of other gatekeepers (for example, manufacturers, distributors, third-party payors, health care institutions, and state-level cannabis markets) in managing the flow of drugs (both those within and outside of the pharmaceutical market).[99] Second, even at the practitioner-patient level, centering physicians ignores the significant role of other institutional forces and individuals in prescribing, dispensing, administering, and filling prescriptions for pharmaceutical controlled substances.[100] Two examples are illustrative: (1) pharmacists and

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[96] Lawrence & Pozen, *supra* note 1, at 855.

[97] For example, even in the pharmaceutical and research realm, the DEA sets the total number of Schedule I and II pharmaceuticals that enter the market through multiple quota requirements by drug class and schedule for aggregate production, individual manufacturing, and procurement quotas, with additional subcategorical quotas. *See* 21 C.F.R. § 1303.03–.04 (2023). The agency also sets quotas and establishes a variety of controls on listed chemicals — that is, chemicals used in the manufacturing of a controlled substance. *See* 21 C.F.R. § 1300.02(b) (2020) (defining listed chemical and list I and II chemicals); 21 C.F.R. § 1313.01–.57 (2016). The DEA also sets four types of quotas for total manufacturing and distribution of ephedrine, pseudoephedrine, and phenylpropanolamine. 21 C.F.R. § 1315.01–.62 (2023).

[98] Just one example of the power of state actors in controlling the flow of pharmaceutical controlled substances is through prescription drug monitoring programs. One of us, along with other scholars, has extensively studied these effects, either through explicit requirements or through the associated chilling effects. *See, e.g.*, Jennifer D. Oliva, *Dosing Discrimination: Regulating PDMP Risk Scores*, 110 CALIF. L. REV. 47, 74–80 (2022) (providing a comprehensive account of practitioner drug monitoring programs and how law enforcement has managed to embed a sweeping surveillance tool into everyday clinical care); Jennifer D. Oliva, *Expecting Medication Surveillance*, 93 FORDHAM L. REV. 509, 526–28 (2024) (explaining the use of law enforcement anti-diversion tools to surveil reproductive health care).

[99] *See generally, e.g.*, David A. Simon, *Gatekeeping Drugs*, 57 ARIZ. ST. L.J. 289 (2025) (identifying and analyzing the dual gatekeeping regime governing off-label pharmaceutical access involving both the FDA and the Centers for Medicare & Medicaid Services).

[100] For example, pharmacists are powerful gatekeepers of access after a prescription is issued. *See, e.g.*, Elizabeth Chiarello, *The War on Drugs Comes to the Pharmacy Counter: Frontline Work in the Shadow of Discrepant Institutional Logics*, 40 L. & SOC. INQUIRY 86, 98 (2015).

pharmacies,[101] and (2) third-party payors,[102] both of whom can and often do render meaningless the order or prescription by gatekeeping access.

Third, even as restricted to *prescribing* (or ordering) practitioners,[103] it fails to account for the many other practitioners with prescriptive authority and the practice settings for which the DEA's requirements are far from "ministerial" but instead require multiple registrations, heightened surveillance, tracking, and documentation that disincentivize appropriate care.[104] Physicians are but one of many practitioners (in the language of the CSA) authorized to prescribe or dispense controlled substances.[105] Physicians, dentists, veterinarians, podiatrists, advanced

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[101] Lauren Textor, Daniel Ventricelli & Shoshana V. Aronowitz, *"Red Flags" and "Red Tape": Telehealth and Pharmacy-Level Barriers to Buprenorphine in the United States,* 105 INT'L J. DRUG POL'Y, July 2022, art. 103703, at 2–5 (summarizing the literature on pharmacy gatekeeping of controlled drugs and conducting qualitative research with prescribing practitioners (physicians, physician assistants/associates (PAs), and Advanced Practice Registered Nurses (APRNs)), pharmacists, and patients and identifying numerous strategies employed by pharmacists and pharmacies to refuse filling buprenorphine prescriptions and reasons for refusals, including visceral fear of the DEA and state licensing boards).

[102] *See e.g.*, Dineen, *Definitions Matter*, *supra* note 18, at 968 (describing hard and soft edits employed by insurance companies to prevent patients from receiving prescribed controlled substances); Simon, *supra* note 99, at 294.

