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DRUG SCHEDULING AS INSTITUTIONAL DESIGN

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CONTENTS

DRUG SCHEDULING AS INSTITUTIONAL DESIGN

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The United States makes bad choices when it comes to psychoactive drugs. Under the Controlled Substances Act (CSA), U.S. drug law has simultaneously fueled mass incarceration, inhibited needed access, and enabled an opioid crisis. To make better choices, this Article argues that the CSA's institutional design must account for three distinctive features of psychoactive drugs: the prohibition problem (drug bans tend to backfire when demand is inelastic), the pharma problem (drug companies have supercharged incentives to manipulate markets and exploit consumers), and the pluralism problem (drug policy involves irreducibly political questions that no expert discipline can answer). On their own, each of these problems calls for reform to the CSA. Taken together, they call for a fundamental reassessment of drug law structures and procedures.

Reconceptualizing the nation's drug policy debacle as a failure of institutional design yields badly needed interventions for a reform movement that has stalled out and a cannabis regime that has splintered. The CSA should be fixed through pragmatic changes that foster democratization without domination in rulemaking processes and legalization without laissez faire in consumer markets. Such changes include eliminating the Drug Enforcement Administration's authority to schedule substances, broadening participation in scheduling decisions, creating new schedules for nonmedical use, and imposing administrative controls on lobbying and advertising by drug manufacturers. A pragmatic approach to drug regulation along these lines, we contend, is not only superior from the standpoint of public health and the CSA's goals but also constitutionally permissible and politically plausible.

INTRODUCTION

The Controlled Substances Act[1] (CSA) recently turned fifty. It was not a happy birthday. The law's half century as the "super-statute"[2] at the center of psychoactive drug regulation in the United States has been marked by perverse consequences and profound injustices.[3] During this period, more than a million Americans have died of drug overdoses, tens of millions have been arrested for drug offenses, and

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

[2] William N. Eskridge, Jr., & Kevin S. Schwartz, Feature, Chevron *and Agency Norm-Entrepreneurship*, 115 YALE L.J. 2623, 2624 (2006) (describing the CSA as a "super-statute[]").

[3] By "psychoactive drugs," we refer broadly to nonfood "substances that, when taken in or administered into one's system, affect mental processes" such as "perception, consciousness, cognition[,] or mood and emotions." *Drugs (Psychoactive)*, WORLD HEALTH ORG., https://www.who.int/health-topics/drugs-psychoactive [https://perma.cc/5R6S-455W].

hundreds of millions have been channeled into illicit markets or denied access to needed substances.[4] The CSA has not only failed to rationalize drug policy or advance public health but also contributed to a cascade of negative externalities, from the rise of mass incarceration and the subordination of Black and brown communities to the degradation of civil liberties and the delegitimation of the administrative state.[5] Why should anyone trust the government to address a wicked problem like poverty or climate change if decades of vigorous efforts to address drug harms have yielded such dispiriting returns?

Broadly speaking, two types of legal scholarship have sought to make sense of the "abject failure"[6] of the CSA and the war on drugs with which it became synonymous. One is sweeping in its critical and historical ambition — identifying ways in which deep social forces such as racism, moralism, and neoliberalism have shaped and been shaped by the country's drug policies over time.[7] The other familiar approach is granular and applied — asking whether the government has misclassified or misregulated particular substances, or whether a certain aspect

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[4] *See, e.g.*, DAVID POZEN, THE CONSTITUTION OF THE WAR ON DRUGS 14, 151–52 (2024) (explaining that marijuana alone generated over eight million arrests in the United States in the 2000s and that survey data from that decade indicated illegal drug use by over 100 million Americans); Brian Mann, *More than a Million Americans Have Died from Overdoses During the Opioid Epidemic*, NPR (Dec. 30, 2021, at 10:26 ET), https://www.npr.org/2021/12/30/1069062738/more-than-a-million-americans-have-died-from-overdoses-during-the-opioid-epidemi [https://perma.cc/2QJP-NFFB] (reporting opioid overdose death estimates); Ike Swetlitz, *Adderall's Disappearing Act Has Left Millions Without Treatment*, BLOOMBERG (Feb. 16, 2023, at 09:00 ET), https://www.bloomberg.com/news/articles/2023-02-16/adderall-shortage-2023-teva-s-adhd-drug-is-missing-for-millions-of-americans [https://perma.cc/P4TK-K82F] (discussing recent Adderall shortages).

[5] Vast literatures address these disappointments and disasters. For a cogent summary, see Jennifer D. Oliva & Taleed El-Sabawi, *The "New" Drug War*, 110 VA. L. REV. 1103, 1118–26 (2024). *See also* Jeffrey Friedman, *The Legitimacy Crisis*, NISKANEN CTR. (Oct. 4, 2017), https://www.niskanencenter.org/the-legitimacy-crisis [https://perma.cc/WLP2-URC3] (linking the U.S. government's "legitimacy crisis" to the "ignominious" track record of the war on drugs).

[6] John F. Galliher, David P. Keys & Michael Elsner, Lindesmith v. Anslinger*: An Early Government Victory in the Failed War on Drugs*, 88 J. CRIM. L. & CRIMINOLOGY 661, 681 (1998) ("[W]hile drug policy researchers may disagree on the best method of dealing with drug abuse, they nearly all agree that the current policy is an abject failure."); *see also* andré douglas pond cummings & Steven A. Ramirez, *The Racist Roots of the War on Drugs & the Myth of Equal Protection for People of Color*, 44 U. ARK. LITTLE ROCK L. REV. 453, 457–58 & nn.19–22 (2022) (collecting sources depicting U.S. drug policy as an "epic failure," *id.* at 457).

[7] *See generally, e.g.*, MICHELLE ALEXANDER, THE NEW JIM CROW: MASS INCARCERATION IN THE AGE OF COLORBLINDNESS (2010) (arguing famously that the drug war amounts to "[t]he New Jim Crow," *id.* at 58); BERNARD E. HARCOURT, THE ILLUSION OF FREE MARKETS: PUNISHMENT AND THE MYTH OF NATURAL ORDER 40–43, 202–08 (2011) (arguing that U.S. drug policy reflects a logic of "neoliberal penality," *id.* at 41); DAVID A. J. RICHARDS, SEX, DRUGS, DEATH, AND THE LAW: AN ESSAY ON HUMAN RIGHTS AND OVERCRIMINALIZATION 193 (1982) (arguing that "a formerly religious but now secular ideal of moral perfectionism" animates U.S. drug law).

of the CSA or related laws ought to be revised on one or another margin.[8]

Both strains of scholarship have generated crucial insights. All but absent from the literature, however, is theory in the "middle range"[9] that interrogates the structure and assumptions of the CSA's governance model, which assigns drugs to one of five "schedules" (or leaves them unscheduled) based on their potential for abuse and medical utility.[10] More than five decades into its disastrous reign, as Professor Alex Kreit has noted, "almost nothing has been written about the classification and regulatory provisions" at the heart of the CSA.[11] While drug law scholars have long debated the right schedule for marijuana[12] and have recently begun to debate the right schedule for MDMA and other drugs,[13] few have considered whether the CSA's scheduling system is right in the first place or what a better designed system might look like.[14] The

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[8] *See, e.g.*, Barry Friedman & Genevieve Lakier, *"To Regulate," Not "to Prohibit": Limiting the Commerce Power*, 2012 SUP. CT. REV. 255, 286–320 (2013) (contending that the CSA should not apply to certain drug transactions that are permitted under state law); Erica Zunkel & Alison Siegler, *The Federal Judiciary's Role in Drug Law Reform in an Era of Congressional Dysfunction*, 18 OHIO ST. J. CRIM. L. 283, 286–88 (2020) (reviewing criticisms of mandatory minimum penalties in federal drug laws that followed the CSA); Alyssa M. McClure, Note, *Illegitimate Overprescription: How* Burrage v. United States *Is Hindering Punishment of Physicians and Bolstering the Opioid Epidemic*, 93 NOTRE DAME L. REV. 1747, 1766–70 (2018) (proposing that the CSA be amended to permit greater punishment of doctors with unsafe opioid prescribing practices).

[9] ROBERT K. MERTON, SOCIAL THEORY AND SOCIAL STRUCTURE 39–40 (enlarged ed. 1968) (describing middle-range theories and noting that their "seminal ideas . . . are characteristically simple," *id.* at 40).

[10] *See* JOANNA R. LAMPE, CONG. RSCH. SERV., R45948, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 118TH CONGRESS 5–6 (2023) ("The heart of the CSA is its system for classifying controlled substances, as nearly all the obligations and penalties that the Act establishes flow from the classification system." *Id.* at 5.).

[11] Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332, 333 (2013).

[12] *Cf.* POZEN, *supra* note 4, at 54–66 (reviewing decades of constitutional challenges to marijuana's placement in Schedule I of the CSA and state-level counterparts). This Article uses "marijuana" and "cannabis" interchangeably to refer to cannabis plants or products that contain more than trace amounts of the psychoactive chemical tetrahydrocannabinol (THC). On the etymology of "marijuana" in U.S. drug policy discourse and reasons to continue using the term, at least for now, see JOHN HUDAK, MARIJUANA: A SHORT HISTORY 23–26 (2d ed. 2020). *See also* Robert A. Mikos & Cindy D. Kam, *Has the "M" Word Been Framed? Marijuana, Cannabis, and Public Opinion*, PLOS ONE (Oct. 31, 2019), https://doi.org/10.1371/journal.pone.0224289 [https://perma.cc/6BGP-R6RL] (finding "no support for the notion that changing the name of the drug from 'marijuana' to 'cannabis' affects public opinion").

[13] *See, e.g.*, Mason M. Marks, Recent Development, *Controlled Substance Regulation for the COVID-19 Mental Health Crisis*, 72 ADMIN. L. REV. 649, 711–12 (2020) (urging that MDMA be moved to Schedule IV or Schedule V and that psilocybin be descheduled); Nabil Al-Khaled, Note, *MDMA and Psilocybin for Mental Health: Deconstructing the Controlled Substances Act's Usage of "Currently Accepted Medical Use*," 99 WASH. U. L. REV. 1023, 1050–52 (2021) (urging that MDMA and psilocybin be removed from Schedule I).

[14] For an important recent exception, albeit with a much narrower focus than this Article's, see Robert A. Mikos, *Marijuana and the Tyrannies of Scheduling*, 93 FORDHAM L. REV. 473, 475–76 (2024) (arguing that the DEA "should stop insisting that a drug must be placed on Schedule I if it has no [currently accepted medical use]," *id.* at 475, and "propos[ing] a more flexible approach for determining whether a drug belongs on Schedule I," *id.* at 476).

regulatory regimes created by other super-statutes have been studied in depth.[15] "Somehow, the underpinnings of our current drug policy have slipped through the cracks."[16]

This Article begins to fill this gap by reconceptualizing drug policy as a question of institutional design and developing a pragmatic theory for regulating mind-altering drugs.[17] We identify the CSA's core design features and their underlying assumptions. We explain why these features have led to unintended consequences and will continue to do so unless changed. And, against the thrust of much drug scholarship and advocacy today, we suggest that reformers should seek to fix rather than abandon the law's administrative framework for deciding how to regulate particular substances.

Foundational to our pragmatic theory of drug regulation are three features of psychoactive drugs that complicate institutional design.[18] The *prohibition problem* is the best known: Most attempts to prohibit the sale or use of these drugs are bound to backfire, given both the inelasticity of consumer demand and the criminogenic, harm-enhancing effects of the prohibitions themselves. The "capital-P Prohibition"[19] of alcohol is a canonical case in point.[20] Yet, while the prohibition problem counsels a shift toward regulated access, the realities of drug misuse and addiction exacerbate the threat of private industry exploiting vulnerable

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[15] *See generally, e.g.*, Mark Barenberg, *The Political Economy of the Wagner Act: Power, Symbol, and Workplace Cooperation*, 106 HARV. L. REV. 1379 (1993) (National Labor Relations Act); William N. Eskridge Jr. & John Ferejohn, *The APA as a Super-Statute: Deep Compromise and Judicial Review of Notice-and-Comment Rulemaking*, 98 NOTRE DAME L. REV. 1893 (2023) (Administrative Procedure Act); David Schoenbrod, *Goals Statutes or Rules Statutes: The Case of the Clean Air Act*, 30 UCLA L. REV. 740 (1983) (Clean Air Act).

[16] Kreit, *supra* note 11, at 333.

[17] In taking this approach, we aim to follow in the footsteps of scholars who have generated novel insights and lines of inquiry, and in some cases spurred significant policy change, by reconceptualizing other fields of law from the standpoint of institutional design. *See generally, e.g.*, Oren Bar-Gill & Elizabeth Warren, *Making Credit Safer*, 157 U. PA. L. REV. 1 (2008) (consumer credit); Anne Joseph O'Connell, *The Architecture of Smart Intelligence: Structuring and Overseeing Agencies in the Post-9/11 World*, 94 CALIF. L. REV. 1655 (2006) (national security); David A. Weisbach & Jacob Nussim, *The Integration of Tax and Spending Programs*, 113 YALE L.J. 955 (2004) (tax). In describing our theory of drug regulation as "pragmatic," we mean, most simply, that it emphasizes practicality over principle in solving problems. We further contend that the distinctive challenges of drug regulation make it an especially apt field in which to apply the method of pragmatism, emphasizing "usefulness, fallibility, empirically based experimentalism, and pluralism" in the pursuit of sustainable solutions. Clare Huntington, *Pragmatic Family Law*, 136 HARV. L. REV. 1501, 1538 (2023) (identifying these as "core tenets" of pragmatism); *see infra* section III.A, pp. 879–82.

[18] On all points in this paragraph, see *infra* Part II, pp. 863–79. While versions of these features appear in other regulatory fields, we argue that they take an especially acute and challenging form in the context of psychoactive drugs.

[19] POZEN, *supra* note 4, at 156.

[20] *See* LISA MCGIRR, THE WAR ON ALCOHOL: PROHIBITION AND THE RISE OF THE AMERICAN STATE 250 (2016) (discussing the "wide consensus that Prohibition of the liquor traffic was a fundamentally flawed crusade with devastating consequences"); POZEN, *supra* note 4, at 156 (characterizing Prohibition as having been "relegated to the constitutional anticanon").

parties and capturing the regulatory process — a threat that already looms large in the health care and consumer protection fields.[21] Purdue Pharma's role in driving the contemporary opioid crisis is illustrative.[22] We call this the *pharma problem*. Administrative law's go-to answer for capture concerns is to empower an independent agency to regulate with reduced political accountability.[23] Whatever its merits in other contexts, however, this approach founders in the face of psychoactive drugs because of the *pluralism problem*. Politically insulated experts may be able to predict some of these drugs' risks and benefits for some users. But their ability to set sociologically and normatively legitimate rules in the public interest is bedeviled by the radical epistemic uncertainty, value incommensurability, and cultural conflict associated with American drug debates.

On their own, the prohibition, pharma, and pluralism problems each make "ideal" drug regulation hard; collectively, they make it impossible. Small wonder, then, that drug policy remains stuck in a quagmire, with the CSA unable to curb dangerous drug behaviors and the federal marijuana rescheduling process unable to deliver a sustainable outcome.[24] Sobering though this realization may be, it not only helps to clarify where the CSA went wrong but also offers lessons for redesigning the nation's drug policy framework to better manage what cannot be solved. Taking seriously the regulatory challenges posed by the prohibition, pharma, and pluralism problems — and especially their interaction —

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[21] *See, e.g.*, Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15, 65 (2010) (describing consumer protection regulation as "the ideal breeding ground for agency capture and one-sided political pressure"); Liza Vertinsky, *Pharmaceutical (Re)Capture*, 20 YALE J. HEALTH POL'Y L. & ETHICS 146, 223 (2021) (describing "the myriad ways in which pharmaceutical companies exert influence over the construction and regulation of pharmaceutical markets").

[22] For leading accounts of Purdue Pharma's role in driving the crisis and the FDA's failures in regulating OxyContin, see generally PATRICK RADDEN KEEFE, EMPIRE OF PAIN: THE SECRET HISTORY OF THE SACKLER DYNASTY (2021), and BETH MACY, DOPESICK: DEALERS, DOCTORS, AND THE DRUG COMPANY THAT ADDICTED AMERICA (2018).

[23] *See, e.g.*, Barkow, *supra* note 21, at 17 ("[T]he creation of an independent agency is often motivated by a concern with agency capture.").

[24] As this Article was going to press, President Trump issued an executive order directing the Attorney General to "take all necessary steps to complete the rulemaking process related to rescheduling marijuana to Schedule III of the CSA in the most expeditious manner in accordance with Federal law, including 21 U.S.C. 811." Exec. Order No. 14,370, 90 Fed. Reg. 60541, 60542 (Dec. 18, 2025). Prior to this intervention, the previously noticed hearing on marijuana rescheduling had been canceled by the presiding administrative law judge, with no new date set, Order Regarding Vill. Farms Int'l, Hemp for Victory, & OCO, et al.'s Motion to Reconsider, *In re* Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, DEA Dkt. No. 1362, Hearing Dkt. No. 24-44, at 5 (Jan. 13, 2025) (order canceling hearing on the merits that had been scheduled for January 21, 2025), amid growing complaints that the DEA had sought to bias the hearing and growing recognition that moving marijuana to Schedule III may accomplish little, *see* Robert A. Mikos, *The False Promise of Rescheduling*, 60 TULSA L. REV. 1, 19–24 (2024). We discuss the problems with this rescheduling process to date and the implications for drug policy design in section III.B.3, pp. 890–94. Although we are unable to address the just-issued executive order, nothing in the order alters the analysis offered in that section.

yields a set of pragmatic imperatives. First, decisions about how to schedule drugs should be democratized through procedures that incorporate a wide range of interests and perspectives, including those of public health researchers and people who use or prescribe the drugs in question. Second, the scheduling system should include a means to legalize drugs while subjecting them to enhanced administrative controls that shield consumers from extractive capitalism.

These twinned imperatives provide cause for hesitation about the trend in drug policy and advocacy toward substance-specific legislative fixes, which satisfy neither of the two. Instead, the best path forward likely involves retaining the CSA's categorical scheduling approach, which dilutes the influence of particular drug manufacturers and industries while promoting congressional and public engagement. Within this scaffolding, however, pragmatism counsels an array of changes, from revoking the Drug Enforcement Administration's decisional authority and giving weight to "recreational" variables in the scheduling process to imposing new restrictions on lobbying and advertising by drug manufacturers and creating new schedules permitting but regulating nonmedical use. The details are complex and contestable, and we leave many for another day. More than anything else, we hope that the Article's theory of drug regulation helps to stimulate and facilitate a comprehensive reassessment of the CSA's institutional design, along with serious consideration of alternative models that would be far less punitive yet also far from laissez faire.[25]

The Article proceeds in four parts. Part I describes the regulatory theory embedded in the CSA's scheduling scheme, which relies primarily on doctors and secondarily on law enforcement officers to manage the flow of potentially addictive drugs. Part II explicates the prohibition,

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[25] At the same time, we hope that the Article contributes to a number of adjacent literatures. First, while our focus is on the federal level, our pragmatic theory of drug regulation has significant implications for the states, all of which "have their own mini-CSAs that are pretty much lock-step with the federal CSA." *Marijuana as Schedule III: Woe Is Me?*, HARRIS SLIWOSKY: CANNA L. BLOG (Sep. 6, 2023), https://harris-sliwoski.com/cannalawblog/marijuana-as-schedule-iii-woe-is-me [https://perma.cc/LYC6-5WEE]. Second, for those who lament that administrative law scholarship tends to privilege abstract, transsubstantive analyses, *see, e.g.*, Sanne Knudsen, *Sidestepping Substance: How Administrative Law Plays an Outsized Role in Shaping Environmental Policy and Why Recalibration Is Necessary*, 76 ADMIN. L. REV. 519, 531–36 (2024), this Article offers a relatively rare illustration of the value and methodology of applied institutional design. Third, and speaking to the transsubstantive strains of the public law literature, we explain ways in which scheduling regimes may offer an attractive hybrid of legislative delineation and administrative delegation. Further work might elaborate this claim and explore its relevance beyond drug policy, bringing "scheduling" fully alongside "big waiver," David J. Barron & Todd D. Rakoff, *In Defense of Big Waiver*, 113 COLUM. L. REV. 265, 272–91 (2013), as a distinctive tool of regulation. Fourth and most broadly, in highlighting downsides to the current trend away from administrative processes for making drug policy, *see infra* section III.B.1, pp. 883–87, our project fits within an emerging body of law-and-political-economy scholarship that defends the administrative state after years of mounting attacks, *see, e.g.*, Blake Emerson, *The Existential Challenge to the Administrative State*, 113 GEO. L.J. 1263, 1306–25 (2025); Gillian E. Metzger, *The Supreme Court, 2016 Term — Foreword: 1930s Redux: The Administrative State Under Siege*, 131 HARV. L. REV. 1, 87–91 (2017).

pharma, and pluralism problems and the dilemmas they create for drug regulation. To navigate these problems, Part III suggests a range of reforms to the CSA's scheduling scheme that would swap idealism for pragmatism, professional control for political accountability, exclusion for participation, and criminal sanctions for checks on capture and commercialism. Finally, Part IV addresses potential objections on grounds of feasibility and constitutionality.

I. THE CSA'S REGULATORY REGIME

Prior to the CSA, federal drug policy consisted of "[a] patchwork of regulatory, revenue, and criminal measures."[26] Many of these measures were predicated on Congress's power to tax, given uncertainty about the scope of the commerce power until the mid-twentieth century.[27] The 91st Congress determined to replace the patchwork with a framework statute. Enacted as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970[28] ("1970 Act"), the CSA created a unified scheme for addressing the manufacture, distribution, and possession of psychoactive drugs, excluding alcohol and tobacco.[29] Other components of the 1970 Act repealed mandatory minimum sentences[30] and increased support for education, research, and treatment.[31]

It would have been relatively easy to draft a law banning any form of access to any psychoactive substance (which is not to say that such a law would be successful). Pushing in this direction, the CSA criminalizes all nonmedical uses and sales of the drugs it covers, as well as all medical uses and sales of certain drugs.[32] Yet, while the CSA relies on "punitive prohibitionism" to a significant extent[33] — a feature we

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[26] RICHARD J. BONNIE & CHARLES H. WHITEBREAD II, THE MARIHUANA CONVICTION: A HISTORY OF MARIHUANA PROHIBITION IN THE UNITED STATES 242 (1974); *see also* Nat'l Org. for the Reform of Marijuana L. v. Bell, 488 F. Supp. 123, 126 (D.D.C. 1980) (stating that the CSA "ended the patchwork federal effort against drug abuse"). For an overview of federal drug regulation prior to the CSA, see Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 CATH. U. L. REV. 586, 588–605, 618–21 (1973).

[27] *See* POZEN, *supra* note 4, at 44–47.

[28] Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended in scattered sections of 21 U.S.C.).

[29] *See* Alex Kreit, *Drug Truce*, 77 OHIO ST. L.J. 1323, 1330 (2016) ("The [CSA] cleared away nearly all then-existing federal drug laws in favor of a single comprehensive statutory scheme . . . ."). Without explanation, Congress specifically exempted alcohol and tobacco from the CSA. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 102(6), 84 Stat. at 1243 (codified at 21 U.S.C. § 802(6)).

[30] *See* Molly M. Gill, *Correcting Course: Lessons from the 1970 Repeal of Mandatory Minimums*, 21 FED. SENT'G REP. 55, 55 (2008) (explaining that the 1970 Act "repealed mandatory minimum drug sentences except in limited and serious circumstances").

[31] *See* David T. Courtwright, *The Controlled Substances Act: How a "Big Tent" Reform Became a Punitive Drug Law*, 76 DRUG & ALCOHOL DEPENDENCE 9, 11–12 (2004) (discussing "unmistakably public-health initiatives" that were "part of the same legislation as the CSA," *id.* at 11).

[32] 21 U.S.C. §§ 812, 841–843.

[33] POZEN, *supra* note 4, at 13; *see id.* at 12–16; *cf.* Gregory Kau, Comment, *Flashback to the Federal Analog Act of 1986: Mixing Rules and Standards in the Cauldron*, 156 U. PA. L. REV. 1077, 1082 (2008) (describing the CSA as "the first comprehensive federal drug prohibition legislation").

criticize in the next Part — its overall drug control strategy is more complicated. As the very first lines of its findings emphasize, the CSA is premised on the Janus-faced nature of psychoactive drugs, which can both help and hurt.[34] The law's text, structure, and legislative history indicate a desire to harness the health benefits of these drugs while minimizing harms.[35]

Having decided that U.S. drug policy would strike such a balance, it also would have been relatively easy for Congress to punt on the question of how to accomplish this goal. Prior Congresses had addressed difficult policy challenges by conferring broad authority on executive branch agencies to figure out solutions, directing the Department of Transportation to set "appropriate Federal motor vehicle safety standards,"[36] the Federal Trade Commission to prevent "unfair methods of competition,"[37] and so forth. The CSA did not go this route either. Rather than delegate away most of its regulatory power, Congress devised an intricate framework to structure decisions about psychoactive drugs at each phase in their life cycle, from importation and manufacture to distribution and personal use.

This Part briefly reviews that framework with an eye toward the key institutional design choices it embeds. We first explain how the CSA attempts to manage the flow of drugs. We then explain how it determines which drugs get managed in which ways.

A. Physicians and Prohibitions

The central choice that Congress leaves to the executive branch under the CSA is that of "scheduling": sorting drugs into one of a handful of statutorily defined categories that are not subject to revision through the regulatory process.[38] The CSA assigns such scheduling authority to the Attorney General,[39] who in turn has subdelegated it to the Drug Enforcement Administration (DEA) ever since the DEA's creation in 1973.[40] Prior legal scholarship on the CSA has explored the law's

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[34] The law's first finding emphasizes the "help," pointing out that many psychoactive drugs "are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). Its second finding acknowledges the "hurt," which is that such drugs can "have a substantial and detrimental effect on the health and general welfare of the American people." *Id.* § 801(2).

[35] *See* LAMPE, *supra* note 10, at 2 ("[The CSA] simultaneously aims to protect the public from the dangers of controlled substances while ensuring access to controlled substances for legitimate purposes.").

[36] National Traffic and Motor Vehicle Safety Act of 1966, Pub. L. No. 89-563, § 103(a), 80 Stat. 718, 719 (codified as amended at 49 U.S.C. § 30111(a)).

[37] Federal Trade Commission Act of 1914, Pub. L. No. 63-203, § 5, 38 Stat. 717, 719 (codified as amended at 15 U.S.C. § 45(a)(2)).

[38] 21 U.S.C. § 811(a).

[39] *Id.*

[40] 38 Fed. Reg. 18380 (July 10, 1973) (codified as amended at 28 C.F.R. § 0.100(b)). Congress retains the authority to schedule substances or change the status of controlled substances through legislation. *See* JOANNA R. LAMPE, CONG. RSCH. SERV., IF12709, LEGISLATIVE SCHEDULING OF CONTROLLED SUBSTANCES (2025).

scheduling criteria and the DEA's application of these criteria to particular drugs.[41] In the next section, we consider the design of the scheduling framework itself.

To understand the CSA's plan for controlling psychoactive drugs, however, it is helpful to begin not with schedules but with channels. The House Committee on Interstate and Foreign Commerce's 1970 report on the CSA explains that the law aims to establish and secure "legitimate channels" in which psychoactive drugs can flow.[42] This metaphor has come to define how the DEA sees its job. The agency's primary regulatory office is titled Diversion Control, which seeks to "ensur[e] an adequate and uninterrupted supply" of controlled substances for lawful ends while preventing their "diversion" into illicit channels.[43] As of November 2025, the DEA had employed the channels metaphor in describing its regulatory approach in more than 180 Federal Register publications.[44]

For some drugs, *no* channels are considered legitimate. This is Schedule I, which imposes a criminal ban on substances with "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use . . . under medical supervision."[45] The DEA's field offices have primary responsibility for keeping Schedule I drugs out of circulation and for identifying and deterring violators.[46]

For all other scheduled drugs, physicians serve as the primary gatekeepers to the legitimate channels. With very limited exceptions, drugs in Schedules II through V may be released to individual users pursuant to a prescription from a certified physician, and only pursuant to such a prescription.[47] The CSA thus effectively delegates to doctors the final

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41 *See, e.g.*, Kreit, *supra* note 11, at 337–52; Jack Malich, *A (Loper) Bright Future?: How the Supreme Court Opened a Path for Drug Reform*, 65 SANTA CLARA L. REV. 405, 411–16 (2025); Mikos, *supra* note 14, at 476–95.

42 H.R. REP. NO. 91-1444, pt. 1, at 6 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572.

43 *About Us*, DIVERSION CONTROL DIV., U.S. DRUG ENF'T ADMIN., https://www.deadiversion.usdoj.gov/about-us.html [https://perma.cc/DMZ4-4X85]; *see also* United States v. Blanton, 730 F.2d 1425, 1427 (11th Cir. 1984) ("In passing the Controlled Substances Act, 'Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels.'" (quoting United States v. Moore, 423 U.S. 122, 135 (1975))).

44 WESTLAW, "(agency /15 'drug enforcement administration' dea) & 'legitimate channels,'" 182 results (Nov. 25, 2025) (on file with the Harvard Law School Library).

45 21 U.S.C. § 812(b)(1). Schedule I's criminal ban is tempered only by a narrow exception for federally approved research studies. *Id.* § 823(g).

46 *See DEA Fact Sheet*, U.S. DRUG ENF'T ADMIN. (Mar. 2015), https://www.dea.gov/sites/default/files/docs/factsheet.pdf [https://perma.cc/2HK9-64C9]. The DEA's law enforcement efforts run primarily through its 200-plus domestic offices, governed by twenty-one divisions. *Id.* A majority of DEA personnel are special agents or investigators assigned to these offices. *Id.*

47 21 U.S.C. § 829(a)–(c). Subject to the approval of both the FDA and state regulators, the CSA allows over-the-counter pharmacy access (without a physician's prescription) for certain Schedule III, IV, and V substances. *See id.* § 829(b)–(c); U.S. DRUG ENF'T ADMIN., PRACTITIONER'S

say on access to most controlled substances. In this, the CSA follows an approach taken by the 89th Congress when it turned doctors into "bedside bureaucrats" by delegating to them millions of decisions each year about which services Medicare would pay for.[48] That choice proved disastrous in light of these "bureaucrats'" financial incentives, leading Congress to overhaul Medicare's payment system in later years.[49] At the turn of the 1970s, however, public confidence in the medical profession was still near its apex.[50] Although the CSA subjects physicians to numerous regulatory requirements,[51] it generally does not tell them how to make drug-access decisions within their medical authority, and occasional efforts by the DEA to intrude on such medical judgments have been rebuffed by courts as exceeding the agency's statutory mandate.[52] If Schedule I is the province of federal law enforcement, Schedules II through V are the province of the medical establishment and its highly decentralized network of practitioners.

Having opted to leave end-user access decisions to the medical profession, and the regulation of medical practice to the states, the next question facing Congress was how to secure the channels from which doctors may obtain and release drugs. Here, the CSA's response is a familiar one in administrative law: the combination of a licensure regime with a criminal backstop. From transporting hazardous waste[53] to

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MANUAL 27 (2023) [hereinafter DEA PRACTITIONER'S MANUAL], https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner%27s_Manual_(final).pdf [https://perma.cc/98JW-UGSP]. The FDA imposes additional controls on certain prescription drugs through its Risk Evaluation and Mitigation Strategies program. *See Risk Evaluation and Mitigation Strategies*, FDA (May 20, 2025), https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems [https://perma.cc/8D8P-MTFD].

48 Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 522–23 (2013) (discussing Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended in scattered sections of 42 U.S.C.)); *see also id.* at 522 (describing the 1965 reforms as "put[ting] physicians at the center of the program" and "crippl[ing] Medicare's ability to exert control over its physician-bureaucrats").

49 *See id.* at 540–41.

50 *See* LEWIS A. GROSSMAN, CHOOSE YOUR MEDICINE: FREEDOM OF THERAPEUTIC CHOICE IN AMERICA 8 (2021) (describing "the 1930s through the 1960s" as the "peak" of "Americans' confidence in government health regulators, the medical establishment, and pharmaceutical companies"); PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 379 (1982) (explaining that the view that "medical professionals . . . were best equipped to decide how to organize [health] services" persisted until the 1970s).

51 *See generally* DEA PRACTITIONER'S MANUAL, *supra* note 47.

52 *See, e.g.*, Ruan v. United States, 142 S. Ct. 2370, 2382 (2022) (stating that "the scope of a doctor's prescribing authority" under the CSA is determined by "objective criteria such as 'legitimate medical purpose' and 'usual course' of 'professional practice'" (quoting 21 C.F.R. § 1306.04(a))); Gonzales v. Oregon, 546 U.S. 243, 266 (2006) ("The structure of the CSA . . . conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise."). Qualifying the CSA's generally hands-off approach to the doctor-patient relationship outside of Schedule I, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 prohibits the teleprescribing of controlled substances without a prior in-person medical evaluation. Pub. L. No. 110-425, § 2, 122 Stat. 4820, 4820–21 (codified at 21 U.S.C. § 829(e)).

53 49 U.S.C. § 5103a.

exhibiting zoo animals,[54] Congress routinely empowers agencies to award licenses or permits to engage in a certain activity, uses conditions on these awards to shape the behavior of recipients, and forbids the activity otherwise.[55] Sections 822 and 823 of the CSA create a process, administered by the Attorney General, by which any person seeking to manufacture, distribute, or dispense a controlled substance may register to do so.[56] The registration requirements for those who seek to manufacture or distribute drugs in bulk are arduous. Successful registrants must not only safeguard their stocks of controlled substances but also maintain "effective controls against diversion"[57] and "design and operate a system to identify suspicious orders."[58] By contrast, the registration process for physicians and pharmacists to dispense drugs by prescribing them or filling prescriptions is almost ministerial. The CSA obligates the Justice Department to register most state-licensed medical practitioners who apply to distribute a controlled substance.[59] And, while the statute demands that these practitioners keep track of their inventory,[60] it does not impose any constraints on the issuance of prescriptions.

Criminal law plays a supporting role in this framework. Making it unlawful for any person knowingly or intentionally to possess, manufacture, distribute, or dispense a controlled substance except as authorized by the CSA,[61] Part D of the statute aims to ensure that drugs never leave the legitimate channels established by its civil regulatory provisions. The Justice Department, through its component the DEA, simultaneously administers these regulatory provisions and enforces the accompanying criminal prohibitions.

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54 7 U.S.C. §§ 2132–2133.

55 *See* Eric Biber & J.B. Ruhl, *The Permit Power Revisited: The Theory and Practice of Regulatory Permits in the Administrative State*, 64 DUKE L.J. 133, 149 (2014) ("Permitting is one of the workhorses of the administrative state . . . ."). The Administrative Procedure Act has a dedicated section on procedures for licensing determinations. 5 U.S.C. § 558(c).

56 21 U.S.C. §§ 822–823.

57 *Id.* § 823(a)(1).

58 *Id.* § 832(a)(1).

59 *Id.* § 823(b), (f). As originally enacted, the CSA gave the Justice Department no power to deny registration to state-licensed physicians. *See* COMPTROLLER GEN., U.S. GEN. ACCT. OFF., GGD-78-22, RETAIL DIVERSION OF LEGAL DRUGS — A MAJOR PROBLEM WITH NO EASY SOLUTION 12–14 (1978). After it became clear that physicians' profit motive could lead them to dispense controlled substances even when unnecessary for or harmful to patients, *see id.* at 10, the law was amended in 1984 to allow the Department to deny registration to licensed physicians in limited circumstances. Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, § 511, 98 Stat. 1837, 2073 (amending 21 U.S.C. § 823(f)). In practice, adverse registration decisions for medical professionals are exceedingly rare. *Cf.* Conant v. Walters, 309 F.3d 629, 632 (9th Cir. 2002) (upholding a district court order permanently enjoining the DEA from threatening to revoke licenses of physicians who recommend medical marijuana).

60 21 U.S.C. § 827.

61 *Id.* §§ 841(a)(1), 844(a).

B. Schedules

The controls that the CSA places on registered drug manufacturers, distributors, and dispensers, as well as the penalties for production, distribution, and possession of controlled substances outside the registration system, are not left to the executive branch's discretion; they are statutorily specified. The law creates five different packages of controls of varying levels of stringency, known as schedules.[62] And, as already noted, it empowers the Attorney General to decide which drugs will be assigned to which schedule and to move drugs between schedules.[63] The Attorney General, in other words, selects from a preset regulatory menu designed by Congress when deciding how to handle any given substance.

Although there are five schedules, there are really three distinct models of drug control embedded in the CSA. Access to some drugs is banned altogether, save for tightly limited research uses. This is Schedule I and punitive prohibitionism.[64] Access to other drugs is permitted with a doctor's prescription. This is Schedule II through Schedule V and the "medical use" model.[65] Finally, access to some drugs is permitted without any role for the DEA. This is the market realm of unscheduled substances, such as alcohol, nicotine, and caffeine, subject to consumer protection and competition laws but not to any of the special strictures of the CSA.[66]

The regulatory variations across the medical use schedules (II, III, IV, and V) concern the stringency of the checks meant to protect the integrity of the "legitimate channels." The lower the schedule number, the more stringent the checks. Notable discrepancies include that production levels are capped and tracked for Schedule II drugs;[67] pharmacists may not provide refills for Schedule II drugs;[68] and applications to manufacture Schedule II drugs require an affirmative finding by the

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[62] *Id.* § 812.

[63] *Id.* § 811(a); *see supra* note 39 and accompanying text. In a recent essay, Professor Mason Marks argues that the CSA is best read to give the Department of Health and Human Services (HHS) a veto over scheduling decisions, even though the Justice Department and the courts have not accepted this view and HHS has effectively "abdicat[ed]" any such authority. Mason Marks, *Separation of Drug Scheduling Powers*, 134 YALE L.J.F. 976, 1004, 1020 (2025). Without taking a position on Marks's important argument, this Part describes the CSA's scheduling system as it currently operates.

[64] 21 U.S.C. § 812(b)(1); *see supra* note 33 and accompanying text.

[65] 21 U.S.C. § 812(b)(2)–(5). Schedules II, III, IV, and V each require that a drug have "a currently accepted medical use in treatment in the United States." *Id.*

[66] *Id.* § 802(6). For a complementary taxonomy that applies beyond the CSA, 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, 706–10 (2010) (distinguishing among "market," *id.* at 706, "public health," *id.* at 708, and "criminal," *id.* at 709, drug regulatory regimes).

[67] 21 U.S.C. § 826. Schedule II production quotas are based on the Attorney General's estimate of "medical, scientific, research, and industrial needs," *id.* § 826(a)(1), and must be raised as necessary in case of a "shortage," *id.* § 826(h).

[68] *Id.* § 829(a) ("No prescription for a controlled substance in schedule II may be refilled.").

Attorney General that such registration would be consistent with the public interest, whereas the Attorney General must show the opposite in order to deny registration for manufacturers of Schedule III, IV, and V drugs.[69] But overall, the regulatory differences across Schedules II, III, IV, and V are differences in degree, while the differences across Schedule I, Schedules II through V, and the unscheduled realm are differences in kind.

To an extent that is unusual in administrative delegations, the CSA constrains the Attorney General's determinations as to which substances belong in which schedule. First, the Attorney General must make scheduling decisions through formal rulemaking, including an opportunity for comment and a public hearing.[70] Congress dictated this most demanding of administrative procedures in order to provide an "opportunity for consideration of the views of persons who would be adversely affected by control of a drug."[71] Second, to "strike[] a balance between" public safety and medical expertise,[72] the Attorney General must seek the views of the Secretary of Health and Human Services (Secretary) before initiating a rulemaking to schedule, reschedule, or deschedule a drug, and must thereafter give significant deference to the Secretary's "scientific and medical" conclusions.[73] Third, the crucial agenda-setting choice of when to consider scheduling or rescheduling a drug is not the Attorney General's alone; scheduling proceedings may be forced by the Secretary or by any interested party through a petition for rulemaking.[74] Fourth, the Attorney General's scheduling decisions are immediately reviewable in a federal court of appeals.[75] And fifth, the CSA delineates with some

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[69] *Compare id.* § 823(a) ("The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II *if he determines that such registration is consistent with the public interest* . . . ." (emphasis added)), *with id.* § 823(e) ("The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, *unless he determines that the issuance of such registration is inconsistent with the public interest*." (emphasis added)).

[70] *See id.* § 811(a).

[71] H.R. REP. NO. 91-1444, pt. 1, at 23 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4589.

[72] *Id.* at 22 (describing the CSA as "strik[ing] a balance between the extent to which control decisions should be based upon law enforcement criteria, and the extent to which such decisions should be based on medical and scientific determinations").

[73] 21 U.S.C. § 811(b); *see* Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. (Apr. 11, 2024) (slip op. at 23) (concluding that the Secretary's "scientific and medical determinations" "bind" the DEA "until the initiation of formal rulemaking," after which point they are entitled to "significant deference"). The Secretary has subdelegated the authority to make scheduling recommendations to the Assistant Secretary for Health, who relies on the FDA and the National Institute on Drug Abuse to guide such recommendations. *See* FDA, MOU 225-85-8251, MEMORANDUM OF UNDERSTANDING BETWEEN THE NATIONAL INSTITUTE ON DRUG ABUSE AND THE FOOD AND DRUG ADMINISTRATION (2017), https://www.fda.gov/about-fda/domestic-mous/mou-225-85-8251 [https://perma.cc/SZZ4-D7S3].

[74] 21 U.S.C. § 811(a) (providing that scheduling proceedings "may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party").

[75] *Id.* § 877.

precision the criteria that the Attorney General (or her delegee[76]) must apply when making scheduling decisions, focused on the substance in question's "potential for abuse" and its "currently accepted medical use."[77] The statute also enumerates eight factors that the Attorney General must consider in making findings relevant to these decisions, including "[s]cientific evidence" of the substance's "pharmacological effect," "[i]ts history and current pattern of abuse," risks "to the public health," and "[w]hether the substance is an immediate precursor of a substance already controlled" under the CSA.[78]

These constraints evince an intent to foster public participation in scheduling choices, guard against the tendency toward administrative ossification, and encourage the Attorney General to remain continually open to reconsidering a drug's classification based on the best available evidence. If all were to go as planned, drugs whose harms trounce their benefits could be removed from circulation except for research studies, drugs with significant benefits as well as harms could be directed to individuals they would help, and all other drugs could be left untouched by the DEA. In this way, drug policy would make the American people healthier and safer without excessive intrusion on their liberties.

Would that any of these goals had come to pass. With the benefit of hindsight, the CSA's plan seems painfully naïve. Among other obvious signs of failure elaborated upon below, the law's criminal provisions have proven not secondary but primary to its operation, scheduling has indeed become ossified, and widespread harms have occurred within (not due to diversion from) the approved channels of professional control. Meanwhile, the rate of drug overdose deaths in the United States has been on "an exponential growth curve since at least 1979."[79] What went wrong?

II. WHY IS DRUG POLICY SO HARD?

The CSA's legislative plan has backfired, this Part argues, because it overlooks or discounts several features of psychoactive drugs that pose distinctive challenges for institutional design, individually and especially in their interaction. The first of these — that criminal prohibition does not work for many addictive substances — is well known to drug policy researchers. We discuss the CSA's failure to address this

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[76] 21 U.S.C. § 871(a) (authorizing the Attorney General to "delegate any of his functions under [subchapter I of the CSA] to any officer or employee of the Department of Justice").

[77] *Id.* § 812(b).

[78] *Id.* § 811(c). These factors, and their relationship to the scheduling criteria set forth in § 812(b), have been described as "somewhat mysterious." Kreit, *supra* note 11, at 345; *see also* United States v. Pastor, 419 F. Supp. 1318, 1339 n.6 (S.D.N.Y. 1975) (quoting an unpublished Department of Health, Education, and Welfare memorandum lamenting that the "eight factors . . . are for the most part vague and redundant").

[79] Hawre Jalal et al., *Changing Dynamics of the Drug Overdose Epidemic in the United States from 1979 Through 2016*, SCIENCE, Sep. 21, 2018, at 1, 5.

prohibition problem in section A. At the same time, two other vexing features of psychoactive drugs have undermined the noncriminal provisions of the CSA (and threaten to undermine any future attempts to replace prohibition with decriminalization or legalization). Section B describes the *pharma problem* and its implications for the political economy of drug regulation. Section C explores the *pluralism problem* and its implications for the role of expertise in drug policymaking. These problems interfere with the operation of each of the CSA's main features: The prohibition problem undermines the statute's criminal backstop, the pharma problem undermines its reliance on medical control, and the pluralism problem undermines its reliance on scientific evidence in sorting drugs into schedules.

A. The Prohibition Problem

As explained in Part I, the CSA criminalizes essentially all production, distribution, and possession of drugs in Schedule I as well as the unlicensed production, distribution, and possession of drugs in Schedules II through V.[80] Yet, notwithstanding these extensive criminal prohibitions and the billions of dollars spent each year to enforce them,[81] the rate of drug-associated death and disease has continually gone up since the CSA's enactment.[82] Basic attributes of drug markets help explain why.

By definition, people who are addicted to drugs have a "compulsive" drive to use them despite the harm from doing so.[83] This means that increasing the drug's cost through the severity of sanctions cannot be counted on to reduce usage. In economic terms, demand for any given class of addictive substances tends to be inelastic.[84] And, while not all

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[80] *See supra* section I.A, pp. 857–60.

[81] *Staffing and Budget*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/data-and-statistics/staffing-and-budget [https://perma.cc/CH6M-EUNT] (reporting that the DEA's annual budget has been over a billion dollars since fiscal year 1995).

[82] *See, e.g.*, Jalal et al., *supra* note 79, at 1 (charting "[e]xponential growth" in drug overdose deaths from 1979 through 2016).

[83] *E.g.*, *Definition of Addiction*, AM. SOC'Y OF ADDICTION MED. (Sep. 15, 2019), https://www.asam.org/quality-care/definition-of-addiction [https://perma.cc/6D68-L2D4] ("People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences."); *see also, e.g.*, José C. Perales et al., *Learning to Lose Control: A Process-Based Account of Behavioral Addiction*, 108 NEUROSCI. & BIOBEHAV. REVS. 771, 774 (2020) ("[T]he *signature* of addiction is the increasing role that compulsivity plays in the activity that one becomes addicted to."). Although the definition of addiction has long been contested, the element of compulsivity is relatively uncontroversial. *See* Matthew B. Lawrence, *Addiction and Liberty*, 108 CORN. L. REV. 259, 310–12 (2023). *But cf.* Hanna Pickard, *Addiction and the Self*, 55 NOÛS 737, 738–42 (2021) (challenging the "dominant" view of drug addiction as "a neurobiological disease of compulsion," *id.* at 738, in light of "evidence demonstrating flexibility in behavior and responsiveness to incentives in addiction," *id.* at 742).

[84] *See, e.g.*, A. Morgan Cloud III, *Cocaine, Demand, and Addiction: A Study of the Possible Convergence of Rational Theory and National Policy*, 42 VAND. L. REV. 725, 763 (1989) ("[T]hose

substances covered by the CSA are addictive in this sense, many of them are, at least for some users.[85] Separate from the addiction issue, moreover, intensifying interdiction efforts against a widely used drug incentivizes illicit sellers to develop smaller, more potent versions of the drug, or substitutes for it, in order to serve the existing market while reducing the likelihood of punishment.[86] This has come to be known as the "iron law of drug prohibition"[87]: "[t]he harder the enforcement, the harder the drugs."[88]

The progression of the opioid crisis illustrates this prohibition problem.[89] In the 1990s, the crisis was initially fueled by use and misuse of prescription painkillers pushed by Purdue Pharma and other industry actors, a point to which we return below.[90] By the time widespread concern emerged in the late aughts, more than 20,000 Americans were dying from opioid overdose annually.[91] The DEA and other law enforcement agencies then joined with the medical profession in cracking down on opioid prescription and distribution, constricting the lawful channel through which the drugs had been flowing.[92] But this response forgot the prohibition problem. The crackdown drove people suffering from opioid use disorder to the illicit market, where increasingly

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consumers who are addicts represent inelastic demand. Addicts are less likely than nonaddicts to be responsive to changes in price . . . ." (footnote omitted)); *see also* Craig A. Gallet, *Can Price Get the Monkey Off Our Back? A Meta-Analysis of Illicit Drug Demand*, 23 HEALTH ECON. 55, 56–58 (2014) (reviewing the literature on the price elasticity of illicit drugs).

85 Although the CSA's scheduling criteria do not expressly refer to addictiveness, some draw on the related concepts of "physical dependence" and "psychological dependence." *E.g.*, 21 U.S.C. § 812(b)(4)(C).

86 *See* Richard C. Cowan, *How the Narcs Created Crack*, NAT'L REV., Dec. 5, 1986, at 26, 26–27.

87 *Id.* at 27 (emphasis omitted).

88 Maia Szalavitz, *Street Opioids Are Getting Deadlier. Overseeing Drug Use Can Reduce Deaths*, THE GUARDIAN (Apr. 26, 2016, at 07:00 ET), https://www.theguardian.com/commentisfree/2016/apr/26/street-opioids-use-deaths-perscription-drugs-fentanyl [https://perma.cc/E72M-3KGA] (attributing this phrase to Richard Cowan and noting that it has "been demonstrated throughout the history of drug policy: the more authorities target a class of drugs, the more potent and dangerous the versions on the street become").

89 Although this Article's examples focus primarily on opioids and marijuana, given the extent to which they dominate current drug debates as well as the outsized resources devoted to their regulation, nothing in our thesis is keyed to specific substances.

90 *See infra* section II.B, pp. 869–73. Beyond prescribing practices, the opioid crisis was "fundamentally fueled by economic and social" forces such as "physical and psychological trauma, concentrated disadvantage, isolation, and hopelessness." Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 182 (2018).

91 *See Drug Overdose Deaths: Facts and Figures*, NAT'L INST. ON DRUG ABUSE fig. 3 (Aug. 2024) [hereinafter *Drug Overdose Deaths*], https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig3 [https://perma.cc/7NRH-KM45].

92 *See* Jennifer D. Oliva, *Prescription-Drug Policing: The Right to Health Information Privacy Pre- and Post-*Carpenter, 69 DUKE L.J. 775, 779–82 (2020) (describing "the enactment of numerous dragnet-style laws at the state and federal level aimed at cracking down on rogue prescribers, pain-pill mills, and prescription-drug 'doctor shoppers,'" along with "the rapid rise of prescriber and patient surveillance" programs, *id.* at 779).

sophisticated heroin dealers moved quickly to meet the new demand.[93] When the resulting spike in heroin use was declared a national emergency in 2017, death rates were approaching 50,000 annually.[94] That led to intensified efforts to shut down the heroin supply, which in turn drove a transition to fentanyl,[95] a synthetic opioid many times more potent than heroin.[96] Fentanyl's relative potency makes it not only easier to smuggle but also riskier for users. In 2023, there were nearly 80,000 opioid overdose deaths in the United States.[97]

This is not to say that prohibition never works. If there is no critical mass of demand for a drug, prohibition may be able to prevent one from developing.[98] Thus, in one of the DEA's rare successes, the agency effectively shut down a nascent market for methaqualone (Quaalude) — a drug first synthesized in 1951 and marketed as a sedative beginning in the 1960s — shortly after it emerged as a club drug in the 1970s.[99] The CSA, however, depends on punitive prohibition regardless of whether there is an established market for a drug or a safer substitute toward which consumers can be steered, a design flaw that not only chronically fails to reduce dangerous drug behaviors but also lies behind three of American drug policy's most infamous consequences.