[103] There are important distinctions between ordering and prescribing, including in institutional settings and under regulations for opioid treatment programs. *See, e.g.*, 21 C.F.R. § 1306.07(a) (providing that a practitioner may administer or dispense directly (but not prescribe) a narcotic drug for "detoxification" or "maintenance treatment"); *id.* § 1306.07(b) (allowing practitioners without a separate special registration as an opioid treatment practitioner to administer or dispense (but not prescribe) a three-day supply of medication when necessary to relieve acute withdrawal symptoms).

[104] The DEA remains committed to erecting as many hurdles as possible to controlled substances prescribing and resists any efforts to expand access. For example, while Lawrence and Pozen point to the special registration provision in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), Pub. L. No. 110-425, 122 Stat. 4820 (codified in scattered sections of 21 U.S.C.), as a possible model, Lawrence & Pozen, *supra* note 1, at 897, in fact, the DEA has never actually created the category — despite not one, but two congressional mandates. Seventeen years after the Ryan Haight Act and seven years after the SUPPORT Act mandated the special registration category once again, Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894, 3950 (2018) (codified at 21 U.S.C. § 831(h)(2)), the DEA finally issued a *proposed rule* that would create the special registration category under the Ryan Haight Act, *see* Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6541 (proposed Jan. 17, 2025). That proposal has been widely criticized for creating extensive control and surveillance with little concern for access. *See, e.g.*, Letter from Ashley Thompson, Senior Vice President, Am. Hosp. Ass'n, to Derek Maltz, Acting Adm'r, DEA (Mar. 18, 2025), https://www.aha.org/lettercomment/2025-03-18-aha-comments-dea-proposed-rule-special-registrations-telemedicine-prescribing [https://perma.cc/RG7E-79ZV] (noting throughout that the proposal is oppressive and intrusive without justification and stating that the "proposed process would be inefficient and unnecessarily burdensome" and "recommend[ing] the agency adopt a more streamlined process . . . [that] would achieve the agency's crucial goal of mitigating diversion while minimizing excessive burdens on our already overtaxed clinical workforce").

[105] There are institutional practitioners (for example, hospitals, clinics, other entities excluding pharmacies), individual practitioners (for example, physicians, dentists, veterinarians, podiatrists), and mid-level practitioners. 21 C.F.R. § 1300.01(b) (defining individual, institutional, and mid-level

practice registered nurses (APRNs),[106] physician assistants/associates (PAs),[107] pharmacists,[108] and many others play critical roles,[109] often under distinct and more complex regulatory constraints. This is not a matter of minutia — each year, nonphysician practitioners with prescriptive authority occupy a larger slice of the workforce and fill important gaps in access to and quality of care across geographic regions and practice areas,[110] including the myriad conditions for which controlled substances are part of everyday standard-of-care practice.[111] But the state-level requirements and restrictions that apply to these prescribers are often more stringent and more variable by state than for their physician

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practitioners, the latter of which includes "an individual, other than a physician, dentist, veterinarian, or podiatrist, who is . . . [authorized by U.S. or state law], to dispense a controlled substance . . . . Examples . . . include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants . . . .").

106 For a general overview of the laws governing APRNs, see Benjamin J. McMichael & Sara Markowitz, *Toward a Uniform Classification of Nurse Practitioner Scope of Practice Laws* 4–5, 20–31 (Nat'l Bureau of Econ. Rsch., Working Paper No. 28192, 2023) http://www.nber.org/papers/w28192 [https://perma.cc/866E-JKUN]. Their role in controlled substances prescribing is also significant, with competing literature on specific prescribing patterns. *Compare, e.g.*, Lucas D. Cusimano & Nicole Maestas, *High-Risk Opioid Prescribing and Nurse Practitioner Independence*, JAMA HEALTH F., Dec. 2024, e244544, at 8 (finding no differences in opioid prescribing by nurse practitioners as compared to physicians after states expanded scope-of-practice laws); *with, e.g.*, M. James Lozada et al., *Opioid Prescribing by Primary Care Providers: A Cross-Sectional Analysis of Nurse Practitioner, Physician Assistant, and Physician Prescribing Patterns*, 35 J. GEN. INTERN. MED. 2584, 2586 (2020) (finding that APRNs and PAs prescribed fewer long-term opioids than do physicians but prescribed opioids at higher rates, with APRNs and PAs in independent practice states prescribing opioids at higher rates than do APRNs and PAs in other states).