First, U.S. drug law's failure to account for the prohibition problem has been a driver of mass incarceration and the growth of the carceral

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93 *See* MAIA SZALAVITZ, UNDOING DRUGS: THE UNTOLD STORY OF HARM REDUCTION AND THE FUTURE OF ADDICTION 287 (2021); Leo Beletsky & Corey S. Davis, *Today's Fentanyl Crisis: Prohibition's Iron Law, Revisited*, 46 INT'L J. DRUG POL'Y 156, 156 (2017).

94 *See Drug Overdose Deaths*, *supra* note 91.

95 *See* Beletsky & Davis, *supra* note 93, at 157–58.

96 *Fentanyl Facts*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 2, 2024), https://www.cdc.gov/stop-overdose/caring/fentanyl-facts.html [https://perma.cc/QRN5-TWL9].

97 *See Drug Overdose Deaths*, *supra* note 91. The number of overdose deaths declined in 2024, but neither the reason for the decline nor its likelihood of persisting is well understood at this time. *See* Jan Hoffman & Noah Weiland, *What's Behind the Remarkable Drop in U.S. Overdose Deaths*, N.Y. TIMES (Nov. 21, 2024), https://www.nytimes.com/2024/11/21/health/overdose-deaths-decline-drug-supply.html [https://perma.cc/XK6S-WUKW]. One possibility is that a new illicit additive, xylazine, reduces the risk of overdose death from fentanyl even as it causes "horrific" physical side effects. *Id.*

98 Because nonusers' demand for addictive drugs is relatively elastic, increasing the cost of such drugs through excise taxes or other regulatory measures may also help to curb new use. *See, e.g.*, Frank J. Chaloupka & Kenneth E. Warner, *The Economics of Smoking*, *in* 1B HANDBOOK OF HEALTH ECONOMICS 1539, 1554–55 (Anthony J. Culyer & Joseph P. Newhouse eds., 2000) (reviewing mixed evidence on the impact of cigarette price changes on smoking initiation).

99 *See* DAVID HERZBERG, WHITE MARKET DRUGS: BIG PHARMA AND THE HIDDEN HISTORY OF ADDICTION IN AMERICA 223 (2020); David Herzberg, *Quaalude Nostalgia: A Retro Drug that Everyone Remembers Fondly*, THE ATLANTIC (Feb. 21, 2012), https://www.theatlantic.com/health/archive/2012/02/quaalude-nostalgia-a-retro-drug-that-everyone-remembers-fondly/252285 [https://perma.cc/5MP5-KLHR]. The DEA's crackdown on methaqualone "work[ed] so well," HERZBERG, *supra*, at 232, in part because safer sedatives, such as Valium, remained relatively accessible, *id.* at 234.

state.[100] Even as policymakers acknowledge that "we cannot arrest our way out of [the drug] problem,"[101] the main tool for addressing illicit use that the CSA gives the federal executive — and that the statute's state-level counterparts give state executives — is criminal punishment.[102] And they use it. In the late 2010s, for example, more than 1.5 million Americans were arrested annually for drug offenses,[103] and some half a million Americans were "behind bars on any given night for a drug law violation."[104]

Second and relatedly, prohibition has fueled discriminatory and subordinating police practices. With tens of millions of Americans violating criminal drug bans each year, and with no "victim" to report the overwhelming majority of these crimes, law enforcement has tremendous discretion to determine which offenders to pursue. The door is thus opened to a wide range of intrusive investigatory tactics, from stop-and-frisk and no-knock raids to wiretaps and informants.[105] And given the myriad race- and class-based biases that affect policing in the United States, these tactics are liable to be concentrated in Black and brown communities, notwithstanding similar rates of drug selling, buying, and using across racial groups.[106] Now-standard complaints that the war on drugs has "decimat[ed] the Bill of Rights"[107] and become the "New

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100 Although the degree to which criminal drug laws have driven mass incarceration is the subject of debate, *see generally, e.g.*, JOHN F. PFAFF, LOCKED IN: THE TRUE CAUSES OF MASS INCARCERATION AND HOW TO ACHIEVE REAL REFORM (2017) (challenging the "Standard Story," *id.* at 5), no one disputes that they have been a contributing factor, *see, e.g.*, LEO BELETSKY, ACAD. FOR JUST. & DRUG ENF'T & POL'Y CTR., CONTROLLED SUBSTANCES ACT AT 50: A BLUEPRINT FOR REFORM 2 (2020), https://law.asu.edu/sites/default/files/pdf/academy_for_justice/csa_at_50_blueprint.pdf [https://perma.cc/KTN4-XHKE] ("The CSA and its progeny have helped make the U.S. the undisputed world leader in mass incarceration. . . . Outside of criminal law, the CSA has injected carceral policies into many other social structures.").

101 *We Can Beat the Opioid Epidemic*, MIKE LEE: U.S. SENATOR FOR UTAH (May 10, 2018), https://www.lee.senate.gov/2018/5/we-can-beat-the-opioid-epidemic [https://perma.cc/92EN-LJRT].

102 *See supra* section I.A, pp. 857–60.

103 *See, e.g.*, *Persons Arrested*, FBI: UNIFORM CRIME REPORTING, https://ucr.fbi.gov/crime-in-the-u.s/2019/crime-in-the-u.s.-2019/topic-pages/persons-arrested [https://perma.cc/DPM2-5Y3J] (estimating 1,558,862 arrests "for drug abuse violations" in 2019, the single highest category of arrests nationwide).

104 DRUG POL'Y ALL., THE DRUG WAR, MASS INCARCERATION AND RACE 1 (2015), https://www.unodc.org/documents/ungass2016/Contributions/Civil/DrugPolicyAlliance/DPA_Fact_Sheet_Drug_War_Mass_Incarceration_and_Race_June2015.pdf [https://perma.cc/4B92-NBFZ].

105 *See* Alex Kreit, *Marijuana Legalization and Pretextual Stops*, 50 U.C. DAVIS L. REV. 741, 745–46 (2016) (explaining that such tactics have been "[o]ne of the defining features of the war on drugs," *id.* at 745); Dara Lind, *Cops Do 20,000 No-Knock Raids a Year. Civilians Often Pay the Price When They Go Wrong.*, VOX (May 15, 2015, at 12:12 ET), https://www.vox.com/2014/10/29/7083371/swat-no-knock-raids-police-killed-civilians-dangerous-work-drugs [https://perma.cc/K243-ZE5V] (estimating that police were conducting "20,000 or more . . . no-knock raids every year across America," often for "drug busts").

106 *See* POZEN, *supra* note 4, at 13–14, 67, 71; *see also* Amna A. Akbar, *An Abolitionist Horizon for (Police) Reform*, 108 CALIF. L. REV. 1781, 1788 n.18 (2020) (collecting sources on racial, gender, and class biases in policing).

107 Paul Finkelman, *The Second Casualty of War: Civil Liberties and the War on Drugs*, 66 S. CAL. L. REV. 1389, 1449 (1993).

Jim Crow"[108] flow directly from U.S. drug law's emphasis on criminal prohibition.

Third, prohibition makes drug markets far more dangerous than they might otherwise be. By driving these markets underground, prohibition breeds organized crime and violence, increases the supply of adulterated and impure products, and undermines efforts to help people with substance use disorders and associated mental health problems.[109] Syringe exchange programs, safe injection facilities, and other harm reduction measures have been shown to reduce drug users' risk of mortality, infection, and overdose while improving their access to medical care.[110] But federal courts have held that the CSA and related statutes prohibit such measures to varying degrees, on the theory that they are tantamount to facilitating unlawful use.[111] Moreover, even when states have implemented harm reduction policies, many drug users are understandably wary of participating in them for fear that it will lead to their arrest or incarceration.[112]

The ongoing fentanyl crisis offers an acute illustration of these dynamics. Fentanyl can easily be laced in other illicit drugs or incorrectly dosed by the dealer or the user.[113] As a result, most fentanyl deaths today are caused either by inadvertent ingestion or accidental overdose — by people consuming fentanyl without intending to or in larger quantities than they intended.[114] The CSA, however, provides no mechanism for quality control in the illicit fentanyl supply. Quite to the contrary, some law enforcement officials have suggested that even modest

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108 ALEXANDER, *supra* note 7, at 58.

109 *Cf.* Randy E. Barnett, *The Harmful Side Effects of Drug Prohibition*, 2009 UTAH L. REV. 11, 16–31 (reviewing a wide range of "[h]armful [e]ffects" of criminal drug bans, *id.* at 16).

110 *See* Dagmar Hedrich & Richard Lionel Hartnoll, *Harm-Reduction Interventions*, *in* TEXTBOOK OF ADDICTION TREATMENT: INTERNATIONAL PERSPECTIVES 757, 759–70 (Nady el-Guebaly et al. eds., 2d ed. 2021) (reviewing research on the effectiveness of different harm reduction interventions); Timothy W. Levengood et al., *Supervised Injection Facilities as Harm Reduction: A Systematic Review*, 61 AM. J. PREVENTIVE MED. 738, 740–46 (2021) (summarizing evidence that supervised injection facilities reduce harms of drug use).

111 *See, e.g.*, United States v. Safehouse, 985 F.3d 225, 229 (3d Cir. 2021) ("Because Safehouse knows and intends that its visitors will come with a significant purpose of doing drugs, its safe-injection site will break the law. . . . Safehouse's benevolent motive makes no difference.").

112 *See, e.g.*, Ali Farhoudian et al., *Barriers and Facilitators to Substance Use Disorder Treatment: An Overview of Systematic Reviews*, 16 SUBST. ABUSE: RSCH. & TREATMENT 1, 5 tbl. 2 (2022) (finding that fear of incarceration and fear of termination of parental rights are among the leading barriers to participation in substance use disorder treatment).

113 *See One Pill Can Kill*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/onepill [https://perma.cc/EMU2-2RVM].

114 *Cf.* MERIANNE R. SPENCER, MATTHEW F. GARNETT & ARIALDI M. MINIÑO, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, DRUG OVERDOSE DEATHS IN THE UNITED STATES, 2002–2022, at 6 (2024), https://www.cdc.gov/nchs/data/databriefs/db491.pdf [https://perma.cc/64HF-A75B] (reporting that 92.3% of drug overdose deaths in 2022 were "unintentional").

harm reduction interventions like distributing fentanyl test strips are themselves criminal offenses.[115]

B. The Pharma Problem

If the prohibition problem were the only flaw in the CSA's design, the solution might be simple: "Just say no" to prohibition, and replace it with some form of legalization or medical supervision. Beyond failing to grapple with the perversities of prohibition, however, the CSA also fails to grapple with the power of drug manufacturers, distributors, and others who profit from the sale of psychoactive products. This pharma problem has deeply compromised the law's reliance on physicians to control lawful access to drugs in Schedules II through V.[116]

The threat that private industry will use resources acquired through commerce to exploit vulnerable individuals and "capture" the administrative process is a challenge for any regulatory regime, and a particular challenge in the health care and consumer protection domains. As a growing body of scholarship has shown, economic power may be readily translated in these domains into other forms of influence, at the expense of patients, customers, and democratic values.[117] Two features of psychoactive drugs make these risks all the more acute in the context of the CSA.

First is the potential for psychoactive drugs to be habit forming, such that initial use stimulates future demand and, in some cases, physiological or psychological dependence. This gives drug companies a powerful incentive to encourage initial use through tactics such as free samples, targeted outreach to minors, rewards for repeated purchase, and

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[115] *See* NETWORK FOR PUB. HEALTH L., LEGALITY OF DRUG CHECKING EQUIPMENT IN THE UNITED STATES 2 (Aug. 2024), https://www.networkforphl.org/wp-content/uploads/2024/08/2024-50-State-DCE-Fact-Sheet.pdf [https://perma.cc/H8BL-558H].

[116] "Pharma" is a common shorthand for the pharmaceutical industry and also an allusion to the leading industry trade group, PhRMA (short for Pharmaceutical Research and Manufacturers of America). Although our analysis of the "pharma problem" focuses on these actors, it bears emphasis that the problem may apply to any firm that makes or sells habit-forming substances, even if the firm is not considered part of the pharmaceutical industry. *See infra* notes 142–45 and accompanying text (discussing examples).

[117] *See supra* note 21 and accompanying text; *see also, e.g.*, David A. Hyman, *Getting the Haves to Come Out Behind: Fixing the Distributive Injustices of American Health Care*, L. & CONTEMP. PROBS., Autumn 2006, at 265, 279 ("[P]rovider capture of state and federal legislators and regulators is the rule [in health care], and the results have not been pretty."); Luke Herrine, *What Is Consumer Protection For?*, 34 LOY. CONSUMER L. REV. 240, 245 (2022) (discussing concerns that "consumer markets reproduce inequality, enable manipulation of our decisions and our deliberations, and/or infringe on values beyond the accumulation of things"). The interconnectedness of economic power, market power, and political power has been a central concern of the law-and-political-economy literature more broadly. *See* Jedediah Britton-Purdy et al., Feature, *Building a Law-and-Political-Economy Framework: Beyond the Twentieth-Century Synthesis*, 129 YALE L.J. 1784, 1818–23 (2020).

aggressive price discounts early in a drug's commercial life.[118] The incentive "to invest in demand creation"[119] is reinforced by a second, legal feature of U.S. drug markets: their reliance on patents and regulatory exclusivities to encourage drug development.[120] When there are many sellers of a product, collective action problems reduce the returns to lobbying, advertising, and other efforts to create demand.[121] This dynamic changes, however, when one seller enjoys monopolist status or high market share — as pharmaceutical companies frequently do[122] — or when multiple firms are able to form a cohesive trade organization, such as PhRMA.[123] The upshot is that the sorts of firms that make and sell the sorts of substances covered by the CSA will tend to be especially motivated to foster consumption by manipulating politics, consumers, and the information environment.

The CSA does nothing to address this pharma problem, instead assuming that physicians will prescribe Schedule II through V drugs based solely on their patients' best interests.[124] The opioid crisis has laid bare the significance of this design defect, too. While prohibition helped drive the evolution of the crisis from prescription painkillers to heroin to illicit fentanyl, prohibition did not drive its origin. Instead, the crisis was "triggered" in large part by opioid manufacturers and distributors, such as Purdue Pharma, using their economic clout to foster habit formation.[125] As has now been detailed in documentaries,

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118 *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, J.L. & BIOSCIS., Jan.–June 2020, at 1, 20 (discussing price discounts); Lawrence, *supra* note 83, at 275–98 (discussing the cultivation of addiction in other commercial contexts, such as gambling).

119 Hemel & Ouellette, *supra* note 118, at 15.

120 *See id.* at 15–16; *see also* Daniel J. Nam, *Patent & Regulatory Exclusivities: The Two Keys Driving Generic and Follow-on Market Availability*, U.S. PHARMACIST (June 16, 2016), https://www.uspharmacist.com/article/patent-and-regulatory-exclusivities-the-two-keys-driving-generic-and-followon-market-availability [https://perma.cc/6JDH-4CCT] (explaining and distinguishing the roles of patents and "regulatory exclusivities" in the pharmaceutical industry).

121 *Cf.* Alexander Volokh, *Privatization and the Law and Economics of Political Advocacy*, 60 STAN. L. REV. 1197, 1207–13 (2008) (making this point with respect to political advocacy).

122 *See* Robert Pearl, *Pharma Companies: A Conglomerate of Monopolies*, FORBES (Jan. 31, 2023, at 04:30 ET), https://www.forbes.com/sites/robertpearl/2023/01/31/pharma-companies-a-conglomerate-of-monopolies [https://perma.cc/J2N9-3MDL]. This concern is significantly reduced for substances that are unpatentable (for example, because they are naturally occurring), off-patent, or off-exclusivity. Since at least 2006, most opioids supplied to U.S. pharmacies have been generic drugs. *See* Aaron C. Davis, Shawn Boburg & Robert O'Harrow Jr., *Little-Known Makers of Generic Drugs Played Central Role in Opioid Crisis, Records Show*, WASH. POST (July 27, 2019), https://www.washingtonpost.com/investigations/little-known-generic-drug-companies-played-central-role-in-opioid-crisis-documents-reveal/2019/07/26/95e08b46-ac5c-11e9-a0c9-6d2d7818f3da_story.html [https://perma.cc/FNR6-DWM3].

123 *See* Matthew B. Lawrence, *Super-Groups: Legal Empowerment and "Public Law,"* 100 IND. L.J. 1179, 1193–94 (2025) (collecting literature on group cohesion as a determinant of political power); *id.* at 1234–35, 1235 n.311 (discussing PhRMA as a leading interest group).

124 *See supra* section I.A, pp. 857–60 (explaining physicians' gatekeeping role under the CSA).

125 Mariano-Florentino Cuéllar & Keith Humphreys, *The Political Economy of the Opioid Epidemic*, 38 YALE L. & POL'Y REV. 1, 4 (2019).

lawsuits, hearings, and books, after receiving a patent in the mid-1990s Purdue promoted consumption of OxyContin on myriad fronts, including liberally distributing free starter coupons and branded gifts;[126] hiring former DEA officials;[127] spending vast sums lobbying state and federal legislators, regulators, and accreditation bodies;[128] ghostwriting research studies;[129] funding seemingly grassroots organizations to advocate expanded access to opioids (a practice known as astroturfing);[130] and hosting all-expenses-paid conferences at lavish locales to encourage physicians to prescribe OxyContin.[131] Through these efforts, Purdue and its network of economic partners achieved a fourfold increase in opioid prescribing in a ten-year span.[132]

The CSA's vulnerability to economic distortion has been shown repeatedly over the past fifty years; the opioid crisis is not an aberration in this respect. During the COVID pandemic, for example, private-equity-backed telehealth companies Cerebral and Done Global allegedly pushed nonmedical use of Adderall through targeted advertisements on social media, astroturfing, lobbying, and financial incentives for

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126 *See* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 222 (2009).

127 *See* Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, WASH. POST (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html [https://perma.cc/W2B5-2A9T]; Laura Strickler, *Former DEA Official Now Working for OxyContin Maker Purdue Pharma*, NBC NEWS (Mar. 20, 2019, at 04:30 ET), https://www.nbcnews.com/health/health-care/former-dea-official-now-working-oxycontin-maker-purdue-pharma-n984646 [https://perma.cc/UUS2-L7CM].

128 *See* HERZBERG, *supra* note 99, at 272 (describing ways in which Purdue "coopt[ed] the professional and state regulatory bodies that governed medical standards"); Patrick Radden Keefe, *The Family that Built an Empire of Pain*, NEW YORKER (Oct. 23, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain [https://perma.cc/MB9U-ZVWX] ("Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly nine hundred million dollars on lobbying and political contributions — eight times what the gun lobby spent during that period.").

129 *See* Brian W. Gac, Hanna Yakubi & Dorie E. Apollonio, *Issues Arising from the Study Design, Conduct, and Promotion of Clinical Trials Funded by Opioid Manufacturers: A Review of Internal Pharmaceutical Industry Documents*, 19 EVIDENCE & POL'Y 536, 542–44 (2023); *see also* DAVID MICHAELS, THE TRIUMPH OF DOUBT: DARK MONEY AND THE SCIENCE OF DECEPTION 108 (2020) ("The evidence is simply overwhelming: opioid producers suppressed some studies, misrepresented and elevated others, [and] claimed their drugs were neither addictive nor easily abused . . . .").

130 *See* Andrea Bowra et al., *Interconnected Influence: Unraveling Purdue Pharmaceutical's Role in the Global Response to the Opioid Crisis*, INT'L J. DRUG POL'Y, Nov. 2024, at 1, 6–7.

131 *See* Ameet Sarpatwari, Michael S. Sinha & Aaron S. Kesselheim, *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L & POL'Y REV. 463, 467 (2017). Because OxyContin is a Schedule II drug, every prescription must come from a licensed practitioner. 21 U.S.C. § 829(a).

132 *See* Vertinsky, *supra* note 21, at 209 (describing "the web of stakeholders with commercial interests in growing the opioid market"); Deborah Dowell et al., *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022*, MORBIDITY & MORTALITY WKLY. REP.: RECOMMENDATIONS & REPS., Nov. 4, 2022, at 1, 3 ("In the United States, opioid prescribing increased fourfold during 1999–2010; this increase was paralleled by an approximately fourfold increase in overdose deaths involving prescription opioids during the same period . . . .").

prescribers.[133] The resulting surge in Adderall use contributed to subsequent shortages.[134] Scholars have documented similarly successful efforts to foster dependence on anticonvulsants such as Lyrica and Gabapentin,[135] antidepressants such as Prozac,[136] and benzodiazepines such as Valium,[137] among others.[138] The flaw in the CSA that these drug companies have exploited — its trust in the medical profession to control lawful access without regard to financial interest — revealed itself as early as 1978, when the Government Accountability Office observed that the CSA gives the DEA "extensive authority over manufacturers and distributors" but relatively "little regulatory authority" over practitioners.[139] The result, then and now, is that the agency "cannot effectively deal with retail diversion."[140]

A version of the pharma problem extends to potentially addictive substances that the CSA does not cover: most obviously, alcohol and tobacco. "Recreational" consumers can be manipulated just like patients and physicians, and market regulators can be captured just like medical regulators.[141] Unsurprisingly, then, a large literature has documented the efforts of alcohol and tobacco companies — as well as social media platforms, processed-food manufacturers, and other firms that deal in habit-forming *non*drugs — "to promote products and choices that are

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133 *See* Press Release, DOJ, Founder/CEO and Clinical President of Digital Health Company Arrested for $100M Adderall Distribution and Health Care Fraud Scheme (June 13, 2024), https://www.justice.gov/opa/pr/founderceo-and-clinical-president-digital-health-company-arrested-100m-adderall-distribution [https://perma.cc/G4NR-EGY7]; Polly Mosendz, *How One Telehealth Firm Is Lobbying US Officials to Keep Prescribing Drugs Online*, BLOOMBERG (Dec. 27, 2022, at 06:00 ET), https://www.bloomberg.com/news/articles/2022-12-27/telehealth-firm-lobbies-to-keep-prescribing-controlled-substances-amid-scrutiny [https://perma.cc/HF9D-XGXV]; Brendan Pierson, *Telehealth Company Cerebral to Pay $3.65 Mln to Resolve Probe of Adderall Sales*, REUTERS (Nov. 5, 2024, at 21:11 ET), https://www.reuters.com/legal/government/telehealth-company-cerebral-pay-365-mln-resolve-probe-adderall-sales-2024-11-05 [https://perma.cc/4WCE-WLQ4]. On the vast potential benefits of teleprescribing controlled substances and the downsides of current federal restrictions, see generally Benjamin A. Barsky, *Internet Drug Prohibition and the Opioid Overdose Crisis*, 99 WASH. L. REV. 361 (2024).

134 *See* Pierson, *supra* note 133 ("U.S. regulators have said that illegal Adderall sales have exacerbated a shortage of the drug that has persisted since 2022.").

135 *See* Rachel V. Smith, Jennifer R. Havens & Sharon L. Walsh, *Gabapentin Misuse, Abuse and Diversion: A Systematic Review*, 111 ADDICTION 1160, 1171 (2016); William Henken, *Pfizer's Lyrica Causing Outcry*, ADDICTION CTR. (Oct. 20, 2025), https://www.addictioncenter.com/news/2021/09/pfizers-lyrica-causing-outcry [https://perma.cc/FSH2-GXUK].

136 *See* DAVID HERZBERG, HAPPY PILLS IN AMERICA: FROM MILTOWN TO PROZAC 169–89 (2009).

137 *Id.* at 137–38.

138 For a systematic effort to document pharmaceutical companies' marketing practices and their influence on prescribing, see *PharmedOut*, GEORGETOWN UNIV. MED. CTR., https://sites.google.com/georgetown.edu/pharmedout/home?authuser=0 [https://perma.cc/Q4RC-QNLX].

139 COMPTROLLER GEN., *supra* note 59, at 12.

140 *Id.*; *see also id.* at 5 (noting that "much of the abuse involves legal drugs diverted at the retail level").

141 *See* Vertinsky, *supra* note 21, at 158–82.

detrimental to health."[142] The harms caused by these licit industries exceed those caused by opioids on most measures.[143] And at least until their 1998 master settlement with state attorneys general, the largest tobacco companies employed many of the same strategies later employed by Purdue, including ghostwriting, astroturfing, targeting adolescents, and misleading the public about known risks.[144]

Across all of these domains, public health scholars emphasize, profit-seeking actors aim to create an "alternative reality" about both the safety of their products and the adverse effects of regulatory interventions.[145] Neither the CSA's medical model nor consumer protection law's market model has been successful at curbing exploitation of vulnerable individuals or addressing the harms caused by mass production and sale of habit-forming commodities.

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[142] Ilona Kickbusch, Luke Allen & Christian Franz, *The Commercial Determinants of Health*, 4 LANCET GLOB. HEALTH e895, e895 (2016); *see also* THE COMMERCIAL DETERMINANTS OF HEALTH (Nason Maani, Mark Petticrew & Sandro Galea eds., 2023) (exploring such efforts across a range of industries); DAVID T. COURTWRIGHT, THE AGE OF ADDICTION: HOW BAD HABITS BECAME BIG BUSINESS 6 (2019) (explaining how modern businesses "encourage excessive consumption and addiction . . . by targeting the limbic system, the part of the brain responsible for feeling and for quick reaction"); Joana Madureira Lima & Sandro Galea, *Corporate Practices and Health: A Framework and Mechanisms*, 14 GLOBALIZATION & HEALTH, 2018, at 1, 2–3 (cataloging practices used by for-profit firms to foster consumption of unhealthful products).

[143] *Compare, e.g.*, Marissa B. Esser et al., *Deaths from Excessive Alcohol Use — United States, 2016–2021*, 73 MORBIDITY & MORTALITY WKLY. REP. 154, 156 (2024) (estimating roughly 178,000 annual deaths in the United States from excessive alcohol use during 2020–2021), *and Burden of Cigarette Use in the U.S.*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 8, 2024), https://www.cdc.gov/tobacco/campaign/tips/resources/data/cigarette-smoking-in-united-states.html [https://perma.cc/9GUG-QGJN] ("Cigarette smoking remains the leading cause of preventable disease and death in the United States. Cigarette smoking kills more than 480,000 Americans each year."), *with Drug Overdose Deaths: Facts and Figures*, NAT'L INST. ON DRUG ABUSE (Aug. 2024), https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig3 [https://perma.cc/L73Y-ZWSE] (reporting a total of 79,358 overdose deaths in 2023 from all opioids).

[144] *See* NAOMI ORESKES & ERIC M. CONWAY, MERCHANTS OF DOUBT: HOW A HANDFUL OF SCIENTISTS OBSCURED THE TRUTH ON ISSUES FROM TOBACCO SMOKE TO GLOBAL WARMING 8–17 (2010); Yussuf Saloojee & Elif Dagli, *Tobacco Industry Tactics for Resisting Public Policy on Health*, 78 BULL. WORLD HEALTH ORG. 902, 903–07 (2000); Selda Ulucanlar, Gary J. Fooks & Anna B. Gilmore, *The Policy Dystopia Model: An Interpretive Analysis of Tobacco Industry Political Activity*, PLOS MED., Sep. 20, 2016, at 1, 6–12. For evidence on the tobacco industry's political spending and its impact, see Michael S. Givel & Stanton A. Glantz, *Tobacco Lobby Political Influence on US State Legislatures in the 1990s*, 10 TOBACCO CONTROL 124, 125–31 (2001), and Douglas A. Luke & Melissa Krauss, *Where There's Smoke There's Money: Tobacco Industry Campaign Contributions and U.S. Congressional Voting*, 27 AM. J. PREVENTIVE MED. 363, 365–70 (2004).

[145] Ulucanlar, Fooks & Gilmore, *supra* note 144, at 13. *See generally* THOMAS O. MCGARITY & WENDY E. WAGNER, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH (2008) (documenting myriad ways in which industry groups in general, and drug companies in particular, distort science to serve their economic interests).

C. The Pluralism Problem

From a certain public health perspective, the answer to this pharma problem seems simple. Given the incentives and resources that manufacturers of potentially addictive products have to cultivate habit formation and political-economic influence, decisions about access to these products should be made not by legislators, consumers, or doctors with financial ties to the manufacturers but by relatively insulated experts.[146] This is a standard approach in regulatory domains that combine a high level of technical complexity with a high risk of capture, such as monetary policy: Turn away from politics and toward expertise.[147] More concretely, as Professor Rachel Barkow explains, the "conventional" administrative law response to concerns that ordinary people will be "outgunned in the political process by well-financed and politically influential special interests" is the creation of a so-called independent agency, the leadership of which "cannot be removed by the President except for cause."[148] Such agencies, the thinking goes, will be better able to "resist short-term partisan pressures and instead place more emphasis on empirical facts that will serve the public interest in the long term."[149]

The CSA incorporates aspects of this approach, particularly in the area of drug scheduling. The statute does not create or rely upon a traditional independent agency, whose head is insulated against removal by the President.[150] But the CSA does delegate scheduling decisions to the Attorney General, a department head who is sometimes said to be more insulated from politics (or at least is supposed to be more insulated

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146 *See, e.g.*, THOMAS F. BABOR ET AL., DRUG POLICY AND THE PUBLIC GOOD 282–83 (2d ed. 2018) (arguing for an "evidence-based," "public health approach" to drug policy, *id.* at 283); Taleed El-Sabawi, *Why the DEA, Not the FDA? Revisiting the Regulation of Potentially-Addictive Substances*, 16 N.Y.U. J.L. & BUS. 317, 343 (2020) (arguing that drug policy decisions should be shifted from the DEA to the FDA as "an agency that prioritizes public health").

147 *See, e.g.*, Edward Rubin, *Hyperdepoliticization*, 47 WAKE FOREST L. REV. 631, 665–68 (2012) (describing the Federal Reserve Board's independence).

148 Barkow, *supra* note 21, at 17.

149 *Id.*; *see also* Neal Devins & David E. Lewis, *Not-So Independent Agencies: Party Polarization and the Limits of Institutional Design*, 88 B.U. L. REV. 459, 463 (2008) ("Independent agencies are preferred to executive agencies because long commissioner tenure, staggered terms, and political insulation are intended to facilitate a non-political environment where regulatory experts can apply their knowledge to complex policy problems."); Jacob E. Gersen, *Designing Agencies*, *in* RESEARCH HANDBOOK ON PUBLIC CHOICE AND PUBLIC LAW 333, 348 (Daniel A. Farber & Anne Joseph O'Connell eds., 2010) (describing "insulation" as "a strategy for allowing agencies to utilize expertise without short-term political pressure").

150 At this writing, the continued constitutionality of such removal protections is very much in question. *See* Trump v. Slaughter, No. 25-332, 2025 WL 2692050 (Sep. 22, 2025) (granting certiorari and directing the parties to brief "whether *Humphrey's Executor v. United States*, 295 U.S. 602[] (1935), should be overruled").

from politics) than most other department heads.[151] The statute further instructs that the Attorney General must give deference to the Secretary of Health and Human Services' "scientific and medical" recommendations,[152] as explained in Part I,[153] and it specifies in some detail the criteria for how scheduling decisions are to be made.[154] This privileging of independence and expertise has been undermined by the Attorney General's subdelegation of scheduling authority to the DEA, insofar as the DEA is "an 'anti-drug' agency with a deep material and ideological investment in prioritizing criminal responses to drug problems."[155] Yet, even if the Attorney General were to withdraw the subdelegation, as she could at any time, this part of the CSA's design contains another fundamental flaw — not that the statute fails to sideline politics as much as it might, but rather that it assumes that sociologically and normatively legitimate scheduling decisions can be made on the basis of empirical facts alone. For a number of reasons, this assumption turns out to be implausible when it comes to psychoactive drugs.

To begin, while many health risks of psychoactive drugs are in principle capable of being measured scientifically, such measurement is notoriously difficult. As reflected in the mantra "set and setting," the same drug may have very different effects on otherwise similar users depending on their mindset, motivation, and physical and social surroundings, not to mention the quantity and purity of the dose.[156] Drug risks, in other words, tend to be "contingent and situated."[157] Extrapharmacological variables determine them to a significant degree. This contingency, moreover, applies even to the most lethal drugs. Some people have died of overdose the first time they tried heroin;[158] others with

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151 *See, e.g.*, Cristina M. Rodríguez, *The Supreme Court, 2020 Term — Foreword: Regime Change*, 135 HARV. L. REV. 1, 39 (2021) (discussing "the norm-based insulation of [the Justice Department's] work from day-to-day partisanship and interference by political actors concerned primarily with electoral prospects or temporary news cycles").

152 21 U.S.C. § 811(b).

153 *See supra* notes 70–78 and accompanying text.

154 *See* 21 U.S.C. §§ 811(b), 812(b)–(c).

155 David Pozen, *Reading the Tea Leaves on Marijuana Rescheduling*, BALKINIZATION (May 20, 2024), https://balkin.blogspot.com/2024/05/reading-tea-leaves-on-marijuana.html [https://perma.cc/PQS7-4GRF].

156 *See* Ido Hartogsohn, *Constructing Drug Effects: A History of Set and Setting*, DRUG SCI. POL'Y & L., Jan.–Dec. 2017, at 1. The influence of set and setting appears to be especially strong for psychedelics and may be weaker, though still potentially "profound," for other drugs. *See id.* at 10–12.

157 Ross Coomber & Nigel South, *Fear and Loathing in Drugs Policy: Risk, Rights and Approaches to Drug Policy and Practice*, *in* PROHIBITION, RELIGIOUS FREEDOM, AND HUMAN RIGHTS: REGULATING TRADITIONAL DRUG USE 235, 240 (Beatriz Caiuby Labate & Clancy Cavnar eds., 2014). This observation continues to hold force even when the drugs are prescribed by a doctor and used as indicated. *See, e.g.*, Richard M. Turner, B. Kevin Park & Munir Pirmohamed, *Parsing Interindividual Drug Variability: An Emerging Role for Systems Pharmacology*, 7 WIREs SYS. BIO. & MED. 221, 221 (2015) ("[T]here exists notable interindividual heterogeneity in drug response, affecting both efficacy and toxicity.").

158 *See* Coomber & South, *supra* note 157, at 239.

access to clean injecting equipment and a clean supply have used heroin "for 20 or 30 years with . . . few harms accruing."[159] Even though certain drugs are demonstrably and undeniably riskier than others, there is no one answer to the question of how dangerous a given drug is.[160] So much depends on context. And the context is itself partly endogenous to law, as when prohibition leads people to consume less safe versions of a drug in less safe environments.[161]

The same variability and measurement difficulties extend to drugs' *desired* effects. The CSA singles out "medical use" as the sole category of desired effects cognizable in scheduling.[162] "Recreational" applications are irrelevant. The statute fails to define medical use, however, and the DEA has long taken the position that testimonials and self-reports from patients, physicians, and laypersons about a drug's medicinal properties have "no scientific merit"[163] — a position that is not itself based on science in any straightforward sense.[164] The medical/recreational divide, moreover, was always hard to pin down and has become increasingly vexed now that psychological conditions such as anxiety and loneliness are recognized by many as medical issues.[165]

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159 *Id.*; *see also* Andrew Koppelman, *Drug Policy and the Liberal Self*, 100 NW. U. L. REV. 279, 292 (2006) ("Drugs are beneficial for the majority of users, who achieve the effects they seek without adverse consequences. They are harmful, sometimes terribly harmful, for a few.").

160 *Cf.* POZEN, *supra* note 4, at 171 ("In response to the question whether any given psychoactive substance is dangerous or safe, the correct answer always is: both.").

161 *See id.* at 139–40, 155.

162 21 U.S.C. § 812(b).

163 *E.g.*, Marijuana Scheduling Petition; Denial of Petition, 54 Fed. Reg. 53767, 53769–71 (Dec. 29, 1989); Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act; Remand, 53 Fed. Reg. 5156, 5157 (Feb. 22, 1988) (to be codified at 21 C.F.R. pt. 1308). More specifically, the DEA has taken the position that a drug has a "currently accepted medical use" under the CSA only if the FDA has approved the drug or if the drug meets a five-part test that relies "exclusively on certain scientific evidence and the views of some experts and FDA" while "ignoring widespread clinical experience . . . sanctioned by state medical licensing regulators." Questions Related to the Potential Rescheduling of Marijuana, 48 Op. O.L.C. (Apr. 11, 2024) (slip op. at 13–14). In 2024, the Justice Department's Office of Legal Counsel determined that this approach is "impermissibly narrow." *Id.* at 35.

164 *Cf.* Alana Klein, *Harm Reduction Works: Evidence and Inclusion in Drug Policy and Advocacy*, 28 HEALTH CARE ANALYSIS 404, 404 (2020) (explaining that harm reduction advocates "make particular claims about what constitute valid, methodologically rigorous evidence bases for action," grounded in the "lived experience" of drug users); Kari Lancaster, Carla Treloar & Alison Ritter, *"Naloxone Works": The Politics of Knowledge in "Evidence-Based" Drug Policy*, 21 HEALTH 278, 281–90 (2017) (describing controversies over the "hierarchy of evidence" in drug policy). The DEA is not entirely consistent in this approach. The agency has relied on anecdotal evidence to support the scheduling of uncontrolled substances, even though it disparages such evidence when reviewing petitions for rescheduling or descheduling. *See* Marks, *supra* note 63, at 995 (criticizing this asymmetry).

165 *See* Matt Lamkin, *Legitimate Medicine in the Age of Consumerism*, 53 U.C. DAVIS L. REV. 385, 421 (2019) ("As doctors increasingly prescribe psychotropic drugs to healthy people to relieve stress, enhance performance, and otherwise obtain desired mental states, it becomes harder to distinguish these uses from 'recreational' drug-taking. . . . [I]n many cases drug 'abusers' consume

More fundamentally, it has never been clear why this divide ought to matter so much. People use drugs for a great variety of reasons, "including social lubrication, creative stimulation, spiritual and psychological exploration, mental and physical relaxation, pain relief, escapism, energy, sleep, sex — for ends of great moral seriousness, frivolous fun, and everything in between."[166] That some of these ends are hard to evaluate scientifically does not make them any less meaningful to those who seek them. Throughout many other areas of administrative law, cost-benefit analysis (CBA) is employed to identify, quantify, and weigh all relevant costs and benefits of a proposed regulatory act.[167] The EPA, for example, has incorporated "[r]ecreation activities," "aesthetics,"[168] and other "hedonic" considerations into its economic benefits analyses for years.[169] With drugs, by contrast, the government does no formal CBA and implicitly ignores most of the "B." Subjectively experienced non-"medical" benefits are arbitrarily assigned a value of zero.

Finally, drug addiction (known medically as substance use disorder) is not only a neurobiological phenomenon but also a "disease[] of despair" whose root causes lie in isolation, adverse childhood events, and other social determinants of health.[170] Absent unlimited resources, any effort to reduce addiction-related harms must decide where along the stream of causation to intervene — upstream at social determinants, midstream at drug supply and demand prevention, or downstream at harm reduction. These decisions implicate a wide range of political and practical variables, from regulatory capacity and predictions of comparative effectiveness to popular support and beliefs about the appropriate role for the state.

On multiple levels, then, drug policy is a field marked by profound pluralism — in the types of drugs that are out there, in the risks and rewards they present, in the purposes for which people take them, in the effects experienced across and even within users, in the research

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drugs for precisely the same purposes as legitimate users."); Mike Jay, Opinion, *Is Everyone High?*, N.Y. TIMES (Dec. 23, 2024), https://www.nytimes.com/2024/12/23/opinion/is-everyone-high.html [https://perma.cc/F52H-9SLB] ("The old distinction between medical and recreational drugs is breaking down."). *See generally* Craig Konnoth, *Medicalization and the New Civil Rights*, 72 STAN. L. REV. 1165, 1185–202 (2020) (discussing the proliferation and routinization of "medical rights" claims in drug law and beyond, *id.* at 1193).

166 POZEN, *supra* note 4, at 20 (internal quotation marks and footnote omitted); *see also id.* at 171 ("[P]roponents of drug rights often contend that illicit substances enable shifts in consciousness or feeling that would be difficult to achieve any other way, that drugs open their hearts and minds to otherwise unattainable perspectives, profundities, and pleasures.").

167 *See, e.g.*, Michelle N. Meyer, *Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem*, 65 ADMIN. L. REV. 237, 269 (2013) (noting that CBA "is ubiquitous in the regulatory state"); Eyal Zamir & Barak Medina, *Law, Morality, and Economics: Integrating Moral Constraints with Economic Analysis of Law*, 96 CALIF. L. REV. 323, 353 (2008) ("Standard CBA monetizes and aggregates all costs and benefits involved in an act.").

168 EPA, GUIDELINES FOR PREPARING ECONOMIC ANALYSES ch. 7, 7-9 (2010).

169 *Id.* at 7-10.

170 Dasgupta, Beletsky & Ciccarone, *supra* note 90, at 183, 184.

methodologies and epistemologies claimed to be valid, and in the values at stake. Drugs are so protean, Professor Kimani Paul-Emile has argued, as to lack any objective social significance; they "begin as blank slates onto which meaning is conferred" through the regulatory enterprise itself.[171] Like the related concept of disability, the concept of addiction may be especially susceptible to social construction.[172] And because drug controversies are so often bound up with controversies and prejudices relating to race, class, and culture, the processes by which meaning is conferred onto particular drugs and drug behaviors are deeply and "inherently political."[173]

Against this backdrop, turning over drug policy to government-approved experts has little hope of producing decisions that are widely seen as "science-driven and . . . apolitical,"[174] much less socially optimal. The CSA places particular emphasis on expertise when it comes to scheduling decisions, as explained above.[175] That has not stopped countless critics since the early 1970s from assailing the allocation of certain drugs to certain schedules as "illogical and capricious,"[176] "absolutely absurd,"[177] and the very "opposite of what rational risk assessment call[s] for."[178]

As with the prohibition and pharma problems, the CSA's response to the pluralism problem is to pretend that it does not exist — to assume that there are "correct" answers to questions about how particular drugs should be regulated, discernible by a narrow set of administrators based on a narrow set of scientific criteria. And as with the prohibition and

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171 Paul-Emile, *supra* note 66, at 694. Indeed, there is no consensus among drug researchers as to what counts as a "drug." *See* Paul Gootenberg, *Introduction: A New Global History of Drugs*, *in* THE OXFORD HANDBOOK OF GLOBAL DRUG HISTORY 1, 12 (Paul Gootenberg ed., 2022) (stating that "What are drugs?" is "the field's complexly protean central puzzle").

172 *See generally, e.g.*, Bradley A. Areheart, *Disability Trouble*, 29 YALE L. & POL'Y REV. 347 (2011) (discussing the social construction of disability within and beyond the legal system); Richard Hammersley, *Sociology of Addiction*, *in* THE ROUTLEDGE HANDBOOK OF SCIENCE AND PHILOSOPHY OF ADDICTION 220 (Hanna Pickard & Serge H. Ahmed eds., 2020) (reviewing a wide range of social factors that may affect which behaviors are understood as addictive).

173 Paul-Emile, *supra* note 66, at 695; *see also* TOBY SEDDON, RETHINKING DRUG LAWS 127, 154 (2023) (contending that drug "regulatory choices . . . are always also choices about political ends and values," *id.* at 127, and that efforts "to neutralise or evade the political, in favour of science or evidence," *id.* at 154, are therefore misguided in this domain).

174 Eli Y. Adashi, Rohit S. Rajan & I. Glenn Cohen, *When Science and Politics Collide: Enhancing the FDA*, 364 SCIENCE 628, 630 (2019) (arguing that while "[d]etermining the basic facts about safety, efficacy, or adverse events reporting should be science-driven and as apolitical as possible," determining how to regulate or review any given class of drugs "is an inherently political judgment and should be transparently marked as such").

175 *See supra* notes 151–54 and accompanying text.

176 EDWARD M. BRECHER & EDS. OF CONSUMER REPS., LICIT AND ILLICIT DRUGS 525 (1972).

177 Fenit Nirappil & David Ovalle, *Why Marijuana Rescheduling May Not Be Reform Win*, WASH. POST (Nov. 22, 2023), https://www.washingtonpost.com/health/2023/11/22/marijuana-rescheduling-research-penalties [https://perma.cc/5K4F-DXSJ] (quoting Professor Carrie Cuttler).

178 POZEN, *supra* note 4, at 54 (emphasis omitted); *see also id.* at 192 n.50 (collecting similar statements from leading drug-law and health-policy scholars).

pharma problems, this response is self-defeating. No one disputes that science (however understood) has an important role to play in informing drug policy.[179] But the pluralism problem underscores the limits to this role, both descriptively and normatively. Marginalizing the perspectives of millions of drug users leads to policies that misalign with public preferences to such an extent as to invite widespread defiance. That defiance, in turn, drives criminalization and incarceration, contributes to access shortages for patients who rely on substances subject to high rates of nonmedical use,[180] and undermines the authority of law and expertise both.[181]

III. NAVIGATING THE THREE PS

The CSA has failed as a framework statute, we contend, because it fails to address "the three Ps": the prohibition, pharma, and pluralism problems. And yet, because of the way these problems interact, addressing each of them satisfactorily is very hard to do. Can the CSA be saved? Should it be?

This Part proposes a path forward for federal drug law. Section A sketches the case for a pragmatic approach to navigating the prohibition, pharma, and pluralism problems. Sections B and C develop and illustrate applications of this approach within the broad scheme of the CSA.

A. From Idealism to Fatalism to Pragmatism

Few drug policymakers identify as idealists these days. Ubiquitous in the 1980s and 1990s, appeals to a "drug-free" future no longer play a significant role in regulatory debates.[182] Full-throated libertarian

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[179] For a balanced assessment, briefly rendered, see Keith Humphreys & Peter Piot, *Scientific Evidence Alone Is Not Sufficient Basis for Health Policy*, BMJ, Apr. 28, 2012, at 24. For an overview of the ways in which science and politics are "deeply intertwined" in U.S. public health regulation, including drug regulation, see Samuel R. Bagenstos, *Science and Politics in Public Health Regulation*, 58 U. MICH. J.L. REFORM 719, 721 (2025).

[180] Because the CSA's production quotas for drugs in Schedule II are based on estimates of medical need, shortages may arise whenever these drugs are diverted to nonmedical users. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-202, DRUG SHORTAGES 8–23 (2015), https://www.gao.gov/assets/gao-15-202.pdf [https://perma.cc/N4UZ-5EDB].

[181] *See, e.g.*, Joslin v. Fourteenth Dist. Judge, 255 N.W.2d 782, 788 (Mich. Ct. App. 1977) (T.M. Burns, J., concurring) (discussing "the inestimable costs to both individuals and society of making criminals of decent human beings" through bans on popular drugs "and the encouragement of the citizenry, particularly the young, to disrespect and distrust our laws and those who make and enforce them"); Matthew A. Christiansen, *A Great Schism: Social Norms and Marijuana Prohibition*, 4 HARV. L. & POL'Y REV. 229, 231 (2010) (describing how widespread defiance of drug prohibitions "has a deleterious effect on the institution of law itself").

[182] *See, e.g.*, Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, § 5251(b), 102 Stat. 4181, 4310 ("It is the declared policy of the United States Government to create a Drug-Free America by 1995."); *cf.* Benjamin Levin, *Guns and Drugs*, 84 FORDHAM L. REV. 2173, 2219 (2016) (observing

defenses of a drug *law*–free society are, if anything, even harder to find.[183] Yet, while large literatures now address aspects of the prohibition, pharma, and pluralism problems, it is rare for scholars or advocates to consider them in any collective fashion. This leads to reform recommendations that are partially realistic but partially idealistic — fixing the prohibition problem in ways that exacerbate the pharma problem, fixing the pharma problem in ways that exacerbate the pluralism problem, and so on. As discussed in Part II, proposals to replace prohibition with ad hoc legalization or medicalization of specific drugs may invite regulatory capture and consumer exploitation, while proposals to transfer regulatory authority to independent experts may invite myopic decisionmaking and scientific imperialism.[184]

An increasingly influential alternative to idealism treats the difficulties of drug policy as reason to stick with the status quo. This new prohibitionism replaces idealism with fatalism. It can be seen, for example, in the advocacy of Kevin Sabet, a former drug policy advisor in three presidential administrations and cofounder of Smart Approaches to Marijuana, who asserts that keeping marijuana in Schedule I is preferable to allowing "another Big Tobacco."[185] It is evident, too, in comments from public safety officials and parent groups in the ongoing federal proceedings on rescheduling marijuana that defend prohibition not on the ground that it works but on the ground that "[i]f marijuana becomes Schedule III, the Big Marijuana industry will . . . mass

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that "[o]ver the past decade, . . . drug war criticisms [have] reflect[ed] an embrace of realist or post-realist methodologies"). Across disciplines, researchers broadly agree that "drug-free" societies are all but unknown to the modern world. *See, e.g.*, DOUGLAS N. HUSAK, LEGALIZE THIS! THE CASE FOR DECRIMINALIZING DRUGS 128 (2002) ("[N]o known societies — except perhaps that of [Inuit people] — refrain from using drugs for recreational purposes."); Gootenberg, *supra* note 171, at 1 ("Despite their widespread prohibition, illicit drugs such as opiates, cannabis, cocaine, amphetamines, and the myriad of psychedelics and synthetics are fundamental features of the modern world, with historical antecedents in virtually all human societies going back to prehistory.").

183 *See, e.g.*, Randy E. Barnett, *Bad Trip: Drug Prohibition and the Weakness of Public Policy*, 103 YALE L.J. 2593, 2629 (1994) (reviewing STEVEN B. DUKE & ALBERT C. GROSS, AMERICA'S LONGEST WAR: RETHINKING OUR TRAGIC CRUSADE AGAINST DRUGS (1993)) (noting and lamenting the marginalization of "so-called doctrinaire 'libertarian' objections" to drug prohibition).

184 *See supra* notes 133–45, 175–81 and accompanying text.