107 The terminology of physician assistant is in transition to physician associate to better reflect the relationship between these practitioners and their ability to practice independently or semi-independently depending on state law. *See* Ben Blatt & Teddy Rosenbluth, *Physician Assistants Want a New Name and More Power. Not Everyone Is Happy.*, N.Y. TIMES (Feb. 10, 2026), https://www.nytimes.com/2026/01/31/upshot/physician-assistants-doctors-role.html [https://perma.cc/ZXL6-63P3] (describing the shift and noting that three states have changed the terminology under state law).

108 *See, e.g.*, Complete Care Pharmacy, LLC, 91 Fed. Reg. 3547 (Jan. 27, 2026) (DEA decision and order) (revoking the pharmacy's Certificate of Registration, in part, because it filled prescriptions issued by the managing pharmacist whose state prescriptive authority as a clinician-pharmacist had expired).

109 Depending on state law, mid-level prescribers include diverse practitioners such as psychologists, chiropractors, optometrists, and doctors of oriental medicine. *See Mid-Level Practitioner Authorization by State*, NEB. DEP'T HEALTH HUMAN SERVS. (2022), https://dhhs.ne.gov/licensure/Open%20Meeting%20Act%20Docs/APRN%205.20.22%20C1a%20DEA%20-%20Midlevel%20Pracitioners%20by%20State.pdf [https://perma.cc/C7EZ-432Y].

110 By 2019, over twenty-five percent of primary care for traditional Medicare enrollees was delivered directly (independently) by APRNs and PAs in the United States. *See* Sadiq Y. Patel et al., *Provision of Evaluation and Management Visits by Nurse Practitioners and Physician Assistants in the USA from 2013 to 2019: Cross-Sectional Time Series Study*, BMJ, Sep. 2023, e073933, at 6.

111 *See generally* Steve Waxman & James Dechene, *Expanding the Scope of Practice for Nurse Practitioners and Physician Assistants to Enhance Healthcare*, 33 ANNALS HEALTH L. & LIFE SCIS. 101 (2024) (documenting such conditions).

colleagues.[112] Any institutional design proposal that relies on professional gatekeeping would be more persuasive if it explicitly accounted for these differences and for the varied ways in which regulatory pressure is experienced across professional categories.

Fourth, the Article's suggestion that the DEA plays a limited role in shaping practitioner behavior is difficult to reconcile with enforcement patterns over the past several decades and empirical evidence of practitioner behavior.[113] DEA investigations, registrant revocations, and high-profile prosecutions have had a significant chilling effect on prescribing practices, particularly in pain management and addiction treatment.[114] Over many decades, the federal government investigated, charged, tried, and convicted prescribers under the CSA's felony drug distribution provision based on no more, and sometimes less, than a mental state of negligence.[115] The mere threat of legal sanction significantly shapes practice behavior and can lead to serious patient harms.[116] These enforcement dynamics complicate the Article's portrayal of medical discretion and underscore the need to integrate criminal enforcement realities into institutional design analysis.

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[112] *See, e.g.*, Eleanor Turi et al., *State Policies Restrict the Contributions of the Nurse Practitioner Workforce in Delivering Care to Patients with Substance Use Disorders*, 37 J. AM. ASS'N NURSE PRACS. 369, 370 (2025); Phillip Zhang & Preeti Patel, *Practitioners and Prescriptive Authority*, NAT'L LIBR. MED. (Nov. 13, 2023), https://www.ncbi.nlm.nih.gov/sites/books/NBK574557 [https://perma.cc/VZ99-BXF2].