185 Kevin Sabet, *Opinion: Don't Let Big Marijuana Profit at New Jersey's Expense*, NORTHJERSEY.COM (Jan. 16, 2018, at 06:00 ET), https://www.northjersey.com/story/opinion/contributors/2018/01/16/big-marijuana-profit-new-jerseys-expense/1029692001 [https://perma.cc/7LXU-93Q7]; *see also* Kevin Sabet, *Trump Can't Make America Healthy Again and Support Addictive Drugs in Our Communities*, SMART APPROACHES TO MARIJUANA (Jan. 20, 2025), https://learnaboutsam.org/2025/01/trump-cant-make-america-healthy-again-and-support-addictive-drugs-in-our-communities [https://perma.cc/J84S-3H7Q] ("Any federal effort to normalize, legalize or support marijuana or any other drug would empower the addiction industry's biggest investors, including Big Tobacco and Big Pharma, at the expense of millions of Americans."); Charles Fain Lehman, *The Real Problem with Legal Weed*, N.Y. TIMES MAG. (July 3, 2024), https://www.nytimes.com/2024/07/03/magazine/marijuana-legalization-new-york.html [https://perma.cc/KK79-W3ZW] ("[C]ombining addiction with the profit motive creates perverse incentives, letting corporations compete to help people ruin their lives.").

commercialize high-potency THC."[186] These commentators deploy the rhetoric of reaction to delegitimate the project of progressive drug reform.[187] In this discourse, drug regulatory decisions are cast as a Hobson's choice between overcriminalization and overcommercialization — between the prohibition and pharma problems. This line of thought finds friends on the left wary of corporate power and friends on the right wary of public health expertise. And it is having an impact. After years of gaining ground, federal and state liberalization campaigns for marijuana and other Schedule I substances seem to have stalled.[188]

Pragmatism offers another way forward. Nearly everyone today acknowledges that drug policy should, in the words of the CSA, advance "the health and general welfare of the American people."[189] Yet there is no consensus on how to realize or conceptualize that ambition. By eschewing abstract theory and rigid ideology, the pragmatic method holds out hope for progress by focusing attention on relatively concrete, widely appreciated problems.[190] The overriding question is: "What works?"[191] To answer that question, pragmatism counsels an ongoing, reflexive process for determining metrics and criteria for success, along with a flexible understanding of what counts as relevant knowledge, "looking to lived experience as well as more traditional sources of empirical evidence."[192]

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[186] Jan Beyer, Comment Letter on Proposed Rule on Schedules of Controlled Substances: Rescheduling of Marijuana (May 29, 2024), https://www.regulations.gov/comment/DEA-2024-0059-6458 [https://perma.cc/3YES-VC3E]; *see also, e.g.*, Every Brain Matters, Comment Letter on Proposed Rule on Schedules of Controlled Substances: Rescheduling of Marijuana (July 22, 2024), https://www.regulations.gov/comment/DEA-2024-0059-39263 [https://perma.cc/GE9W-WHFF] ("This political move, motivated by Big Cannabis for increased profits, is reckless and will have severe repercussions.").

[187] *See generally* ALBERT O. HIRSCHMAN, THE RHETORIC OF REACTION (1991) (describing the standard rhetorical moves made by opponents of progressive reform, sounding in "perversity, futility, and jeopardy," *id.* at 7).

[188] Adam Hoffer & Jacob Macumber-Rosin, *Momentum Slows for State Drug Legalization Policies via 2024 State Ballot Initiatives*, TAX FOUND. (Nov. 14, 2024), https://taxfoundation.org/blog/state-drug-policy-marijuana-legalization [https://perma.cc/9KGC-K5PE] (discussing 2024 state ballot initiatives).

[189] 21 U.S.C. §§ 801(1), (2); *see also* Oliva & El-Sabawi, *supra* note 5, at 1108–10 (explaining that contemporary drug policymakers have embraced "health-oriented" language and concepts, *id.* at 1108, even though many punitive policies remain, *id.* at 1109–10).

[190] *See* RICHARD A. POSNER, LAW, PRAGMATISM, AND DEMOCRACY 59–73 (2003) (discussing principles informing pragmatic adjudication); Michael C. Dorf & Charles F. Sabel, *A Constitution of Democratic Experimentalism*, 98 COLUM. L. REV. 267, 284–86 (1998).

[191] *See, e.g.*, RICHARD A. POSNER, OVERCOMING LAW 4 (1995) (describing legal pragmatism as "interested in what works and what is useful rather than in what 'really' is"); Richard J. Bonnie, *The Virtues of Pragmatism in Drug Policy*, 13 J. HEALTH CARE L. & POL'Y 7, 30 (2010) ("[P]ragmatism in drug policy . . . focuses our attention on what works best.").

[192] Huntington, *supra* note 17, at 1506; *see also* MELVIN L. ROGERS, THE UNDISCOVERED DEWEY 195 (2008) (explaining that, in the view of leading pragmatist John Dewey, "those most affected" by social problems "ought to serve as the beginning and terminal points for developing and testing solutions").

Pragmatism's problem-oriented, context-sensitive approach is well suited to a field marked by broad agreement about high-level goals (advance Americans' health and welfare) and an intractable set of problems that have been thwarting those goals (the three Ps). A federal statute like the CSA cannot hope to address any number of discrete drug issues affecting particular communities. The sheer volume and variety of psychoactive substances — the CSA covers more than 500 at this writing[193] — in themselves ensure this. What a pragmatic version of the CSA could do, and should do, is establish processes and structures that are conducive to the search for workable regulatory solutions. This means establishing an institutional framework within which to navigate the prohibition, pharma, and pluralism problems. Those are the central problems in the field. On a pragmatic accounting, they must therefore be a central focus of reform.

We do not mean to suggest that pragmatism is the only constructive way to think about drug policy, and we do not have the space to theorize drug policy pragmatism in any depth. Our relatively modest claim here is that pragmatism offers a useful approach for motivating and guiding reforms to the CSA's institutional design in light of the prohibition, pharma, and pluralism problems that have systematically frustrated its goals. Proponents of harm reduction appeal to pragmatism to defend interventions such as needle exchange programs and safe injection facilities.[194] The remainder of this Part shows how the turn to pragmatism can be taken further — not just to reduce harms from drug use but also to reduce harms from drug regulation, and not just to inform the design of specific policies but also to inform the design of the drug regulatory system.

B. Democratization Without Domination

Recall the basic dilemma created by the interaction of the three Ps. Drug bans rarely work and frequently prove perverse. Yet, if policymakers address this prohibition problem by legalizing or medicalizing potentially addictive substances, they open the door to predatory practices by drug companies. And if policymakers address this pharma problem by deferring to politically insulated experts, they open the door to alternative forms of corporate capture as well as the tyranny of technocracy. Is there any escape from this vicious circle?

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[193] U.S. DRUG ENF'T ADMIN., CONTROLLED SUBSTANCES — ALPHABETICAL ORDER (2025), https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf [https://perma.cc/45GL-TNZ9].

[194] *See, e.g.*, Klein, *supra* note 164, at 405 ("Pragmatism, or grounding in 'what works,' is . . . one of the distinguishing characteristics of harm reduction."); *id.* at 406 (noting that harm reduction reforms "are often linked with evidence-based policy"); G. Alan Marlatt & Katie Witkiewitz, *Update on Harm-Reduction Policy and Intervention Research*, 6 ANN. REV. CLINICAL PSYCH. 591, 593 (2010) ("The principles of harm-reduction efforts are often firmly rooted in the ideals of pragmatism . . . ."); *see also supra* notes 110–15 and accompanying text (discussing harm reduction).

Although perfect answers may be elusive, we can begin to make headway by recognizing that all three problems involve concerns about domination. Whether it is the DEA, the pharmaceutical industry, or a particular slice of the scientific establishment, one group wields a degree of influence over drug policy that millions of Americans experience as arbitrary and authoritarian. The most effective regulatory responses to such concerns, Professor K. Sabeel Rahman has argued, draw on "Deweyan pragmatism" to counter domination with democracy — empowering citizens to challenge dominant perspectives while harnessing "the experimentalist and epistemic benefits of participation and iteration."[195] Following Rahman, we now consider what a pragmatic approach of this sort would entail for three of the biggest questions in drug policy design.

1. Drug-Agnostic Scheduling Rather than Drug-Specific Legislation. — Perhaps surprisingly, the goal of democratization without domination provides a new way to understand and *defend* the CSA's central design feature: the placement of all psychoactive drugs it covers into one of several regulatory schedules. In response to the CSA's manifold failures, a growing number of scholars and policymakers have endorsed, and in some cases implemented, reforms that would abandon the CSA's comprehensive scheduling scheme in favor of legislation for specific substances.[196] The more this trend continues, the more American drug policy will return to the patchwork of regulatory regimes that prevailed prior to the CSA and that still govern alcohol and tobacco.[197]

In contrast to other fields that have seen extended debate about analogous choices between "ad hoc" or "exceptional" approaches, on the one hand, and transsubstantive or categorical approaches, on the other,[198] drug law scholars have rarely even acknowledged this ongoing shift from administrative scheduling to legislative specification.[199] A

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195 K. SABEEL RAHMAN, DEMOCRACY AGAINST DOMINATION 28 (2017).

196 *See, e.g.*, Agriculture Improvement Act of 2018, Pub. L. No. 115-334, §§ 297A–297E, 10114, 132 Stat. 4490, 4908–14 (codified at 7 U.S.C. §§ 16390–1639s) (removing regulation of hemp products from the CSA framework); Alex W. Chalk, *Legalization of Marijuana: The Benefits of Federal Legislation*, T. MARSHALL L. REV. ONLINE, Spring 2018, at *4, *30–31 (advocating federal legislation to legalize marijuana); O. Hayden Griffin, III, *A Democracy Deficit Within American Drug Policy*, 26 S. CAL. REV. L. & SOC. JUST. 103, 129–30 (2017) (arguing that administrative scheduling of drugs creates a "democracy deficit"); Mason Marks, *State Drug Laws*, 93 FORDHAM L. REV. 439, 445–66 (2024) (surveying a wide range of state drug law reforms adopted in recent years, many of which are addressed to specific illicit substances).

197 *See supra* notes 26–29 and accompanying text; *see also, e.g.*, Alcoholic Beverage Labeling Act of 1988, Pub. L. No. 100-690, 102 Stat. 4518 (codified at 27 U.S.C. §§ 213–219(a)).

198 *See, e.g.*, Pamela K. Bookman & David L. Noll, *Ad Hoc Procedure*, 92 N.Y.U. L. REV. 767, 772–73 (2017) (civil procedure); James M. Puckett, *Structural Tax Exceptionalism*, 49 GA. L. REV. 1067, 1069 (2015) (tax); *see also* Jennifer Nou & Edward H. Stiglitz, *Regulatory Bundling*, 128 YALE L.J. 1174, 1225–28 (2019) (exploring analogous questions within the administrative rulemaking process).

199 In a rare treatment that acknowledges this shift, Kreit tentatively defends it while noting the need for further thinking on what a reformed scheduling regime might entail. *See* Alex Kreit,

pragmatic perspective offers new grounds for skepticism. Even if substance-specific legislation might yield real benefits in certain cases, drug scheduling has the potential to promote democratization without domination — and thus to mitigate both the pharma and the pluralism problems — in several interrelated ways.

Most fundamentally, scheduling shifts decisionmaking to an administrative arena that can be insulated against domination in ways that congressional lawmaking cannot. As Professor Edward Stiglitz explains, Congress cannot credibly commit to most procedural constraints, which leaves the legislative process vulnerable to democratic pathologies like interest-group concentration and the translation of wealth into political power.[200] Congress can delegate authority to agencies, however, and bind them to procedures that are designed to limit the access of certain groups while facilitating public participation.[201] This general point is a familiar justification for the administrative state. Less familiar is that a scheduling framework such as the CSA's is itself a mechanism for facilitating participation and combating capture.

This framework is a hybrid of delegation and delineation. Congress specifies the main models of drug regulation and the tests for determining which drugs belong in which models, and then leaves the rest to the executive branch.[202] By making the regulatory rules drug-agnostic within a given schedule, the statute diversifies the range of groups with a stake in lobbying and advocating for changes to those rules. Since the Founding, institutional designers have understood that such diversification reduces the risk that well-resourced interests will dominate policymaking processes.[203] And for all that has gone wrong with the CSA, its categorical approach has in fact engaged a wide range of groups in debates about the controls imposed by each schedule and the criteria for assigning drugs to particular schedules.[204] By contrast, when

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Federal Marijuana Reform and the Controlled Substances Act, 101 B.U. L. REV. 1231, 1252 (2021) ("[E]xception making may be preferable to attempting to create a truly uniform approach to regulating all substances. . . . Still, the prospect of marijuana reform does at least raise the question of whether Congress should consider developing a regulatory pathway within the CSA to expressly permit the nonmedical use of some substances.").

200 EDWARD STIGLITZ, THE REASONING STATE 7–17 (2022).

201 *See id.* at 15–17.

202 *See supra* section I.B, pp. 861–63.

203 For the canonical reference, see THE FEDERALIST NO. 10, at 77 (James Madison) (Clinton Rossiter ed., 2003) ("[H]owever small the republic may be the representatives must be raised to a certain number in order to guard against the cabals of a few . . . ."). For a more recent exposition of this point in the institutional design literature, see David A. Hyman & William E. Kovacic, *Why Who Does What Matters: Governmental Design and Agency Performance*, 82 GEO. WASH. L. REV. 1446, 1464 (2014) ("Expansion may . . . reduce the risk of capture by individual business constituencies.").

204 For example, in 2020 the DEA proposed to change the "suspicious order report[ing]" requirement for registrants to manufacture, distribute, or dispense controlled substances. Suspicious Orders of Controlled Substances, 85 Fed. Reg. 69282, 69282 (proposed Nov. 2, 2020) (to be codified

policymakers have opted to develop controls on a substance-specific basis, racialized moral panics have frequently played a role and concentrated industry lobbies have frequently emerged as leading proponents or opponents. The recent legalization of hemp-derived THC is a case in point.[205] Other notorious examples include Congress's imposition of criminal sentencing rules for crack cocaine in the 1980s[206] and its

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at 21 C.F.R. pts. 1300, 1301). This proposal attracted comments not only from registrants but also from pharmacists, public health scholars, and even public health students offering an expert counterweight to the industry perspective. *Compare, e.g.*, Pfizer, Inc., Comment Letter on Proposed Suspicious Orders of Controlled Substances Rule 2 (Jan. 4, 2021), https://www.regulations.gov/comment/DEA-2021-0003-0031 [https://perma.cc/QFE9-NRTA] (asserting that the DEA's new definition of "order" would be "overly broad"), *and* Am. Soc'y of Health Sys. Pharmacists, Nat'l Ass'n of Chain Drug Stores & Nat'l Cmty. Pharmacists Ass'n, Comment Letter on Reopening of Comment Period Regarding Proposed Suspicious Orders of Controlled Substances Rule 2 (Mar. 29, 2021), https://www.regulations.gov/comment/DEA-2021-0003-0040 [https://perma.cc/R7VP-NRAJ] (expressing concern that the proposed rule "would codify vague and subjective standards for what constitutes a suspicious order"), *with* Omar Pirzada, Univ. of Mich. Sch. of Pub. Health, Comment Letter on Proposed Suspicious Orders of Controlled Substances Rule 2 (Nov. 8, 2020), https://www.regulations.gov/comment/DEA-2021-0003-0020 [https://perma.cc/5ZMN-VF55] (supporting the proposed rule as "a strong strategy to try to slow down the opioid epidemic"), *and* Michaela Hollis, Comment Letter on Proposed Suspicious Orders of Controlled Substances Rule 2 (Nov. 15, 2020), https://www.regulations.gov/comment/DEA-2021-0003-0005 [https://perma.cc/UCW4-YLWB] (offering a public health student's view that the new requirements are both "necessary and not too burdensome").

205 In the 2018 farm bill, Congress created a new set of controls for hemp while empowering the FDA to supplement and elaborate those controls. *See* RENÉE JOHNSON, CONG. RSCH. SERV., IN12381, HEMP PROVISIONS IN THE HOUSE FARM BILL AND FY2025 AGRICULTURE APPROPRIATIONS BILL 1 (2024). Observers realized almost immediately that this reform had inadvertently legalized THC (the main psychoactive ingredient in cannabis) derived from hemp products, opening the door to the commercial marketing and sale of THC beverages and gummies nationwide. *See* Alyssa F. Harlow, Adam M. Leventhal & Jessica L. Barrington-Trimis, *Closing the Loophole on Hemp-Derived Cannabis Products: A Public Health Priority*, 328 JAMA 2007, 2007 (2022). Until a recent spending bill reversed course, *see* Nicholas Florko, *Pour One Out for Weed Seltzer*, THE ATLANTIC (Nov. 21, 2025), https://www.theatlantic.com/health/2025/11/thc-marijuana-hemp-loophole/685016 [https://perma.cc/A79M-E5UV], congressional and FDA efforts to shut down this burgeoning market were stymied for years by the newly developed consumable hemp industry, which fought to maintain the loophole that brought it into existence, *see, e.g.*, *Hemp Industry Priorities for the 2024 Farm Bill*, U.S. HEMP ROUNDTABLE (2024), https://hempsupporter.com/wp-content/uploads/2024/01/Updated-Farm-Bill-Priorities.pdf [https://perma.cc/N3TC-3J7J] (urging Congress to maintain the current definition of "hemp" and to reduce regulatory hurdles for hemp farmers); Kyle Jaeger, *Hemp Industry Pushes Back Against Marijuana Companies Advocating for Intoxicating Cannabinoid Ban in Farm Bill*, MARIJUANA MOMENT (May 15, 2024), https://www.marijuanamoment.net/hemp-industry-pushes-back-against-marijuana-companies-advocating-for-intoxicating-cannabinoid-ban-in-farm-bill [https://perma.cc/NZ2M-ZGX7] (discussing the hemp industry's opposition to potential restrictions on delta-8 THC).

206 Disparate sentencing rules for crack versus powder cocaine offenses — and the profound racial disparities in arrests and convictions that followed — were not due to the CSA, whose original scheduling scheme treated the two substances identically. *See* LISA N. SACCO & KRISTIN FINKLEA, CONG. RSCH. SERV., IF11965, COCAINE: CRACK AND POWDER SENTENCING DISPARITIES 1 (2021). The disparities came from the Anti-Drug Abuse Acts of 1986 and 1988, enacted at the height of the crack panic. *See* POZEN, *supra* note 4, at 79; *see also* ERICH GOODE & NACHMAN BEN-YEHUDA, MORAL PANICS: THE SOCIAL CONSTRUCTION OF DEVIANCE 197–217 (2d ed. 2009) (analyzing this episode in the context of other "drug abuse panics").

repeated concessions to the tobacco industry throughout the twentieth century.[207]

In addition to this diversification of stakeholders, scheduling facilitates monitoring of the regulatory process by simplifying and increasing the salience of regulatory choices. When regulatory regimes are highly complex, most congressional staffs and civil society groups will not have the capacity to track, interpret, and intervene in their workings without the help of industry insiders.[208] Administrative complexity, and the reliance on industry it fosters, thus increases the risk of capture.[209] Mindful of this challenge, public choice scholars working in the "structure and process" tradition have recommended various institutional designs to lower the cost of congressional and public monitoring.[210]

Scheduling can itself be such a design. The idea of "drug schedules," each of which comes with its own distinct package of regulation, has penetrated public discourse in ways that few administrative regimes can claim. The idea comes up semi-regularly on social media,[211] in the popular press,[212] in election campaigns,[213] and even in music and movies.[214] This salience has helped spur Congress to pass numerous pieces of scheduling-related legislation.[215] It has also created a focal point for

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[207] *See supra* notes 142–45 and accompanying text.

[208] *See* Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L.J. 1321, 1326 (2010) ("[D]iffuse beneficiaries . . . face substantial impediments to participating in costly rulemakings when the rules are detailed, complex, technical, and involve issues that are difficult to translate into salient risks for donors, the public, and the media.").

[209] *See id.* at 1326, 1333–34.

[210] *See, e.g.*, Jonathan R. Macey, *Organizational Design and Political Control of Administrative Agencies*, 8 J.L. ECON. & ORG. 93, 94–99, 108–09 (1992). *See generally* Mathew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 J.L. ECON. & ORG. 243 (1987) (exploring "the role of administrative law in assisting political actors in controlling the bureaucracy," *id.* at 246); Mathew D. McCubbins & Thomas Schwartz, *Congressional Oversight Overlooked: Police Patrols Versus Fire Alarms*, 28 AM. J. POL. SCI. 165 (1984) (developing a model of congressional choice of oversight policy).

[211] *See, e.g.*, POWERFULJRE, *Joe Rogan Experience #2143 — Tulsi Gabbard*, at 05:10 (YouTube, May 1, 2024), https://www.youtube.com/watch?v=UQrNRtxvCJc [https://perma.cc/G23A-GSRU] ("Congratulations to the marijuana enjoyers of the world. 'Cause the DEA officially [announced] . . . [t]hey're gonna reschedule to schedule three.").

[212] *See, e.g.*, Alex Halperin, *What Will Rescheduling Marijuana Mean for the Pot Industry?*, ROLLING STONE (Apr. 20, 2016), https://www.rollingstone.com/culture/culture-news/what-will-rescheduling-marijuana-mean-for-the-pot-industry-203124 [https://perma.cc/W7F6-3YRB].

[213] *See e.g.*, Michael Scherer et al., *Democrats Hope Move to Reschedule Marijuana Will Help Them in November*, WASH. POST (May 1, 2024), https://www.washingtonpost.com/politics/2024/05/01/marijuana-biden-democrats-election [https://perma.cc/QLC4-EPQG].

[214] *See, e.g.*, KANKAN, *Stay to Myself / Schedule II*, *on* WAY2GEEKED (Spotify, EMPIRE Sep. 30, 2022).

[215] *See, e.g.*, Synthetic Drug Abuse Prevention Act of 2012, Pub. L. No. 112-144, § 1152, 126 Stat. 1130, 1130–32 (codified at 21 U.S.C. § 812(c)–(d)) (mandating that various synthetic compounds be placed in Schedule I); Controlled Substance Analogue Enforcement Act of 1986, Pub. L. No. 99-570, § 1202, 100 Stat. 3207-13, 3207-13 (codified as amended at 21 U.S.C. § 813(a)) (mandating that certain chemicals be treated as Schedule I substances if intended for human consumption).

political mobilization and advocacy, as reflected in the ongoing marijuana and MDMA rescheduling campaigns.[216]

To be clear, we do not mean to suggest that the DEA has gotten most drug controls or scheduling choices "right" as a policy matter. Far from it. Nor do we mean to suggest that Congress had antidomination goals in mind when it devised the CSA's scheduling framework.[217] The pragmatic benefits of such a framework nevertheless give cause to worry that the current trend toward abandoning the CSA, rather than fixing it, may be a mistake. Keeping the DEA in charge of drug scheduling is another matter.

2. Political Accountability Rather than Bureaucratic Autonomy. — Plainly, the DEA has made problematic choices in implementing the CSA. This is partly because of the statute's substantive and procedural criteria for scheduling decisions — a matter to which we return below.[218] But, to a significant extent, the DEA's struggles with the three Ps have also flowed from the nature of the agency.

The DEA did not exist when the CSA was enacted. President Nixon created it three years later through an executive order consolidating government activities "relat[ing] to the suppression of illicit traffic in narcotics, dangerous drugs, or marihuana."[219] From the start, criminal interdiction and enforcement have been at the core of the DEA's mission. As critics have emphasized, this focus on public safety may lead the agency to prioritize law enforcement imperatives to the exclusion of public health or the public welfare, more broadly understood.[220] The DEA's crackdown on "pill mills" in the late 2000s and early 2010s,[221] which seems to have driven up overdose deaths by pushing opioid patients into more dangerous illicit markets, has been cited as an

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[216] *See, e.g.*, *A Brief History of Cannabis Rescheduling Petitions in the United States*, NORML, https://norml.org/marijuana/fact-sheets/a-brief-history-of-cannabis-rescheduling-petitions-in-the-united-states [https://perma.cc/Y4CZ-VPQW]; Amanda Feilding, *Why MDMA Must Be Reclassified as a Schedule 2 Drug*, HEALTH EUROPA (Dec. 16, 2019), https://www.healtheuropa.com/why-mdma-must-be-reclassified-as-a-schedule-2-drug/95780 [https://perma.cc/7F4E-UBUN].

[217] *Cf.* William B. McAllister, *The Global Political Economy of Scheduling: The International-Historical Context of the Controlled Substances Act*, 76 DRUG & ALCOHOL DEPENDENCE 3, 3–7 (2004) (tracing the origins of the CSA's tiered scheduling system to a 1931 convention on narcotics adopted by the League of Nations).

[218] *See infra* section III.B.3, pp. 890–94.

[219] Reorganization Plan No. 2 of 1973, 38 Fed. Reg. 15932, 15932 (July 1, 1973), *reprinted in* 5 U.S.C. app. at 186–87 (1994); *see also* LISA N. SACCO, CONG. RSCH. SERV., R43749, DRUG ENFORCEMENT IN THE UNITED STATES: HISTORY, POLICY, AND TRENDS 5–7 (2014) (summarizing this history).

[220] *See generally, e.g.*, DRUG POL'Y ALL. & MULTIDISCIPLINARY ASS'N FOR PSYCHEDELIC STUD., THE DEA: FOUR DECADES OF IMPEDING AND REJECTING SCIENCE (2014), https://maps.org/wp-content/uploads/2014/06/DPA-MAPS_DEA_Science_Final.pdf [https://perma.cc/XMT2-FLM3] (compiling case studies of the DEA failing "to exercise its responsibilities in a fair and impartial manner or to act in accord with the scientific evidence," *id.* at 2).

[221] Steven Rich & David Ovalle, *Overdoses Soared Even as Prescription Pain Pills Plunged*, WASH. POST (Sep. 12, 2023), https://www.washingtonpost.com/investigations/2023/09/12/us-overdose-deaths-opioid-crisis [https://perma.cc/PW5B-HFHE].

example.[222] A similar dynamic plays out in scheduling, where the DEA's cultural and historical commitment to criminal law enforcement is reinforced by a budgetary incentive to maintain and expand criminal controls.[223] The DEA's scheduling authority thus feeds the prohibition problem.

In light of the DEA's "abysmal" track record,[224] several scholars have suggested that drug scheduling authority (if not also broader policymaking authority) should be moved from the DEA to the FDA, an agency within the Department of Health and Human Services (HHS).[225] We agree that this is a constructive suggestion; trading public safety expertise for public health expertise might well be a step forward, especially with regard to the prohibition problem. But this trade would not necessarily make any significant progress on the pharma and pluralism problems. Recent scholarship has highlighted the "revolving door" between FDA staff and the pharmaceutical industry.[226] Even if this door could be closed, and even if the FDA's own pharma problem could be eliminated altogether, pharmacologists and toxicologists are not equipped to grapple with the full range of costs and benefits of drug regulatory decisions, given the myriad extra-scientific variables that may be relevant. Moreover, asking experts to decide matters that their disciplines are incapable of answering is a recipe for manipulation by well-financed actors and the delegitimation of expertise.[227]

Appreciation of the unavoidably political nature of drug scheduling suggests an additional tack: reallocating the DEA's scheduling authority

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[222] *See* Leo Beletsky & Jeremiah Goulka, *The Federal Agency that Fuels the Opioid Crisis*, N.Y. TIMES (Sep. 17, 2018), https://www.nytimes.com/2018/09/17/opinion/drugs-dea-defund-heroin.html [https://perma.cc/NF6Y-WBE7]; *see also supra* notes 89–97 and accompanying text (recounting this history).

[223] *See* POZEN, *supra* note 4, at 59 (noting the "structural bias" inherent in an agency "that simultaneously schedules drugs and enforces criminal drug laws"); *see also* Daniel C. Richman, *Defining Crime, Delegating Authority — How Different Are Administrative Crimes?*, 39 YALE J. ON REGUL. 304, 317 (2022) ("Since very significant sentencing consequences follow from the scheduling of a drug at a particular level, the [CSA] comes close to authorizing crime-definition by the very department in charge of prosecutions.").

[224] Beletsky & Goulka, *supra* note 222.

[225] *See, e.g.*, El-Sabawi, *supra* note 146, at 342–43; Christopher J. Frisina, *Let FDA Regulate Its Own Drugs!: An Argument for Narcotic Control and Enforcement Under the Risk Evaluation and Mitigation Strategies (REMS)*, 27 LOY. CONSUMER L. REV. 238, 273 (2015); *cf.* DRUG POL'Y ALL. & MULTIDISCIPLINARY ASS'N FOR PSYCHEDELIC STUD., *supra* note 220, at 3 (suggesting that scheduling authority be transferred to the National Academy of Sciences); Ifetayo Harvey, *Time to Abolish the DEA: Evaluating the Agency's Failures and Calling for Community Investments*, 93 FORDHAM L. REV. 423, 437 (2024) ("[T]he DEA should be abolished and replaced with an agency led by drug user organizers and movement leaders . . . .").

[226] Laura Karas, *FDA's Revolving Door: Reckoning and Reform*, 34 STAN. L. & POL'Y REV. 1, 3–16 (2023).

[227] *See supra* section II.C, pp. 874–79; *see also, e.g.*, Lev Facher, *The Methadone Clinic Monopoly: Opioid Treatment Chains Backed by Private Equity Are Fighting Calls for Reform*, STAT NEWS (Mar. 19, 2024), https://www.statnews.com/2024/03/19/methadone-clinics-opioid-addiction-private-equity [https://perma.cc/738P-SZ68] (discussing growing concerns about the influence of private equity lobbying on medical regulatory decisions relating to addiction treatment).

not just horizontally, from one administrative body to another, but also vertically, to a more visible and politically accountable decisionmaker. The CSA has always delegated scheduling authority to the Attorney General, rather than to the DEA Administrator.[228] The most straightforward option would therefore be to rescind the Attorney General's subdelegation of this authority to the Administrator, as well as the Administrator's further subdelegation to employees within the DEA.[229] Better still, scheduling decisions could be moved out of the Justice Department altogether and given to a health-oriented agency such as HHS — as recently proposed by Professor Mason Marks[230] — while, again, avoiding subdelegation and keeping these decisions with an agency head directly responsible to the President.[231]

In privileging specialized expertise over political responsiveness, administrative law scholars have shown that subdelegation can increase industry influence and insulate policies against change.[232] Both of these pathologies have characterized scheduling by the DEA, which "has never once granted a rescheduling petition not submitted by a pharmaceutical company."[233] Insofar as increasing political accountability increases the likelihood of scheduling shifts across administrations, that would generally be a virtue, not a vice, in such an ossified realm, as long as the reliance interests of relevant parties are adequately addressed in any decision to strengthen controls on a particular drug.[234]

We are unaware of prior commentary criticizing the Attorney General for subdelegating drug policy authority. On the contrary, the Supreme Court expressed skepticism when, in the early 2000s, the Attorney

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[228] *See supra* note 39–40 and accompanying text.

[229] *See* 28 C.F.R. § 0.104 (authorizing the DEA Administrator to "redelegate" any of her "powers and functions"). If the Attorney General were to rescind this subdelegation, she would need to designate staff with a range of experience to advise on scheduling decisions. Staff with relevant backgrounds might be drawn not only from within the Justice Department but also from HHS, FDA, state agencies, and academia. *See* Isaac Cui et al., *Governing by Assignment*, 173 U. PA. L. REV. 157, 159, 173–74 (2024) (describing agency authorities to draw staff through temporary assignments under the Intergovernmental Personnel Act of 1970).

[230] *See* Marks, *supra* note 63, at 1018 ("Congress could shift scheduling authority to a single agency. Giving HHS primary control with input from DEA is a sensible option . . . .").

[231] *Cf.* Kennedy v. Braidwood Mgmt., Inc., 145 S. Ct. 2427, 2461 (2025) (noting that "the Secretary of HHS . . . answers to the President of the United States").

[232] *See* Jennifer Nou, Essay, *Subdelegating Powers*, 117 COLUM. L. REV. 473, 479, 523–24 (2017); *see also* Stephen Migala, *Delegation Inside the Executive Branch*, 24 NEV. L.J. 147, 174 (2023) (arguing that subdelegation "degrades lines of accountability and important democratic checks"). High-ranking cabinet officials are hardly immune from industry influence. *See, e.g.*, Lindsey Dillon et al., *The Environmental Protection Agency in the Early Trump Administration: Prelude to Regulatory Capture*, 108 AM. J. PUB. HEALTH S89, S89 (Supp. 2 2018) (arguing that the Administrator of the EPA facilitated regulatory capture during President Trump's first term). But the question for institutional designers is a comparative one, and — as we have stressed throughout — there are no perfect answers when it comes to drug regulation.

[233] POZEN, *supra* note 4, at 59.

[234] The new schedules that we propose in section III.C, pp. 894–903, along with the new decisionmaking procedures that we propose in section III.B.3, pp. 890–94, would facilitate consideration of the reliance interests of people who use a given drug.

General took the rare step of directly asserting his prerogatives under the CSA.[235] The recent intervention of then–Attorney General Merrick Garland in support of marijuana rescheduling generated broader backlash for "playing politics" with what ought to be a bureaucratic matter.[236] President Trump's initial pick to serve as acting DEA Administrator, Derek Maltz, has gone so far as to complain that "the Justice Department hijacked the rescheduling process."[237] But this is backward.[238] The Administrator reports to the Attorney General, not the other way around. And drug scheduling is inescapably political. Pretending otherwise does not make the politics go away, although it does tend to privilege entrenched interests and impede pragmatic problem solving.

3. Inclusive Decisionmaking Rather than Exclusionary Tests and Procedures. — Whoever makes the final decision as to which drugs go into which schedules, it also matters greatly how they decide, both substantively and procedurally. The ongoing marijuana rescheduling controversy helps illustrate flaws in the current approach.

In May 2024, marijuana reformers celebrated as the Attorney General submitted a notice of proposed rulemaking to consider shifting the substance from Schedule I (punitive prohibitionism) to Schedule III (the medical use model),[239] a move that President Biden described as "monumental."[240] That celebration appears to have been premature. At this writing, the marijuana rescheduling process has broken down entirely. After repeated delays, the DEA's Chief Administrative Law Judge Mulrooney has canceled the hearing that had been set for January 21, 2025, with no new hearing date announced.[241]

The crux of the current dispute concerns who gets a seat at the table in the rescheduling hearing. Far more groups sought to participate than

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[235] *See* Gonzales v. Oregon, 546 U.S. 243, 258–59 (2006). *Gonzales* did not concern drug scheduling but rather the "use of controlled substances for physician-assisted suicide." *Id.* at 254.

[236] Scherer et al., *supra* note 213.

[237] Joshua Goodman & Jim Mustian, *Top US Drug Agency a Notable Holdout in Biden's Push to Loosen Federal Marijuana Restrictions*, AP NEWS (May 20, 2024, at 20:58 ET), https://apnews.com/article/marijuana-pot-dea-legalization-biden-cb7869d3286094f0124de728320d89c1 [https://perma.cc/7UL2-U9N5].

[238] And also somewhat nonsensical, given that the DEA is a component of the Justice Department.

[239] *See* Press Release, DOJ, Justice Department Submits Proposed Regulation to Reschedule Marijuana (May 16, 2024), https://www.justice.gov/archives/opa/pr/justice-department-submits-proposed-regulation-reschedule-marijuana [https://perma.cc/LV2Y-PD4P].

[240] Eileen Sullivan, *The U.S. Is Easing Marijuana Restrictions. Here's How It Works.*, N.Y. TIMES (May 16, 2024), https://www.nytimes.com/2024/05/16/us/politics/marijuana-schedule-drug-biden.html [https://perma.cc/9LSY-JHKS].

[241] *See* Jean Smith-Gonnell, Zie Alere & Nick Ramos, *Cannabis Rescheduling: ALJ Cancels Upcoming Hearings on Proposed Rulemaking*, TROUTMAN PEPPER LOCKE (Jan. 15, 2025), https://www.regulatoryoversight.com/2025/01/cannabis-rescheduling-alj-cancels-upcoming-hearings-on-proposed-rulemaking [https://perma.cc/V9EX-Z2JZ].

could do so.[242] DEA regulations require that participants in such hearings be "[i]nterested person[s] . . . adversely affected or aggrieved" by the current or proposed rule,[243] without offering guidance on how to select among interested persons.[244] A veterans group and a Cherokee marijuana entrepreneur, each of whom wished to speak to nonmedical benefits of marijuana use, challenged their exclusion in federal court.[245] The complaint in the latter suit emphasizes that the DEA Administrator's list of twenty-five participants "didn't include a single Native American tribe, individual or organization, and additionally no group from a marginalized community."[246] Several organizations that were included on this list filed a motion with Chief Judge Mulrooney alleging that the Administrator may have stacked the deck with anti-rescheduling participants and that DEA officials had engaged in improper *ex parte* contacts with anti-rescheduling advocates.[247] After denying this motion and a motion to reconsider, Chief Judge Mulrooney granted these organizations leave to file an interlocutory appeal with the Administrator.[248]

At one level, the chaos in the marijuana rescheduling proceeding is a function of the DEA's apparent disagreement with the former Attorney General about whether rescheduling is a good idea.[249] The reform proposed in the previous subsection would resolve such disputes in favor of the Attorney General. At a deeper level, however, the chaos stems from the CSA's limitations on the factors that may be considered in a scheduling proceeding and, hence, on the participants and perspectives seen as relevant.

The CSA instructs that scheduling decisions be based on three criteria: a drug's "potential for abuse," "dependence" risk, and "currently accepted medical use."[250] The DEA has taken a narrow view of what counts as medical use, tied to the successful completion of randomized

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[242] *See* Opposition to Emergency Motion for an Injunction Pending Appeal at 2, Drs. for Drug Pol'y Reform v. Drug Enf't Admin., No. 24-1365 (D.C. Cir. dismissed Apr. 11, 2025).

[243] 21 C.F.R. § 1300.01(b) (2024).

[244] *Id.* § 1308.44(a)–(b).

[245] *See* Petition for Review at 1–2, Veterans Action Council v. Drug Enf't Admin., No. 24-1374 (D.C. Cir. Dec. 5, 2024); Complaint and Request for Declaratory and Injunctive Relief ¶¶ 2, 11, Heldreth v. Garland, No. 24-cv-1817 (W.D. Wash. Nov. 5, 2024).

[246] Complaint and Request for Declaratory and Injunctive Relief ¶¶ 8, 53, *Heldreth*, No. 24-cv-1817.

[247] Hemp for Victory and Village Farms' Joint Motion Requesting Supplementation of the Record and Disqualification and Removal of DEA from the Role of Proponent of the Rule in These Proceedings at 14, 16–18, Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, DEA Dkt. No. 1362, Hearing Dkt. No. 24-44 (Nov. 18, 2024).

[248] Briefing Order Regarding Village Farms International, Hemp for Victory, and OCO, et al.'s Motion to Reconsider at 5, Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, DEA Dkt. No. 1362, Hearing Dkt. No. 24-44 (Jan. 13, 2025).

[249] *See* Pozen, *supra* note 155.

[250] 21 U.S.C. § 812(b).

controlled trials.[251] The Justice Department's Office of Legal Counsel recently endorsed a more flexible test proposed by HHS.[252] But either way, *medical* considerations are what count. This framework renders inapposite — and, from an evidentiary standpoint, potentially inadmissible — the views of most individuals and organizations with an interest in a drug. As Chief Judge Mulrooney remarked in rejecting witnesses proposed by one pro-rescheduling group on the ground that they had no academic training on the subject: "[P]atient testimonial witnesses — yeah, we're not going to be doing those."[253] And, as the First Circuit pointed out in adjudicating an analogous dispute about the exclusion of groups from a prior rescheduling process, this dismissive approach flows from the text of the CSA.[254] Absent from the statutory criteria are any of the religious, creative, social, recreational, or other nonmedical benefits that a drug might hold for certain users, as well as any consideration of the consequences of applying criminal prohibitions and penalties.[255]

This approach manages to exacerbate all three Ps at once. It limits the analysis to a narrow set of factors that, while undeniably important, capture only a fraction of the values at stake, thereby undermining the credibility of scheduling outcomes and skewing them toward Schedule I and punitive prohibitionism.[256] And it shuts out of the conversation not only values but also voices, including those of marginalized groups that might serve as a counterweight to commercial and carceral lobbies.[257] As a result, drug companies, medical researchers, and law enforcement officials are left to occupy the decisional field. A growing body of administrative law scholarship has highlighted the importance of broad-based participatory processes in cabining industry influence, eliciting information, and safeguarding vulnerable communities.[258] Administrative practice falls short of these aspirations in many areas.[259] With drugs, it doesn't even try.

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[251] *See* Mikos, *supra* note 14, at 481–83; *see also id.* at 488 (observing that this "test is tyrannical because it requires a very specific type of evidence . . . that is almost impossible to generate, especially when a drug is already on Schedule I").

[252] *See id.* at 483–88; *supra* note 163 and accompanying text.

[253] Preliminary Hearing at 00:34:07, Schedules of Controlled Substances: Proposed Rescheduling of Marijuana, DEA Dkt. No. 1362, Hearing Dkt. No. 24-44 (Dec. 2, 2024), https://www.youtube.com/watch?v=GBMHWru0FNo [https://perma.cc/5ZWD-SL4U].

[254] *See* Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 897 (1st Cir. 1987).

[255] *See* 21 U.S.C. § 812(b).

[256] *See supra* section II.C, pp. 874–79.

[257] *Cf.* RALF JÜRGENS, OPEN SOC'Y INST., "NOTHING ABOUT US WITHOUT US" — GREATER, MEANINGFUL INVOLVEMENT OF PEOPLE WHO USE ILLEGAL DRUGS: A PUBLIC HEALTH, ETHICAL, AND HUMAN RIGHTS IMPERATIVE 14–30 (2008) (reviewing evidence on public health benefits of involving people who use drugs in the policymaking process).

[258] *See generally, e.g.*, Brian D. Feinstein, *Identity-Conscious Administrative Law: Lessons from Financial Regulators*, 90 GEO. WASH. L. REV. 1 (2022); Jim Rossi & Kevin M. Stack, *Representative Rulemaking*, 109 IOWA L. REV. 1 (2023); Daniel E. Walters, *The Administrative Agon: A Democratic Theory for a Conflictual Regulatory State*, 132 YALE L.J. 1 (2022).

[259] *See* Feinstein, *supra* note 258, at 3.

From a democratic and pragmatic standpoint, then, the scheduling process should be made more inclusive on two levels. Most importantly, the substantive criteria for choosing schedules should be expanded to cover social, recreational, and fiscal variables, concerning both the effects of consumption and the costs of regulation.[260] Such an expansion would shift the focus from minimizing one sort of private harm to maximizing public health and welfare. This shift could be accomplished any number of ways, perhaps most simply by replacing the CSA's three-factor test with a more comprehensive form of cost-benefit analysis, akin to what is already used in fields like environmental protection.[261] Alternative methodologies such as cost-effectiveness analysis or multicriteria analysis could likewise be used to force attention to nonmedical considerations.[262] Other aspects of our proposal, including the procedural reforms and lobbying controls described below,[263] would reduce the risk of industry manipulation under any of these expanded analytic frameworks.

Procedurally, the institutional arrangements for evaluating scheduling petitions should be revised to incorporate a wider range of voices, in line with Executive Order 14,094's charge that agencies make public participation in rulemaking more "equitable and meaningful."[264] We are mindful that procedural requirements risk increasing expense and delay with limited payoff.[265] Yet, as long as Congress continues to

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[260] *Cf.* Marks, *supra* note 63, at 1009 ("[P]eople who make scheduling decisions should consider an array of variables beyond the risks of drug consumption, including the risks associated with drug scheduling and prohibition.").

[261] *See supra* notes 167–69 and accompanying text. We leave for another day the design details of such drug CBA, including whether and how to incorporate distributional weights, deontological side constraints, hedonic data, and drug users' preferences. *Cf.* Matthew D. Adler & Eric A. Posner, *Implementing Cost-Benefit Analysis When Preferences Are Distorted*, 29 J. LEGAL STUD. 1105, 1120–21 (2000) (explaining that "actual-preference," *id.* at 1120, versions of CBA should take into account the reported preferences of drug users, even when addicted, whereas other versions of CBA may decline to credit preferences seen as distorted or defective); John Bronsteen, Christopher Buccafusco & Jonathan S. Masur, *Well-Being Analysis vs. Cost-Benefit Analysis*, 62 DUKE L.J. 1603, 1615–20 (2013) (arguing for the superiority of "well-being analysis" that focuses on a policy's hedonic impacts); K. Sabeel Rahman, *Anti-Domination and Administration*, 100 N.Y.U. L. REV. 1984, 2037–38 (2025) (discussing Biden Administration techniques for incorporating distributional considerations and antidomination goals into agency CBAs).

[262] *See* Frank Ackerman, Critique of Cost-Benefit Analysis, And Alternative Approaches to Decision-Making 11–18 (Jan. 2008) (unpublished manuscript), https://frankackerman.com/publications/costbenefit/Critique_Cost_Benefit_Analysis.pdf [https://perma.cc/PRD6-BVD3] (describing and defending "multi-criteria analysis," "holistic comparison of costs and benefits," "and cost-effectiveness analysis" as among the alternatives to CBA, *id.* at 11); *see also* SEDDON, *supra* note 173, at 154–57 (advocating that "normative" considerations, *id.* at 155, such as "freedom" and "equality," "be made the explicit focus of analysis" in drug regulation, *id.* at 154).

[263] *See infra* notes 264–70 and accompanying text (procedural reforms); *infra* notes 310–17 and accompanying text (lobbying controls).

[264] Exec. Order No. 14,094, § 2(a), 88 Fed. Reg. 21879, 21879 (Apr. 6, 2023).

[265] *See generally* Sharon Jacobs, *The Challenges of Participatory Administration*, 58 U.C. DAVIS L. REV. 323, 354–80 (2024) (discussing limits and downsides of efforts to promote participation through procedural mechanisms).

require formal rulemaking in this context[266] — a feature of the CSA that we take as given for present purposes — the marginal cost of any new requirement may be low. Even modest measures could help address the pluralism problem, from eliciting or prioritizing the input of public health researchers to allowing pro-rescheduling groups to cross-examine witnesses.[267] More ambitiously, an agency such as HHS could employ randomly selected citizen panels or administrative juries to make scheduling recommendations.[268] Versions of this strategy have already been tried with drug policy decisionmaking at the subfederal level, as more than a dozen states now "require representation of people with lived experience in their opioid settlement" bodies.[269] A pragmatic scheduling process could look to "lived experience" in a similar manner.[270]

C. Legalization Without Laissez Faire

The focus thus far has been on who makes drug scheduling decisions and how. This Part has not yet interrogated the contents of the schedules themselves — the discrete packages of regulation, set out by Congress, that they contain. Perhaps the greatest design flaws of the CSA can be found here.

As with any product or service, the possible mechanisms for regulating access to drugs can be arrayed on a spectrum of restrictiveness.[271] At the most restrictive end of the spectrum come outright bans, backed by criminal sanctions. At the least restrictive end comes no targeted regulation at all, or laissez-faire free enterprise. In between lie a great variety of mechanisms for correcting market failures and controlling access directly or indirectly: age restrictions, registration requirements,

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[266] 21 U.S.C. § 811(a).

[267] For complementary calls to foreground public health considerations in the FDA's drug decisionmaking, see NAT'L ACADS. SCIS., ENG'G & MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 409–14 (Richard J. Bonnie, Morgan A. Ford & Jonathan K. Phillips eds., 2017); Patricia J. Zettler, Margaret Foster Riley & Aaron S. Kesselheim, *Implementing a Public Health Perspective in FDA Drug Regulation*, 73 FOOD & DRUG L.J. 221, 247–56 (2018).

[268] *See* Nikhil Menezes & David E. Pozen, *Looking for the Public in Public Law*, 92 U. CHI. L. REV. 971, 1013–21 (2025) (cataloging techniques for giving laypersons a role in administrative decisionmaking); Alison Ritter, Kari Lancaster & Rosalyn Diprose, *Improving Drug Policy: The Potential of Broader Democratic Participation*, 55 INT'L J. DRUG POL'Y 1, 2–3 (2018) (examining "deliberative democracy," *id.* at 2, approaches to drug policymaking).

[269] Rebekah Falkner, *Engaging with People with Lived Experience in Opioid Settlement Decision-Making*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Jan. 9, 2024), https://nashp.org/engaging-with-people-with-lived-experience-in-opioid-settlement-decision-making [https://perma.cc/2FG2-AJ3H].

[270] *Cf.* Huntington, *supra* note 17, at 1506 (explaining that pragmatism counsels "looking to lived experience," as well as academic studies, clinical trials, and the like, in pursuit of workable solutions).

[271] *Cf.* David Adam Friedman, *Debiasing Advertising: Balancing Risk, Hope, and Social Welfare*, 19 J.L. & POL'Y 539, 555–59 (2011) (arraying regulatory strategies for product safety and advertising along a "paternalism spectrum," *id.* at 558).

zoning rules, excise taxes, warning labels, production quotas, and on and on.[272]

The CSA allows the Attorney General to pick one of three points along this spectrum for any given drug. As explained in Part I, she can assign the drug to Schedule I and thereby impose an outright ban; she can assign it to Schedule II, III, IV, or V and a medical use regime; or she can leave it unscheduled and therefore untouched by the CSA.[273] The statute does not allow the Attorney General to select any other models for regulating access. And, as explained in Part II, the three basic models that it does employ are proven failures when it comes to habit-forming drugs. Schedules I through V have elicited widespread defiance, intrusive and racialized enforcement, and vast illicit markets, with all the harms each entails. Descheduling avoids these problems, but at the price of inviting new industries to join Big Tobacco and Big Alcohol in driving overconsumption through mass marketing, intensive lobbying, targeted outreach to minors, and other such tactics.[274] Under the CSA, scheduling is like a multiple-choice question for which the answer that will often be best — "none of the above" — is not listed.

To do a better job of addressing the three Ps, the CSA thus needs to incorporate another regulatory model apart from prohibition, medicalization, and marketization. It needs a new schedule that deters the use of the most dangerous drugs without running afoul of the Iron Law of Prohibition.[275] And it needs a new schedule that creates an administrative path to legalizing less dangerous drugs without simply "shift[ing] control . . . from a coercive state to an extractive market."[276]

1. Schedule A: Harm Reduction. — Let us start with the most challenging category of substances: those so dangerous that policymakers would prefer to eliminate them, or at least the nonmedical use of them,

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[272] *See* Jonathan B. Wiener & Barak D. Richman, *Mechanism Choice*, *in* RESEARCH HANDBOOK ON PUBLIC CHOICE AND PUBLIC LAW 363, 365–69 (Daniel A. Farber & Anne Joseph O'Connell eds., 2010) (surveying regulatory mechanisms that may be used to correct market failures).

[273] *See supra* notes 45–69 and accompanying text. Because the differences in regulatory mechanisms and stringency across Schedules II through V are differences in degree rather than kind, *see supra* notes 61–69 and accompanying text, we lump these schedules together for purposes of this discussion.

[274] *See supra* sections II.B–C, pp. 869–79.

[275] *See supra* notes 83–97 and accompanying text (discussing the Iron Law of Prohibition).