[113] *See, e.g.*, Leslie W. Suen et al., Commentary, *Prescribing Psychostimulants for the Treatment of Stimulant Use Disorder: Navigating the Federal Legal Landscape*, 19 J. ADDICTION MED. 347, 348 (2025) (explaining that "actual or threatened investigations can have a chilling effect on clinicians' willingness to prescribe psychostimulants for StUD even when the risk of prosecution or other adverse outcomes is minimal"); Textor, Ventricelli & Aronowitz, *supra* note 101, at 2 ("Pharmacists may be disinclined to stock or dispense buprenorphine for fear of oversight from the Drug Enforcement Administration (DEA) or Boards of Pharmacy; some pharmacies have self-imposed buprenorphine restrictions to avoid triggering investigations." (citation omitted)); Cara L. Sedney et al., *"The DEA Would Come in and Destroy You": A Qualitative Study of Fear and Unintended Consequences Among Opioid Prescribers in WV*, SUBSTANCE ABUSE TREATMENT, PREVENTION & POL'Y, Mar. 10, 2022, art. 19, at 4–7.

[114] *See, e.g.*, Dov Fox, *Medical Disobedience*, 136 HARV. L. REV. 1030, 1037 (2023); Dineen, *Definitions Matter*, *supra* note 18, at 50–51.

[115] *E.g.*, Diane E. Hoffman, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231, 234–35 (2008); Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7, 21 (2016); Brief for Amicus Curiae National Pain Advocacy Center in Support of Petitioners at 16, Ruan v. United States, 142 S. Ct. 2370 (2022) (No. 20-1410); Brief of Amici Curiae Professors of Health Law and Policy in Support of Petitioner at 7–13, *Ruan*, 142 S. Ct. 2370 (No. 20-1410); Deborah Hellman, *Prosecuting Doctors for Trusting Patients,* 16 GEO. MASON L. REV. 701, 701 (2009). The decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022), was an important clarification that practitioner prosecution under 21 U.S.C. § 841(a)(1) requires knowledge (just as it does for other defendants). *See* Kelly K. Dineen Gillespie, Ruan v. United States*: "Bad Doctors," Bad Law, and the Promise of Decriminalizing Medical Care*, 2021–2022 CATO SUP. CT. REV. 271, 272, 289 (2022).

[116] *See, e.g.*, Dineen, *Definitions Matter*, *supra* note 18, at 963–64.

IV. Models of Reform, Layering, and the Meaning of "Fundamental Reassessment"

The Article's treatment of opioid treatment programs (OTPs) and harm reduction services illustrates the difficulty of using existing institutions as both cautionary examples and affirmative models. OTPs are described in opaque terms, and it is difficult to determine if the authors see them as access barriers, sites of regulatory capture resistant to reform, or otherwise.[117] They are, however, used as potential templates for newly proposed schedules permitting nonmedical use under tight controls,[118] which is difficult to square with the evidence of harms that have resulted from the overregulation of medical care (OTPs)[119] and the overcriminalization of drug use (harm reduction) in this context.[120]

OTPs operate at the intersection of medicine, criminal law, and administrative oversight, subject to extensive federal and state controls that exceed those applied to most other forms of health care delivery.[121] As a result, they provide a vivid example of how a health intervention can be nested within an enforcement-centered framework.[122] At the same time, they demonstrate that tightly regulated medicalization does not necessarily displace law enforcement authority; rather, it can

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117 Lawrence & Pozen, *supra* note 1, at 898–99.

118 *See id.* at 897–98.