[276] Aziz Rana, *The "War on Drugs" and the Narrowing of Constitutional Imagination*, 3 J. AM. CONST. HIST. 197, 204 (2025) (reviewing DAVID POZEN, THE CONSTITUTION OF THE WAR ON DRUGS (2024)). Because "decriminalization" reforms that merely eliminate criminal penalties for minor use and possession offenses "do[] not remove the harms associated with illicit markets," "prioritize consumer safety," or address the supply of drugs, we bracket them here notwithstanding their potential utility. Brian D. Earp et al., *Racial Justice Requires Ending the War on Drugs*, AM. J. BIOETHICS, Apr. 2021, at 4, 10. *See generally* Ely Aaronson, *Negotiating Decriminalization: Carceral Power and Legal Change*, 9 ANN. REV. CRIMINOLOGY (forthcoming 2026), https://www.annualreviews.org/content/journals/10.1146/annurev-criminol-032924-020244 [https://perma.cc/5XPJ-K7ZV] (providing a nuanced overview of the promises, limitations, and varieties of drug decriminalization).

except that it may be counterproductive to apply a criminal ban (Schedule I) or the medical model (Schedules II through V) because of the prohibition and pharma problems.

Heroin likely falls in this category. Heroin is highly addictive and carries a significant risk of fatal overdose.[277] Yet, as discussed in Part II, heroin prohibition has exacerbated the opioid crisis by exposing hundreds of thousands of Americans with opioid use disorder to illegal markets and adulterated products and by driving the transition of the illicit opioid supply to fentanyl.[278] Recognizing the harms of heroin prohibition, public health scholars have made a strong case for legalizing nonmedical access through "safe injection facilities" that allow consumption under the supervision of trained professionals and that often offer drug testing and other safety aids.[279] For support, these scholars point to the successes claimed by more than ninety such programs operating worldwide.[280] The Third Circuit, however, held in 2021 that the CSA "forbids opening and maintaining any place for visitors to come use drugs," no matter how "laudable" or valuable the "experiment."[281] Harm reduction advocates have subsequently championed state and local measures to decriminalize safe injection facilities, despite their illegality under the CSA.[282] While this movement has made some headway in New York and Rhode Island,[283] it has experienced major setbacks, including

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[277] *See Heroin Research Report: Overview*, NAT'L INST. ON DRUG ABUSE (July 2011), https://nida.nih.gov/publications/research-reports/heroin/overview [https://perma.cc/MQT6-6QGS]; *Drug Overdose Deaths*, *supra* note 91, at fig. 5.

[278] *See supra* notes 89–97 and accompanying text.

[279] *See, e.g.*, Alex Kreit, *Safe Injection Sites and the Federal "Crack House" Statute*, 60 B.C. L. REV. 413, 420–28 (2019) (reviewing empirical findings that safe injection facilities "improve public health and safety outcomes for both users and the community," *id.* at 422, and describing efforts to establish them in the United States).

[280] *See* Brett Wolfson-Stofko et al., *Perspectives on Supervised Injection Facilities Among Service Industry Employees in New York City: A Qualitative Exploration*, 62 INT'L J. DRUG POL'Y 67, 68 (2018) ("Research suggests that [supervised injection facilities] are capable of successfully managing overdoses, reducing overdose deaths, reducing HIV/[hepatitis C] risk behaviour, increasing uptake of addiction treatment, . . . reducing public injection and public disorder[,] . . . are cost-effective[,] and have not been found to increase drug injecting or drug-related crime in the neighbourhoods in which they operate."). *See generally* Levengood et al., *supra* note 110 (synthesizing studies examining supervised injection facilities and finding benefits to public health); Chloé Potier et al., *Supervised Injection Services: What Has Been Demonstrated? A Systematic Literature Review*, 145 DRUG & ALCOHOL DEPENDENCE 48 (2014) (same).

[281] United States v. Safehouse, 985 F.3d 225, 243 (3d Cir. 2021). *But cf.* Kreit, *supra* note 279, at 442–62 (arguing that the CSA's immunity provision should be read to apply to government-run safe injection facilities and discussing alternative theories of their legality).

[282] *See, e.g.*, DRUG POL'Y ALL., OVERDOSE PREVENTION CENTERS (OPCS) 1 (2025), https://drugpolicy.org/wp-content/uploads/2025/04/DPA-OPCs_InDesign-FINAL-1.pdf [https://perma.cc/89KJ-J7S8]; *Supervised Consumption Services*, NAT'L HARM REDUCTION COAL., https://harmreduction.org/issues/supervised-consumption-services [https://perma.cc/6Y2W-6KFT].

[283] *See* Aaron Chalfin, Brandon del Pozo & David Mitre-Becerril, *Overdose Prevention Centers, Crime, and Disorder in New York City*, JAMA NETWORK OPEN, Nov. 13, 2023, at 1, 2; Lev Facher, *Rhode Island Set to Open First Supervised Consumption Site for Illicit Drugs Outside NYC*, STAT NEWS (Dec. 6, 2024), https://www.statnews.com/2024/12/06/opioid-addiction-supervised-consumption-site-rhode-island [https://perma.cc/M6L7-F66Z].

Governor Gavin Newsom's veto of a 2022 bill to decriminalize "overdose prevention programs" in California[284] and the Justice Department's scrutiny of the Safehouse organization in Philadelphia.[285]

If safe injection facilities are an effective response to the prohibition problem for some drugs, then a pragmatic version of the CSA ought to facilitate, not forbid, their development. We propose a new CSA schedule, which for simplicity's sake we will call Schedule A, that would permit lawful access through harm reduction programs such as safe injection facilities. The CSA already allows applicants to register to manufacture and distribute Schedule I and II substances;[286] a new option could be added for registration to dispense Schedule A substances, authorizing their use within these programs. Precedents for such a reform include the Ryan Haight Act's[287] amendment to the CSA requiring the Attorney General to develop a new category of registration for telemedicine,[288] and the Narcotic Addict Treatment Act's[289] amendment requiring the Attorney General to develop a new category of "narcotic treatment" registration to authorize the dispensing of narcotics for "maintenance" or "detoxification."[290]

As the CSA does for all its schedules,[291] specific controls on Schedule A drugs could be enforced as conditions on registration. A registrant who violated these conditions would be subject to suspension, revocation, or other sanctions. In light of the possibility that harm reduction

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284 Letter from Gavin Newsom, Governor of Cal., to the Members of the Cal. State Senate (Aug. 22, 2022), https://www.gov.ca.gov/wp-content/uploads/2022/08/SB-57-veto-msg-August-22-2022.pdf [https://perma.cc/6G46-WMSE].

285 *See* David Ovalle, *Philadelphia Nonprofit Loses Latest Bid to Open Supervised Drug-Use Center*, WASH. POST (Apr. 3, 2024), https://www.washingtonpost.com/health/2024/04/03/drug-use-center-philadelphia-justice-department [https://perma.cc/N775-9LLP].

286 21 U.S.C. § 823(a)–(b).

287 Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (codified in scattered sections of 21 U.S.C.).

288 *See* 21 U.S.C. § 831(h); Special Registrations for Telemedicine and Limited State Telemedicine Registrations, 90 Fed. Reg. 6541 (Jan. 17, 2025) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, 1306).

289 Pub. L. No. 93-281, 88 Stat. 124 (1974) (codified in scattered sections of 21 U.S.C.).

290 *See* 21 U.S.C. § 823(h) (providing for "separate registration" for "narcotic treatment" programs). As of 2020, there were more than 1,700 narcotic treatment programs registered with the DEA. Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11008, 11009 (Feb. 26, 2020) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304). While we would welcome an expansion of these programs, they do not have any effect on scheduling — and so do not address the three Ps — and are limited by statute to dispensing narcotics that have been approved for medical treatment of opioid use disorder, *see* 21 U.S.C. § 823(h). These currently include only methadone (Schedule II) and buprenorphine (Schedule III) among scheduled substances. *See* Medications for the Treatment of Opioid Use Disorder, 89 Fed. Reg. 7528, 7529 (Feb. 2, 2024) (to be codified at 42 C.F.R. pt. 8). Even scholars who criticize the existing regulations as too restrictive do not suggest that "treatment" under the statute could, or should, be redefined to include an individual's self-administration of heroin or other Schedule I substances. *See, e.g.*, Bridget C.E. Dooling & Laura E. Stanley, *Methadone's Regulatory Thicket*, 32 ANNALS HEALTH L. & LIFE SCIS. 191, 209–16 (2023).

291 *See* 21 U.S.C. § 824(a); 21 C.F.R. § 1309.43 (2025).

programs may be desirable not only for substances that are currently subject to prohibition (like heroin[292]) but also for the most dangerous substances that are currently subject to medical control (like fentanyl[293]), placement in Schedule A need not preclude placement in Schedule II, and vice versa. In other words, Schedule A drugs with medical applications could be made lawfully obtainable either through a physician for medical use or through a harm reduction program for nonmedical use. The possibility that certain drugs would be placed in both Schedule A and Schedule II is one reason we favor a letter rather than a number for the former's title.

The addition of Schedule A would allow the administrative process to better navigate the three Ps. Most fundamentally, it would provide an alternative to a blanket ban in situations where prohibition has proven counterproductive or seems likely to do so. Schedule A could also be designed to counter the pharma problem. As far as we are aware, every existing safe injection facility is run by a nonprofit or government entity.[294] Limiting registration under Schedule A to such entities would ensure that there is no profit motive to stimulate new demand.[295] To further check the risk of commercialization, Schedule A could condition registration on a harm reduction program's compliance with more or less detailed controls on dosing, access, supervision, storage, and security.[296]

Beyond any health benefits it may bring for drug users, Schedule A would bring the metabenefit of facilitating continual policy learning. This goal could be made explicit, by authorizing or requiring an executive branch agency such as HHS to run controlled pilot projects or other

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[292] *See* 21 C.F.R. § 1308.11(c)(11) (2025).

[293] *See id.* § 1308.12(c)(9).

[294] *Cf.* Scott Burris et al., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, 53 ST. LOUIS U. L.J. 1089, 1133 (2009) (stating without qualification that a safe injection facility operates "not for its own sake or for profit").

[295] Governmental and nonprofit providers may also have incentives to maintain or increase their budgets, but the absence of a profit motive substantially reduces the risk that they will seek to stimulate new demand. *Cf.* Potier et al., *supra* note 280, at 64 (reporting that "no study" of safe injection sites has "found any increase in the total number" of injection drug users). Outside of the CSA, state monopolies are a relatively common tool of alcohol control in this country. *See* H. Justin Pace & Eden Punch, *Convergence and Divergence of Alcohol and Marijuana Regulation in a Federalist System Post-COVID-19*, 73 U. KAN. L. REV. 615, 621 (2025) (identifying "state-owned or state-supported [alcohol] monopolies" in seventeen states).

[296] The development of such controls would require striking a value-laden balance. While stricter controls would reduce the risk that drugs dispensed through harm reduction programs are diverted to illicit markets, a failure to meet demand through lawful channels would make it more likely that such markets persist. *Cf.* Nick Werle & Ernesto Zedillo, *We Can't Go Cold Turkey: Why Suppressing Drug Markets Endangers Society*, 46 J.L. MED. & ETHICS 325, 329, 338 (2018) (noting that "[s]keptics have cited black markets and diversion as reasons to maintain" tight restrictions on opioid maintenance programs, *id.* at 329, but arguing that such skepticism misunderstands the political economy of addictive drugs and is belied by "the experiences of Switzerland and other countries," *id.* at 338).

experiments under Schedule A.[297] But the goal would be served to some extent even in the absence of congressional instruction. The CSA sets a regulatory floor, leaving states free to impose additional restrictions on particular drugs.[298] Georgia, for example, recently enacted extensive regulations on kratom even though the federal government has thus far declined to schedule the supplement.[299] The placement of a drug like heroin in Schedule A therefore would not prevent a state from continuing to ban it. Inevitably, some states would choose to retain their current bans or to impose special controls, above the federal floor, on Schedule A registrants operating within their borders. By diversifying drug regimes across the country, these choices would harness federalism to mitigate the pluralism problem. They would also generate valuable data and enable interstate comparisons about the effects of prohibition, harm reduction programs, and regulatory controls on such programs — comparisons that could, over time, inform further policy experimentation and refinement in a pragmatic feedback loop.

2. Schedule B: Managed Market Access. — Schedule A gives policymakers a way to deal with drugs they might prefer to criminalize but for the prohibition problem and the risk of leading users toward even more dangerous products and behaviors. What about drugs that policymakers might prefer to legalize but for the pharma problem and the risk of exposing consumers and regulators to corporate manipulation? Marijuana is the obvious example of such a substance at this writing.[300]

In developing their own regimes for regulating marijuana outside of the CSA, officials in legalizing states have looked to the extensive public

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[297] A recent executive order directs the Secretary of HHS to ensure that discretionary grants for substance use disorder prevention and treatment "do not fund programs that fail to achieve adequate outcomes, including so-called 'harm reduction' or 'safe consumption' efforts that only facilitate illegal drug use and its attendant harm." Exec. Order No. 14,321, 90 Fed. Reg. 35817, 35818 (July 24, 2025). This order suggests that the Trump Administration is likely to be hostile to experiments of the sort we propose here, and perhaps to the very concept of Schedule A, although we note that these experiments would do much more than "facilitate illegal drug use and its attendant harm." As explained above, they would bring health benefits, steer vulnerable users toward state services, and enable policy learning.

[298] *See* 21 U.S.C. § 903 (providing that the CSA shall not be read "to occupy the field" of drug regulation or to preempt state law absent "a positive conflict").

[299] Kate Brumback, *Georgia Governor Signs Law Adding Regulations for Production and Sale of Herbal Supplement Kratom*, AP NEWS (May 2, 2024, at 15:26 ET), https://apnews.com/article/kratom-legislation-georgia-501378dc662b5577ab5e8cd719dc4315 [https://perma.cc/Y9GV-DTTH]; *see also* Marks, *supra* note 63, at 1005–06 (explaining that HHS overrode the DEA's proposal to schedule kratom in 2018).

[300] *See supra* notes 184–88 and accompanying text. Psychedelics such as psilocybin and MDMA may well be other substances whose religious, creative, social, recreational, or other nonmedical benefits warrant limited legalization despite the possibility of health harms. *See* Joshua S. Siegel et al., Special Communication, *Psychedelic Drug Legislative Reform and Legalization in the US*, 80 JAMA PSYCHIATRY 77, 79–80 (2023) (surveying recent state reforms to make psychedelics more accessible). If alcohol were not already legal and subject to its own regulatory regime, it would be another candidate for Schedule B. Despite expert consensus that alcohol's carcinogenic effects and

health literature on alcohol and tobacco regulation.[301] According to the World Health Organization (WHO), the three most cost-effective means of regulating the harmful use of alcohol are restrictions on "commercial and public availability," restrictions on "advertising and promotions," and "pricing policies such as excise tax increases."[302] Tobacco researchers have identified two other important categories of controls: restrictions on additives and other product designs that promote initiation or addiction,[303] and checks on lobbying by tobacco companies.[304] State marijuana legalization measures have included these controls in varying combinations and to varying degrees, with the exception of lobbying limits.[305] Public health scholars have lamented this omission.[306]

The CSA, of course, has long imposed a criminal ban on recreational as well as medical marijuana, leading not only to glaring inconsistencies

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other health harms swamp any medical benefits from its consumption, *see, e.g.*, *No Level of Alcohol Consumption Is Safe for Our Health*, WORLD HEALTH ORG. (Jan. 4, 2023), https://www.who.int/europe/news/item/04-01-2023-no-level-of-alcohol-consumption-is-safe-for-our-health [https://perma.cc/UTN7-B4WA], no contemporary U.S. policymakers seriously suggest a return to Prohibition.

[301] *Cf.* Marks, *supra* note 196, at 453 (observing that state marijuana policymakers have adopted regulations modeled on alcohol and tobacco regimes).

[302] WORLD HEALTH ORG., GLOBAL ACTION PLAN FOR THE PREVENTION AND CONTROL OF NONCOMMUNICABLE DISEASES 2013–2020, at 67 (2013); *see also, e.g.*, Dan Chisholm et al., *Are the "Best Buys" for Alcohol Control Still Valid? An Update on the Comparative Cost-Effectiveness of Alcohol Control Strategies at the Global Level*, 79 J. STUD. ON ALCOHOL & DRUGS 514, 518, 520 (2018) (examining more recent data and finding "that little has changed in terms of [the WHO's] key conclusions," *id.* at 520); Carla J. Berg et al., *The Emerging Marijuana Retail Environment: Key Lessons Learned from Tobacco and Alcohol Retail Research*, 81 ADDICTIVE BEHAVS. 26, 28 (2018) ("[L]iterature suggests that spatial access to tobacco and alcohol retailers and exposure to [their] widespread marketing . . . may contribute to substance use and disparities in patterns of use."). *See generally* Carolin Kilian et al., *Reducing Alcohol Use Through Alcohol Control Policies in the General Population and Population Subgroups: A Systematic Review and Meta-Analysis*, ECLINICALMEDICINE, May 10, 2023, art. 101996 (reviewing research on the health effects of alcohol pricing, tax, and availability policies).

[303] *See* Daniel G. Orenstein & Stanton A. Glantz, *Regulating Cannabis Manufacturing: Applying Public Health Best Practices from Tobacco Control*, 50 J. PSYCHOACTIVE DRUGS 19, 25–27 (2018).

[304] *See* Yussuf Saloojee & Elif Dagli, *Tobacco Industry Tactics for Resisting Public Policy on Health*, 78 BULL. WORLD HEALTH ORG. 902, 908 (2000). Consistent with WHO recommendations, the tobacco Master Settlement Agreement requires disclosure of lobbying activities (including through the funding of third parties), restricts coordinated lobbying through trade associations, and prohibits deceptive lobbying. MASTER SETTLEMENT AGREEMENT at III(m)–(r) (1998), https://www.naag.org/wp-content/uploads/2020/09/2019-01-MSA-and-Exhibits-Final.pdf [https://perma.cc/9Z38-DHSH]; *see also* WHO: Framework Convention on Tobacco Control art. 5.3, May 21, 2003, 2302 U.N.T.S. 166 ("In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry . . . .").

[305] *See, e.g.*, CONN. GEN. STAT. § 21a-421j(8) (2025). For state marijuana laws that prohibit advertising to minors, see, for example, CAL. BUS. & PROF. CODE § 26151(c) (West 2024); MONT. ADMIN. R. 42.39.123(11) (2024); N.Y. COMP. CODES R. & REGS. tit. 9, § 129.2(b) (2024); WASH. REV. CODE § 69.50.369(1) (2024).

[306] *See, e.g.*, Thomas Rotering & Dorie E. Apollonio, *Cannabis Industry Lobbying in the Colorado State Legislature in Fiscal Years 2010–2021*, INT'L J. DRUG POL'Y, Apr. 2022, art. 103585, at 6 ("In light of the sophisticated and well-financed influence campaign conducted by the cannabis industry, policymakers should push for stricter separation between the industry and the policymaking process.").

between state and federal laws but also to "federal policies [that] have complicated" — rather than catalyzed or reinforced — "the efforts of state governments to develop cannabis policies that protect public health."[307] Invoking a version of the pharma problem, proponents of keeping marijuana in Schedule I contend that it is better to stick with a dysfunctional status quo than to unleash the next Big Tobacco.[308] A new CSA schedule, which we will call Schedule B, would make it clear that this is a false dichotomy.[309]

Drugs in Schedule B would be legalized at the federal level, but subject to regulatory controls comparable to those already in place for alcohol and tobacco. As with Schedule A, imposing these controls on Schedule B dispensers through the CSA's registration process would be logistically straightforward. Limitations on advertising (such as bans on targeting minors), marketing (such as bans on free samples and loyalty programs), product design (such as potency thresholds), and lobbying (such as disclosure requirements to prevent astroturfing or restraints on coordinated industry efforts to influence state legislation) would be made conditions of registration under Schedule B.[310] Because the pharma problem applies to all types of access, we recommend that these limitations, or variants thereof, be extended to the CSA's medical schedules as well.[311] The details of Schedule B's regulatory controls are debatable, and well beyond the scope of this conceptual discussion, but we note that federal policymakers have at least two important precedents on which to draw: state marijuana legalization regimes and the 1998 tobacco Master Settlement Agreement. Research on the former has found that the most effective mechanisms for reducing excessive use and underage use are "business-oriented policies, defined as policies in which businesses would suffer penalties for failure to comply . . . with product design restrictions, advertising restrictions," retail availability

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[307] NAT'L ACADS. SCIS., ENG'G & MED., CANNABIS POLICY IMPACTS PUBLIC HEALTH AND HEALTH EQUITY 1 (Steven M. Teutsch, Yasmin L. Hurd & Elizabeth Barksdale Boyle eds., 2024).

[308] *See supra* notes 185–88 and accompanying text.

[309] Taken together, Schedules A and B would displace almost all of the current Schedule I. The only substances still eligible for Schedule I would be those that are exceedingly dangerous and yet also especially unsusceptible to the Iron Law of Prohibition. *See supra* notes 98–99 and accompanying text (discussing limits to this "law" and offering methaqualone as an example of a drug successfully controlled through prohibition).

[310] These limitations could be extended to Schedule A registrants as well, although the uniquely onerous controls imposed by that schedule may make such an extension unnecessary. We discuss possible constitutional problems with advertising and lobbying restrictions in the next Part.

[311] As with Schedule A, a substance's inclusion in Schedule B would not preclude its inclusion in a medical use schedule, too. An entity that wished to dispense the substance in both medical and nonmedical settings could register under Schedule II, III, IV, or V in addition to Schedule B. *See supra* notes 291–92 and accompanying text. This is consistent with the approach taken in states that require separate licenses to sell medical and recreational marijuana. *See* Berg et al., *supra* note 302, at 27 (discussing such regimes).

restrictions, and the like.[312] Research on the tobacco Master Settlement Agreement has similarly found that its controls on cigarette manufacturers contributed to a significant decrease in smoking.[313]

The one major category of controls that could not readily be imposed through a CSA schedule is pricing policies such as taxes. The CSA is a regulatory statute, not a fiscal one.[314] That said, there are good reasons to avoid mandating any particular excise tax structure for psychoactive substances, given the conflict of interest that may arise from a government's trying to constrain consumption of a substance while simultaneously earning revenue from its purchase.[315]

Schedule B would not end the decades-long fight over how to regulate a drug like marijuana, but it would create new possibilities for political compromise and legal coherence. States that wish to retain their bans on marijuana would be free to do so; as with Schedule A, Schedule B would not preempt more stringent state regulation.[316] In the near term, entities that already have a license to dispense marijuana under state law would be the most likely to register under Schedule B. Although these entities would not need Schedule B to continue operating in their states, we expect that most of them would register in order to unlock the benefits of federal legal status — from safeguarding the enterprise and its employees from the possibility of criminal enforcement to accessing the tax deductions, banking services, trademark protections, and other corporate law privileges that are currently denied to marijuana firms under federal prohibition.[317] Registrants in states that have legalized marijuana subject to controls that match or exceed those in Schedule B could proceed as they do today. Registrants in states with weaker controls would presumptively need to abide by the tougher requirements of Schedule B, unless Congress chose to waive these requirements for registrants already licensed in states that meet certain criteria

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312 Jason G. Blanchette et al., *Rating the Comparative Efficacy of State-Level Cannabis Policies on Recreational Cannabis Markets in the United States*, INT'L J. DRUG POL'Y, Aug. 2022, art. 103744, at 3. Retail availability restrictions include, for example, requirements that substances be sold in standalone facilities, rather than convenience stores or supermarkets.

313 *See, e.g.*, John P. Pierce et al., *Declines in Cigarette Smoking Among US Adolescents and Young Adults: Indications of Independence from E-Cigarette Vaping Surge*, 34 TOBACCO CONTROL 286, 286 (2025); Frank A. Sloan & Justin G. Trogdon, *The Impact of the Master Settlement Agreement on Cigarette Consumption*, 23 J. POL'Y ANALYSIS & MGMT. 843, 852–54 (2004).

314 *See supra* Part I, pp. 856–63.

315 *See, e.g.*, Andrew J. Haile, *Sin Taxes: When the State Becomes the Sinner*, 82 TEMP. L. REV. 1041, 1053 (2009) ("[T]he states have become dependent on continued tobacco revenues and therefore susceptible to a conflict of interest between protecting a necessary revenue source and protecting their citizens' health.").

316 *See supra* notes 298–98 and accompanying text.

317 *See* Mikos, *supra* note 24, at 19 (describing negative effects of Schedule I status on state-licensed marijuana suppliers); *id.* at 20–23 (describing negative effects that would persist if marijuana were moved to Schedule III); *see also* Andrew K. Jennings & Kimberly D. Krawiec, *Vice Capital*, 15 U.C. IRVINE L. REV. 427, 440–59 (2025) (describing special challenges that gray-market firms, including state-licensed marijuana firms, may face in raising capital).

or authorized an executive branch agency to grant waivers on a state-by-state or registrant-by-registrant basis.[318]

With or without such waivers, Schedule B would complement Schedule A in facilitating pragmatic policy progress. Under the decisionmaking framework described above,[319] the choice to place or retain a given substance in A or B would turn, in part, on the relative costs and benefits of each schedule. Advocates hoping to move a substance from Schedule A to the more liberal Schedule B would have an incentive to highlight any negative social consequences of the former's access restrictions. At the same time, drug companies hoping to keep a substance in Schedule B would have an incentive to avoid driving consumption to the point of producing public health harms that might trigger a shift to Schedule A. Companies hoping to utilize Schedule B would also have an incentive to develop less harmful formulations of drugs in more restrictive schedules, thereby steering individuals dependent on those drugs toward safer substitutes and creating something of a "reverse Iron Law of Prohibition" effect.[320] The interaction of the two new schedules could, in this way, help to support ongoing policy learning and product innovation while serving as a further check on the pharma problem.