119 Dineen, *Definitions Matter*, *supra* note 18, at 963–64.

120 Lawrence & Pozen, *supra* note 1, at 866–69.

121 *See* Lev Facher, *Rigid Rules at Methadone Clinics Are Jeopardizing Patients' Path to Recovery from Opioid Addiction*, STAT NEWS (Mar. 12, 2024), https://www.statnews.com/2024/03/12/methadone-clinics-rigid-rules-opioid-addiction-recovery [https://perma.cc/WSC8-UJDP]; 21 U.S.C. § 823(h); 42 C.F.R. pt. 8; J. Travis Donahoe et al., *Restrictive State Opioid Treatment Program Regulations Constrain Local Access to Methadone Maintenance Treatment*, 44 HEALTH AFFS. 1173, 1173 (2025) (explaining that, among other things, "[s]ome states impose barriers to opening new OTPs, including OTP-specific certificate-of-need laws, which require legal documentation of need for a new OTP before opening; zoning restrictions on where OTPs can be located; and additional licensing requirements"); PEW CHARITABLE TRS., OVERVIEW OF OPIOID TREATMENT PROGRAM REGULATIONS BY STATE 1 (2022), https://www.pew.org/-/media/assets/2022/09/overview-of-opioid-treatment-program-regulations-by-state.pdf [https://perma.cc/3XKS-E8YH]; Richard Bonnie et al., *An Expedited Regulatory Strategy for Expanding Access to Methadone Treatment for Opioid Use Disorder*, HEALTH AFFS. FOREFRONT, May 27, 2022 ("State policies regulating access to methadone are often more restrictive than federal requirements. Similarly, local legal barriers, such as zoning restrictions, may inhibit their therapeutic effectiveness."); Oliva, *supra* note 18 (enumerating the numerous burdensome federal rules that attend to OTPs and their patients); NAT'L ACADS. OF SCIS., ENG'G & MED., MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES 92, 94 (Alan I. Leshner & Michelle Mancher eds., 2019) (listing several of the numerous burdensome federal requirements that attend to OTPs).

122 42 C.F.R. pt. 8; *see, e.g.*, NAT'L ACADS. OF SCIS., ENG'G & MED., METHADONE TREATMENT FOR OPIOID USE DISORDER: IMPROVING ACCESS THROUGH REGULATORY AND LEGAL CHANGE 45 (2022) (explaining that "[l]ayer upon layer of regulations and accreditation standards have resulted in opioid treatment programs (OTPs) that spend more time attending to regulations than caring for patients"); S.L. Calcaterra et al., Perspective, *Methadone Matters: What the United States Can Learn from the Global Effort to Treat Opioid Addiction*, 34 J. GEN. INTERNAL MED. 1039, 1039–41 (2019).

institutionalize surveillance, gatekeeping, and access constraints within a clinical setting.[123]

Taken together, these features complicate the institutional lessons OTPs offer. If OTPs are understood primarily as examples of excessive medicalization, they caution against embedding nonmedical use within highly restrictive clinical regimes. If they are viewed as instances of market capture, they illustrate the risk that specialized regulatory niches may become insulated from broader reform. And, if they are framed as harm reduction operating under severe legal constraints, they underscore how institutional design choices shape who may (and who cannot) access care, under what conditions, and with what degree of state supervision. Clarifying which of these institutional dynamics the Article seeks to replicate — or avoid — would sharpen its use of OTPs as an analogue for new scheduling categories.

The Article appears to draw inspiration from overdose prevention sites and other harm reduction models,[124] but using them as a model for Schedule A drugs raises issues of institutional specificity. The few openly operating existing U.S. overdose prevention sites do not function within a federal scheduling framework or a health care delivery model — for example, they do not and cannot dispense federally authorized controlled substances and often operate without licensed medical personnel on site. Instead, they are community-based and grounded in mutual aid. Their operational models differ in *significant* respects from the tightly medicalized and federally supervised OTP framework.[125] Their legal status remains contested, and their operation depends on complex intergovernmental dynamics,[126] shaped by federal criminal law, state experimentation, and ongoing litigation.[127] Translating such

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123 *See* 42 C.F.R. § 8.12; Stacey McKenna, *We Can Supervise Methadone Dosing Outside of OTPs*, R ST. INST. (May 9, 2024), https://www.rstreet.org/commentary/we-can-supervise-methadone-dosing-outside-of-otps [https://perma.cc/W3AH-9VMK]; Facher, *supra* note 121; Samuel Kelton Roberts, *The Politics of Stigma and Racialization in the Early Years of Methadone Maintenance Regulation*, *in* NAT'L ACADS. OF SCIS., ENG'G & MED., *supra* note 122, at 136, 138–39.

124 *See* Lawrence & Pozen, *supra* note 1, at 896–97.

125 Elizabeth A. Samuels, Dennis A. Bailer & Annajane Yolken, Invited Commentary, *Overdose Prevention Centers: An Essential Strategy to Address the Overdose Crisis*, JAMA NETWORK OPEN, July 15, 2022, at 1, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794326 [https://perma.cc/CV3S-EKNL] (explaining that "[m]odels range from peer-run facilities to mobile units and medical models colocated with addiction treatment programs"); Mary Clare Kennedy et al., *Peer Worker Involvement in Low-Threshold Supervised Consumption Facilities in the Context of an Overdose Epidemic in Vancouver, Canada*, 225 SOC. SCI. & MED. 60, 60 (2019) (noting overdose prevention sites "are primarily staffed by peers . . . trained in overdose response").

126 *See, e.g.*, Burris et al., *supra* note 18, at 4–5.

127 *See* Sharon Otterman, *Federal Officials May Shut Down Overdose Prevention Centers in Manhattan*, N.Y. TIMES (Aug. 10, 2023), https://www.nytimes.com/2023/08/08/nyregion/drug-overdoses-supervised-consumption-nyc.html [https://perma.cc/XS36-6Q8F]; Jeffrey A. Singer, *Overdose Prevention Centers: A Successful Strategy for Preventing Death and Disease*, CATO INST. (Feb. 28, 2023), https://www.cato.org/briefing-paper/overdose-prevention-centers-successful-

models into a formal federal schedule would fundamentally alter the notion of overdose prevention sites and would require widespread statutory and regulatory changes,[128] far beyond creating a special registration category.[129] It would also require specification regarding supply chains, liability protections, practitioner involvement, enforcement safe harbors, and coordination among federal, state, and local actors.[130] In essence, it would require a separate regulatory scheme akin to but more complicated than the current OTP regulatory framework (with no protections from the probable attendant surveillance structures that undermine the core tenets of harm reduction in the first instance).[131]

Without clarity on these institutional mechanics, it is difficult to determine whether Schedule A represents structural redesign or an administratively intricate overlay within the existing regime. Any proposal to formalize similar practices within a federal schedule would require careful attention to these institutional differences and the many

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strategy-preventing-death-disease [https://perma.cc/2GJD-RXWY]; *see, e.g.*, United States v. Safehouse, 985 F.3d 225, 229 (3d Cir. 2021); Alex Kreit, *Safe Injection Sites and the Federal "Crack House" Statute*, 60 B.C. L. REV. 413, 417–18 (2019); Lawrence O. Gostin, James G. Hodge Jr. & Chelsea L. Gulinson, Viewpoint, *Supervised Injection Facilities: Legal and Policy Reforms*, 321 JAMA 745, 745 (2019); Leo Beletsky et al., *The Law (and Politics) of Safe Injection Facilities in the United States*, 98 AM. J. PUB. HEALTH 231, 231 (2008).

128 The description of Schedule A by Lawrence & Pozen would require such sweeping changes to the CSA that it is not possible to detail them in one essay. It would also create a chain reaction that would necessarily create a new market and regulatory structure for manufacturing, shipment in interstate commerce, ordering, distribution, storage, prescribing, and possibly administration. Unexplained in the Article is who would manufacture the Schedule A opioids and what incentives exist to do so, nor is the inevitable emergent two-tiered system in OTPs of Schedule A drug use and other Schedule I drugs. In the end, it may be more pragmatic to advocate for solutions more workable within the current regulatory regime, such as directly observed therapy with pharmaceutical-grade opioids, *see* Evan D. Anderson, Jason Sloan & Leo Beletsky, *Intensive Care for Pain as an Overdose Prevention Tool: Legal Considerations and Policy Imperatives*, 5 U. PA. J.L. & PUB. AFFS. 63, 109–21 (2019) (analyzing the workability of direct observed therapy under the CSA), or approval of heroin as a medication for opioid use disorder, *see* Robert Capodilupo & Jacob James Rich, *The Misinformed & Misguided Prescription Abuse Prevention Act: A Response to Delfino*, YALE L. & POL'Y REV. INTER ALIA, Spring 2023, at 16–17; Robert A. Kleinman & Nathaniel P. Morris, Viewpoint, *Is It Time to Reschedule Heroin?*, 77 JAMA PSYCHIATRY 781, 781–82 (2020); BEAU KILMER ET AL., RAND CORP., CONSIDERING HEROIN-ASSISTED TREATMENT AND SUPERVISED DRUG CONSUMPTION SITES IN THE UNITED STATES 4–5 (2018), https://www.rand.org/content/dam/rand/pubs/research_reports/RR2600/RR2693/RAND_RR2693.pdf [https://perma.cc/S93V-V4CF].

129 Lawrence and Pozen suggest modeling the registration on the special registration under the Ryan Haight Act. *See* Lawrence & Pozen, *supra* note 1, at 897. What they don't mention is that eighteen years after the Act's passage, the special registration category still does not exist in practice. The DEA has resisted all efforts to implement that portion of the law, despite an explicit mandate in the Ryan Haight Act and an additional mandate in 2018 legislation for regulations by October 24, 2019. *See supra* note 104.

130 The CSA's reach is extensive, particularly when it involves clinical care. *See* Dineen & DuBois, *supra* note 18, at 29–35.

131 *See generally* Liam Michaud, Emily van der Meulen & Adrian Guta, *Between Care and Control: Examining Surveillance Practices in Harm Reduction*, 50 CONTEMP. DRUG PROBS. 3 (2023) (noting the drawbacks of unchecked surveillance linked to harm reduction practices).

existing — but unaddressed — regulatory constraints[132] on the execution and implementation of Schedule A as described in the Article. Without such clarification, it is difficult to assess whether the Article envisions extending a medicalized gatekeeping model,[133] constructing a parallel harm reduction track,[134] or developing a distinct governance structure altogether with new forms of market entry, manufacturing, distributing, ordering, administering, and dispensing for certain drugs.

These tensions point to a broader institutional question: whether reform should aim to relax constraints within existing structures, to relocate authority from enforcement agencies to health agencies, or to create genuinely hybrid models that redistribute decision-making power. OTPs and harm reduction programs illuminate the stakes of those choices. They show that institutional form — not merely regulatory category — shapes access, autonomy, oversight, and enforcement exposure. A more explicit engagement with these structural tradeoffs would strengthen the Article's institutional design analysis and clarify how its proposals would function in practice.

Finally, the Article's call for a "fundamental reassessment of drug law structures and procedures"[135] raises an antecedent question: What, in this domain, counts as structural reform? The proposed creation of additional schedules for nonmedical use reflects a thoughtful and serious effort to move beyond the familiar binary of prohibition and laissez-faire.[136] It is not clear, however, that the addition of new schedules necessarily departs from the CSA's longstanding pattern of institutional layering — addressing perceived shortcomings through carve-outs, parallel regimes, and specialized exceptions while leaving the underlying allocation of authority largely intact.

Drug policy in the United States has historically evolved through recalibration rather than reconstruction.[137] As drug governance scholarship has observed, reform frequently proceeds by grafting new regulatory mechanisms onto existing enforcement-centered frameworks rather than displacing them.[138] The emergence of opioid treatment programs, research exceptions, risk evaluation and mitigation strategies, and enhanced surveillance systems illustrates this dynamic: Each

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132 Gostin, Hodge & Gulinson, *supra* note 127, at 745–46.

133 *See, e.g.*, *supra* note 121 and accompanying text.

134 *See, e.g.*, Kennedy et al., *supra* note 125, at 60.

135 Lawrence & Pozen, *supra* note 1, at 850.

136 *Id.* at 895–903.

137 *See, e.g.*, Oliva & El-Sabawi, *supra* note 18, at 1136–50 (arguing that contemporary reforms embed public health rhetoric within enforcement-centered structures rather than displacing them); RITTER, *supra* note 17, at 7–9 (drawing on international examples to explain how governing images and implementation practices may persist despite shifts in formal policy goals).

138 *See, e.g.*, Oliva & El-Sabawi, *supra* note 18, at 1129–30 (describing enhanced surveillance, criminalization, and regulatory tools as extensions of earlier enforcement logics); RITTER, *supra* note 17, at 7–8 (noting differences in emphasis across national strategies without displacement of core enforcement mechanisms).

introduced additional nuance and administrative sophistication, but none fundamentally altered the statute's core allocation of power between health and law enforcement institutions.[139] In this sense, drug policy reform often operates through layering — adding institutional complexity without shifting the system's center of gravity.[140] By most health and equity metrics, this has not been a story of success, at least insofar as success is measured in health, life, and opportunity for people who use drugs.[141]

The central question, then, is whether the proposed new schedules would constitute transformation in kind or refinement in degree. Structural reassessment would require more than additional regulatory categories; it would entail a meaningful reallocation of authority, a recalibration of evidentiary standards, or a reorientation of default enforcement postures (and likely all three). By "structural reform," we mean reform that alters the locus of final decisionmaking authority, the governing evidentiary standards, or the institutional default toward enforcement. Institutional layering, by contrast, preserves those foundations while adding new regulatory categories or procedural refinements within them. If final classification authority, enforcement discretion, and core gatekeeping functions remain vested in the same institutions and shaped by the same incentive structures, new schedules may increase regulatory granularity without reconfiguring the institutional architecture itself.

A similar caution applies to the broader reform project. As other scholarship has emphasized, drug governance is shaped not only by statutory design but also by institutional incentives, bureaucratic identity,[142] and prevailing "governing images" that frame drugs alternately as crime problems, health issues, or economic goods.[143] Reforms that do not address these deeper incentive structures risk being absorbed into existing enforcement logics even when rhetorically framed as health-centered innovation. The history of drug policy demonstrates a persistent capacity to incorporate public health language while preserving enforcement

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[139] While some of these efforts created new legal authority and controls (for example, the OTP regulations created new bureaucratic powers in HHS to control the care of people with OUD), none of them shifted power away from law enforcement in favor of health agencies or toward prioritizing health goals over law enforcement goals. *See, e.g.*, Oliva & El-Sabawi, *supra* note 18, at 1151–56. *See generally id.* (documenting these efforts).

[140] *See* James Mahoney & Kathleen Thelen, *A Theory of Gradual Institutional Change*, *in* EXPLAINING INSTITUTIONAL CHANGE: AMBIGUITY, AGENCY, AND POWER 15 (James Mahoney & Kathleen Thelen eds., 2010) (describing "layering" as institutional change through addition of new rules or arrangements while older structures persist); Mikos, *supra* note 24, at 1423–27 (explaining how state legalization regimes developed alongside continued federal prohibition without displacing federal criminal law).

[141] Lawrence & Pozen, *supra* note 1, at 850–51.

[142] *See* Meier & Smith, *supra* note 12, at 431. *See generally id.* (emphasizing the link between bureaucratic design and drug policy).

[143] RITTER, *supra* note 17, at 7–9.

authority — a dynamic that underscores the importance of attending to political economy alongside formal institutional design.[144]

None of this diminishes the Article's contribution in reframing scheduling as a question of institutional architecture rather than moral valence.[145] To the contrary, it follows directly from the authors' analytic commitments. If institutional design is the core lens, then "fundamental reassessment"[146] must be evaluated in structural terms: who holds decisionmaking authority, under what standards, and subject to which incentives. Clarifying whether the proposed reforms meaningfully redistribute those foundations — or instead refine them — would further strengthen the Article's institutional account and sharpen its reform agenda.

CONCLUSION

Drug Scheduling as Institutional Design makes a substantial and important contribution to drug law scholarship. Its institutional framing, analytic clarity, and willingness to engage hard tradeoffs mark it as a significant intervention. The Article's contributions are most fully realized when read in conversation with interdisciplinary scholarship, with careful attention to agency roles, and with sustained engagement with the legal and clinical realities that shape drug regulation in practice. By foregrounding institutional design, Lawrence and Pozen have opened a conversation that legal scholars, policymakers, and practitioners alike should welcome. Our hope is that this Response contributes to that conversation by highlighting areas where additional grounding and specification can further enhance the Article's impact — and help move drug policy debates toward more durable, humane, and effective solutions. Institutional design offers a powerful analytic lens — but its promise depends on grounding theory in institutional reality.

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144 Oliva & El-Sabawi, *supra* note 18, at 1147.

145 Lawrence & Pozen, *supra* note 1, at 904–05.

146 *Id.* at 850.