IV. POTENTIAL OBJECTIONS

The prescriptions offered in the last Part tackle some of the most important institutional design choices raised by the regulation of psychoactive drugs at the national level. While we have tried to provide both a general framework and a set of proposals that interact synergistically but would add value even if adopted in isolation, our analysis is necessarily preliminary and incomplete. There are endless lower-level design choices on which we take no position. And we leave to another day or to other scholars, for example, implications of our pragmatic approach for addressing the relationship between federal and state drug law outside of Schedules A and B;[321] the relationship between domestic

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[318] *See generally* Barron & Rakoff, *supra* note 25, at 276–91 (discussing the inclusion of state-specific waiver flexibilities in federal regulatory regimes); Jonathan Remy Nash & Richard L. Revesz, *Grandfathering and Environmental Regulation: The Law and Economics of New Source Review*, 101 NW. U. L. REV. 1677, 1724–32 (2007) (discussing "grandfathering" as an institutional design strategy to minimize disruption from transition to a new regime).

[319] *See supra* section III.B.3, pp. 890–94.

[320] *See supra* section II.A, pp. 864–69 (describing the Iron Law of Prohibition).

[321] For a thorough analysis of this relationship and a call for greater local political control, see generally Michael M. O'Hear, *Federalism and Drug Control*, 57 VAND. L. REV. 783 (2004). For an argument that marijuana reform should be pursued through statutorily authorized state-by-state opt-outs, see Erwin Chemerinsky, Jolene Forman, Allen Hopper & Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. REV. 74, 115–16 (2015).

and international drug law;[322] claims of religious liberty or other constitutional rights relating to drugs;[323] the provision of addiction treatment, mental health treatment, educational messaging, and other social services and supports for individuals struggling with or susceptible to substance use disorders;[324] and the question whether the participation-forcing procedures we suggest should be paired with a relaxation of the CSA's formal rulemaking requirements.[325]

However illuminating it might prove to assess drug policy through the lens of institutional design, no approach can claim to be pragmatic (in either the philosophical or ordinary-language sense of that term) if the prescriptions it yields have no hope of implementation in the real world. This Part therefore addresses the feasibility as well as the legality of the reforms outlined in Part III. Section A considers potential objections involving political constraints. Section B considers potential objections involving constitutional constraints. On both fronts, we suggest that our proposed reforms not only receive passing grades but also come with significant advantages over competitors.

A. Political

It is easy to be skeptical about the prospects for significant federal drug law reform. Efforts to deschedule, reschedule, or otherwise reconfigure federal marijuana law have gone nowhere to date, despite years of popular support and an increasingly incoherent "half-in, half-out regime" on account of state legalizations.[326] Efforts to expand access to other controlled substances, such as MDMA, have thus far met

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[322] *But cf. infra* note 376 (discussing one potential benefit, under the United Nations drug conventions, of expanding access through scheduling reform). For a range of perspectives on the international law issues raised by domestic drug liberalization, see generally Symposium, *Drug Decriminalization, Legalization, and International Law*, 114 AM. J. INT'L L. UNBOUND 275 (2020).

[323] *See generally* POZEN, *supra* note 4 (exploring the history of constitutional challenges to drug prohibitions).

[324] For an overview of strategies to reduce dangerous drug behaviors and provide health and social services to people who use drugs, see BABOR ET AL., *supra* note 146, at 113–60.

[325] For a broad discussion of the costs and benefits of formal rulemaking, as well as a qualified defense, see generally Aaron L. Nielson, *In Defense of Formal Rulemaking*, 75 OHIO ST. L.J. 237 (2014).

[326] Standing Akimbo, LLC v. United States, 141 S. Ct. 2236, 2236–37 (2021) (statement of Thomas, J., respecting the denial of certiorari); *see also, e.g.*, Lydia Saad, *Grassroots Support for Legalizing Marijuana Hits Record 70%*, GALLUP (Nov. 8, 2023), https://news.gallup.com/poll/514007/grassroots-support-legalizing-marijuana-hits-record.aspx [https://perma.cc/T69N-KAS9] (charting public polling results on marijuana legalization since 1969); Kyle Jaeger, *These Were the Biggest Federal and Congressional Marijuana Policy Developments of 2024*, MARIJUANA MOMENT (Dec. 26, 2024), https://www.marijuanamoment.net/these-were-the-biggest-federal-and-congressional-marijuana-policy-developments-of-2024 [https://perma.cc/TR4R-F94T] ("Bipartisan cannabis banking legislation stalled out once again . . . .").

disappointment as well.[327] And if committed drug warriors on the political right are apt to see any form of liberalization as a threat to social and moral order, committed libertarians as well as abolitionists on the political left may see anything less than full legalization as inadequate. What chance is there, then, for a legislative overhaul of the CSA?

As a preliminary matter, we note that several of the interventions we have proposed could be implemented without Congress. The Attorney General, for example, could reclaim scheduling authority from the DEA Administrator at any point[328] — as appears to have happened in 2024 with regard to marijuana.[329] In addition, the Attorney General could take numerous steps to make rulemaking under the CSA more representative,[330] and she could use her existing waiver and research-authorization powers under the statute to pilot limited versions of Schedule A or substance-specific experiments in particular jurisdictions.[331] States might also implement many of the reforms suggested in Part III as part of their own regulatory frameworks, even assuming no modifications at the federal level.[332]

That said, the most fundamental changes to the design of drug policymaking that we have discussed, including the creation of new schedules and new criteria for assigning drugs to schedules, would indeed require legislative revision of the CSA.[333] Without denying the difficulty of spurring Congress to act in this area (or any other area), there are several reasons to believe that scheduling reform may be politically viable. First, there is something in it for almost everyone. For those who seek to minimize nonmedical drug use and express moral disapproval,[334] building new constraints on advertising, lobbying, and profiteering into the scheduling system ought to hold appeal. For those who seek to minimize drug arrests and incarcerations and to legalize widely used

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[327] *See* Oshan Jarow, *MDMA Therapy Didn't Get FDA Approval. Now What?*, VOX (Aug. 13, 2024, at 11:36 ET), https://www.vox.com/future-perfect/365820/mdma-therapy-lykos-therapeutics-maps-psychedelics-ecstasy [https://perma.cc/7VQH-BJ4E] (describing reformers' failed attempt to obtain FDA approval for use of MDMA in treating post-traumatic stress disorder).

[328] *See* 21 U.S.C. § 811(a).

[329] *See supra* notes 228–38 and accompanying text.

[330] *See* Rossi & Stack, *supra* note 258, at 33–42 (summarizing tools through which agencies have sought to "enhance representation in rulemaking," *id.* at 37).

[331] *See, e.g.*, 21 U.S.C. § 822(d) ("The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety."); *id.* § 872(e) ("The Attorney General . . . may authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research.").

[332] *See* Marks, *supra* note 196, *passim* (surveying state drug laws that "diverge from federal drug legislation," *id.* at 471). *See generally* Hannah J. Wiseman & Dave Owen, *Federal Laboratories of Democracy*, 52 U.C. DAVIS L. REV. 1119, 1146–82 (2018) (reviewing models of subfederal policy experimentation).

[333] *See* 21 U.S.C. § 812(a) ("There are established five schedules of controlled substances . . . .").

[334] Although irrelevant from a pragmatic perspective, moral disapproval of certain forms of drug use has long played a role in U.S. drug policy. For a detailed history, see generally GEORGE FISHER, BEWARE EUPHORIA: THE MORAL ROOTS AND RACIAL MYTHS OF AMERICA'S WAR ON DRUGS (2024).

substances such as marijuana or psilocybin,[335] scheduling reform provides a clear path toward those ends even if it does not guarantee them.[336] Fundamentalists on both sides of the drug debate, who demand nothing less than widespread prohibition or abolition, will be disappointed. Yet, at this juncture, few elected officials or advocacy groups support either a "war on drugs" or any sort of "legalize it all" response,[337] and the opioid crisis has created a bipartisan opening for pragmatic experimentation in between those poles.[338]

Second, our proposal retains the CSA's preemption framework, which leaves states free to impose stricter drug controls within their borders. There are real costs to this approach — most obviously, that it allows states to maintain counterproductive criminal bans.[339] Yet, while a public health case could be made for expanding federal preemption under a revised CSA, we see little prospect for any such move in the foreseeable future.[340] Federal preemption of state criminal law is exceedingly rare.[341] And it is not clear, as a constitutional matter, how Congress could stamp out more restrictive state drug laws except through extreme measures, such as threatening to withhold drug-related funds from noncompliant jurisdictions or occupying the entire field of

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[335] *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2024 NATIONAL SURVEY ON DRUG USE AND HEALTH 8 (2025) (estimating that, in 2024, over 64 million Americans had used marijuana and over 10 million Americans had used hallucinogens within the past twelve months).

[336] *Cf.* Lindsay F. Wiley, Elizabeth Y. McCuskey, Matthew B. Lawrence & Erin C. Fuse Brown, *Health Reform Reconstruction*, 55 U.C. DAVIS L. REV. 657, 733 (2021) (urging health law reformers to pursue "*confrontational incrementalism*" through measures that represent modest steps forward but disrupt the status quo and "plant the seeds for future transformation").

[337] *See, e.g.*, Christopher Lewis & Adaner Usmani, *Abolition of What?*, 114 J. CRIM. L. & CRIMINOLOGY 525, 564 (2024) (arguing that "in the absence of social democracy, . . . prison and police abolition will remain politically infeasible"); Brian Mann, *After 50 Years of the War on Drugs, "What Good Is It Doing for Us?"*, NPR (June 17, 2021, at 05:00 ET), https://www.npr.org/2021/06/17/1006495476/after-50-years-of-the-war-on-drugs-what-good-is-it-doing-for-us [https://perma.cc/7N5P-L34F] (describing "a growing consensus across the political spectrum — including among some in law enforcement — that the drug war simply didn't work").

[338] *See* Rebecca A. Delfino, *A New Prescription for the Opioid Epidemic: 360-Degree Accountability for Pharmaceutical Companies and Their Executives*, 73 HASTINGS L.J. 301, 361 (2022) (detailing "bipartisan support" in Congress for efforts "to find solutions to combat the opioid epidemic"). *See generally* Taleed El-Sabawi, *What Motivates Legislators to Act: Problem Definition & the Opioid Epidemic, A Case Study*, 15 IND. HEALTH L. REV. 189 (2018) (exploring "why legislators [have] approached problem drug use as a health problem as opposed to a criminal justice problem when deciding how to address the nation's opioid epidemic," *id.* at 193).

[339] *See supra* section III.C.1, pp. 895–99.

[340] We likewise see no realistic prospect of repealing the CSA altogether and returning drug regulation to the states, which would raise difficult questions of administrative capacity, international law compliance, and interjurisdictional coordination, among other issues.

[341] *See* Erin C. Blondel, *The Structure of Criminal Federalism*, 98 NOTRE DAME L. REV. 1037, 1061 (2023) ("Criminal preemption . . . is a story of remarkable federal restraint. Congress basically does not do it.").

controlled substances regulation.[342] Although it prevents a full solution to the prohibition problem, the federalism-friendly structure of the CSA makes scheduling reform more palatable to skeptical states and their representatives.

Third, scheduling reform allows members of Congress to take credit for policy change when legislation is enacted and to avoid blame for policy change (or its absence) when the executive branch implements the law. "A standard explanation for why Congress so often chooses to delegate broad policymaking discretion," as Professor Daryl Levinson relates, "is that members of Congress can claim credit for addressing critical policy problems . . . without actually making the difficult, controversial, and possibly unsuccessful policy choices that threaten to antagonize some set of voters and interest groups."[343] Critics of the administrative state have long assailed this tendency,[344] just as critics of the CSA have long assailed political candidates' "hollow promises" of drug liberalization followed by inertia once in office.[345] Our pragmatic approach pits the first dynamic against the second. It allows politicians to vote for "common sense" improvements in the nation's drug scheduling framework but then distance themselves from the ultimate decisions that might, for example, legalize marijuana, authorize safe injection sites, or take any other potentially controversial steps on particular substances. Although politics are difficult to predict, we note that a number of recent federal drug policy enactments have likewise taken the form of drug-agnostic amendments to the CSA.[346]

Finally, pursuing change at the level of the CSA's design, rather than at the level of specific drugs, would expand the reform coalition. Drug-specific legislative proposals tend to pit a small set of constituencies against one another, in what may be perceived as a zero-sum game.

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[342] *See, e.g.*, Chemerinsky et al., *supra* note 321, at 102–04 (explaining that while "Congress had the authority to occupy the field of controlled substances regulation when it enacted the CSA," *id.* at 104, the Supreme Court's anticommandeering doctrine prevents Congress from forcing states to criminalize any given type of drug conduct).

[343] Daryl J. Levinson, *The Supreme Court, 2015 Term — Foreword: Looking for Power in Public Law*, 130 HARV. L. REV. 31, 71–72 (2016). For foundational work on this dynamic, see Peter H. Aranson, Ernest Gellhorn & Glen O. Robinson, *A Theory of Legislative Delegation*, 68 CORN. L. REV. 1, 56–62 (1982) (discussing "responsibility-shifting" theories of delegation, *id.* at 59), and Morris P. Fiorina, *Legislative Choice of Regulatory Forms: Legal Process or Administrative Process?*, 39 PUB. CHOICE 33, 46–52 (1982) (same).

[344] *See, e.g.*, DAVID SCHOENBROD, POWER WITHOUT RESPONSIBILITY: HOW CONGRESS ABUSES THE PEOPLE THROUGH DELEGATION 84–94 (1993).

[345] *See* Dean Seal, *The Rare Bipartisan Issue in This Year's Election: Recreational Weed*, WALL ST. J. (Oct. 21, 2024, at 10:00 ET), https://www.wsj.com/politics/policy/the-rare-bipartisan-issue-in-this-years-election-recreational-weed-b4950c84 [https://perma.cc/Q3FV-TBV5].

[346] *See, e.g.*, Protecting Patient Access to Emergency Medications Act of 2017, Pub. L. No. 115-83, 131 Stat. 1267 (amending the CSA to allow emergency medical services to administer controlled substances under certain conditions); Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (amending the CSA to limit online distribution of prescription drugs).

Consider the way in which state marijuana legalization and federal hemp legalization have created competing commercial interests, leading marijuana businesses to endorse a return to hemp prohibition and hemp businesses to resist recreational marijuana.[347] Industry players routinely advocate policies that would expand or preserve their markets. The market implications of changes to the CSA's scheduling regime, however, are ambiguous ex ante. By increasing the variety of available schedules and regulatory tools under each schedule, our proposal would dilute vested interests' incentives to fight for the status quo while opening the door to those seeking myriad alternatives, from expanded access to certain drugs to stricter regulation of pharmaceutical marketing to increased investment in harm reduction strategies.

B. Constitutional

Most of the reforms described in Part III raise no constitutional concerns. Congress's authority to regulate the production, distribution, and consumption of psychoactive drugs has been settled for decades.[348] And while state and federal courts have only rarely recognized individual rights to take or make drugs since the 1970s, reducing drug law's reliance on punitive prohibitions could advance a range of constitutional values.[349] Any new advertising or lobbying restrictions on drug companies, however, would limit those companies' expressive activity and therefore invite First Amendment challenge.

The leading cases are *Central Hudson Gas & Electric Corp. v. Public Service Commission*[350] and *44 Liquormart, Inc. v. Rhode Island*.[351] *Central Hudson* established a four-part test for evaluating regulations of commercial speech. Under this test, if (1) the commercial speech "is neither misleading nor related to unlawful activity," government restrictions on it must (2) be supported by "a substantial interest," (3) "directly advance" that interest, and (4) not be "more extensive than is

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[347] *See* Natalie Fertig, *Hemp and Marijuana Go to War*, POLITICO (May 21, 2024, at 14:01 ET), https://www.politico.com/news/2024/05/21/hemp-marijuana-farm-bill-00159040 [https://perma.cc/DNJ4-KLQ9]; Lori Rozsa & David Ovalle, *DeSantis in Middle of Florida Feud Pitting Marijuana Against Hemp*, WASH. POST (Aug. 25, 2024), https://www.washingtonpost.com/nation/2024/08/25/desantis-hemp-marijuana-amendment-florida [https://perma.cc/2ARR-HYD3].

[348] In the Supreme Court's most significant constitutional ruling on the CSA, *Gonzales v. Raich*, 545 U.S. 1 (2005), not even the challengers "dispute[d] that passage of the CSA . . . was well within Congress' commerce power." *Id.* at 15; *see also* Canna Provisions, Inc. v. Garland, 738 F. Supp. 3d 111, 115, 123 (D. Mass. 2024) (granting the government's motion to dismiss in the most recent constitutional challenge to the CSA).

[349] *See* POZEN, *supra* note 4, at 19–42 (explaining that the idea of rights-based constraints on drug prohibition "was commonplace in the late 1800s and early 1900s, routed in the 1910s to accommodate alcohol prohibition, revived in the 1960s . . . , and then largely routed again in the 1970s," *id.* at 41); *id.* at 146 (reviewing longstanding constitutional critiques of punitive "drug laws on grounds of liberty, privacy, equality, federalism, government rationality, proportionate punishment, free speech, and more").

[350] 447 U.S. 557 (1980).

[351] 517 U.S. 484 (1996).

necessary."[352] *44 Liquormart* struck down a Rhode Island law prohibiting the advertising of retail liquor prices except at the place of sale.[353] Even though states may ban alcohol sales altogether, Justice Stevens's plurality opinion held that this law failed the third and fourth prongs of *Central Hudson* because Rhode Island was unable to show that an advertising ban would materially advance its interest in "promoting temperance" or that alternative forms of regulation would not be as effective.[354] Courts have applied these precedents in reviewing challenges to advertising and marketing restrictions on tobacco, gambling, and other "vice" industries.[355]

Such restrictions "almost always" satisfy *Central Hudson*'s second prong,[356] given the government's interests in protecting minors, ensuring public safety, and otherwise promoting public health.[357] As in *44 Liquormart*, the free speech fights typically focus on *Central Hudson*'s third and fourth prongs or their state constitutional equivalents and, consequently, are highly fact intensive.[358] New York's marketing restrictions on marijuana dispensaries, for example, were recently struck down for lack of "evidentiary support in the administrative record,"[359] whereas Washington's location-based restrictions on marijuana advertising were upheld.[360] The FDA's attempt to mandate graphic warning labels on cigarette packages and advertisements was initially invalidated under *Central Hudson*'s fourth prong,[361] and survived constitutional challenge only after a decade of refinement by the agency.[362] There is a dearth of case law on restrictions aimed at the pharma

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[352] *Cent. Hudson*, 447 U.S. at 564–66.

[353] *44 Liquormart*, 517 U.S. at 489.

[354] *Id.* at 505–08 (opinion of Stevens, J.); *see also id.* at 529–31 (O'Connor, J., concurring in the judgment) (finding that the Rhode Island law failed *Central Hudson*'s fourth prong, without addressing the third prong).

[355] *See generally* Lawrence O. Gostin & Gail H. Javitt, *Health Promotion and the First Amendment: Government Control of the Informational Environment*, 79 MILBANK Q. 547, 552–61 (2001) (surveying case law as of 2001); Leslie Gielow Jacobs, *Regulating Marijuana Advertising and Marketing to Promote Public Health: Navigating the Constitutional Minefield*, 21 LEWIS & CLARK L. REV. 1081, 1101–31 (2017) (surveying case law as of 2017).

[356] Gostin & Javitt, *supra* note 355, at 556.

[357] *See, e.g.*, Seattle Events v. State, 512 P.3d 926, 935 (Wash. Ct. App. 2022) ("Like the State's interest in preventing underage tobacco and alcohol use, the State has a substantial interest in preventing underage marijuana use . . . ."); Jacobs, *supra* note 355, at 1115; *see also* NETWORK FOR PUB. HEALTH L., CANNABIS ADVERTISING AND THE FIRST AMENDMENT 2 (2024), https://www.networkforphl.org/wp-content/uploads/2024/09/Cannabis-Advertising-and-the-First-Amendment.pdf [https://perma.cc/7BQU-J5FE] (noting that the substantial-interest prong "is rarely disputed in *Central Hudson* cases").

[358] *See* Jacobs, *supra* note 355, at 1111.

[359] Leafly Holdings, Inc. v. N.Y. State Off. of Cannabis Mgmt., No. 908706-23, slip op. at 2, 12 (N.Y. Sup. Ct. Apr. 4, 2024).

[360] *Seattle Events*, 512 P.3d at 938. Washington's prohibition on medical marijuana advertising, by contrast, was invalidated as more restrictive than necessary. Havsy v. Dep't of Health, No. 14-2-08934-7, slip op. at 2, 4 (Wash. Sup. Ct. Jan. 8, 2015).

[361] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1236 (D.C. Cir. 2012).

[362] R.J. Reynolds Tobacco Co. v. FDA, 96 F.4th 863, 868, 888 (5th Cir. 2024).

problem specifically — the tobacco Master Settlement Agreement is the best example of a regulatory regime with limits on drug company lobbying, and it was not challenged on First Amendment grounds[363] — although courts have "held that government-compelled disclosure of lobbying information is generally constitutional."[364] And while some maintain that lobbying is protected under the Petition Clause as well as the Free Speech Clause, the Supreme Court has not yet squarely resolved whether professional lobbying is protected by the First Amendment at all.[365]

The First Amendment case law on these issues is too complex, and this Article's commercial-speech-related proposals are too preliminary, for us to offer any confident predictions about how they would fare in court. Yet here again, attending to institutional design offers fresh hope. Developing regulations on drug company advertising and lobbying through the CSA's rulemaking process, rather than through separate legislation, holds a number of constitutional advantages.

To start, this approach facilitates — indeed requires — the creation of an evidentiary record, with regard to both the dangers posed by a given substance and the potential benefits of a given regulation. The courts have not made entirely clear what is necessary to satisfy prong three of *Central Hudson*,[366] but the government must at least "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree."[367] One of the most common ways of satisfying this requirement is to "rely on past evidence and parallels with similar products."[368] By incorporating a suite of more and less stringent options for regulating drug companies' commercial speech into the CSA's scheduling framework, and by directing periodic review of these regulations' effects on variables such as rates of addiction and underage use, Congress could go a long way toward developing this evidence base.

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[363] *Cf.* Rahul Rajkumar, Cary P. Gross & Howard P. Forman, *Is the Tobacco Settlement Constitutional?*, 34 J.L. MED. & ETHICS 748, 748 (2006) (describing the main constitutional challenge to the agreement, which alleged that it violates the Compact Clause).

[364] Richard L. Hasen, *Lobbying, Rent-Seeking, and the Constitution*, 64 STAN. L. REV. 191, 209 (2012) (emphasis omitted); *see also* Jonathan C. Zellner, Note, *Artificial Grassroots Advocacy and the Constitutionality of Legislative Identification and Control Measures*, 43 CONN. L. REV. 357, 400 (2010) (arguing that "case law on state-level efforts to address Astroturf lobbying" demonstrates that fears of First Amendment barriers to such efforts "are inflated or unfounded").

[365] *See* Maggie McKinley, *Lobbying and the Petition Clause*, 68 STAN. L. REV. 1131, 1134–39 (2016).

[366] *See, e.g.*, Greater New Orleans Broad. Ass'n v. United States, 527 U.S. 173, 190 (1999) (declining to resolve this question); Gostin & Javitt, *supra* note 355, at 558 n.37 ("After *44 Liquormart*, the level of proof required to demonstrate that a commercial speech regulation directly advances the state's interest has been unclear.").

[367] Edenfield v. Fane, 507 U.S. 761, 770–71 (1993); *see also* Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995) (stating that the government's burden under prong three is "not satisfied by mere speculation or conjecture" (quoting *Edenfield*, 507 U.S. at 770)).

[368] NETWORK FOR PUB. HEALTH L., *supra* note 357, at 2.

Scheduling reform would also bring advantages at step four of *Central Hudson*, which looks to the degree of fit between a commercial speech regulation and the interests it is meant to serve. Legislative enactments can fail this step because of exceptions or loopholes for particular groups or interests.[369] For the same reason that an administrative scheduling framework reduces the risk of industry capture — categories are constructed in advance in a drug-agnostic manner — regulatory controls that are made part of such a framework would be insulated against attack on this ground.

Explicit acknowledgment of the prohibition problem could help further. In Part VI of the plurality opinion in *44 Liquormart*, Justice Stevens advised that the government may not impose "regulations on truthful, nonmisleading advertising when non-speech-related alternatives [a]re available"[370] — and identified "prohibition" as such an alternative.[371] Later courts have invoked this logic in striking down restrictions on alcohol advertising that were adopted in lieu of "banning alcohol consumption."[372] Because there is no First Amendment protection for advertisement of illegal products,[373] this line of doctrine creates perverse incentives to maintain ineffectual prohibitions and to combine de jure criminalization with de facto legalization for substances like marijuana. For if the federal government were to legalize marijuana, commentators warn, the drug's "promotion could not be controlled."[374]

But this need not follow. Putting before a court an administrative judgment that inelasticity of demand makes prohibition an ineffective option for discouraging use would provide a basis for distinguishing *44 Liquormart*. The Ninth Circuit endorsed an analogous argument in upholding Nevada's choice to regulate rather than ban prostitution.[375] Whenever a drug winds up in Schedule A or B, courts will know that prohibition has been determined, through a carefully constructed evidence-

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369 *See, e.g.*, *Greater New Orleans Broad. Ass'n*, 527 U.S. at 189 ("[A]ny measure of the effectiveness of the Government's attempt to minimize the social costs of gambling cannot ignore Congress' simultaneous encouragement of tribal casino gambling . . . ."); *Rubin*, 514 U.S. at 488 (striking down a provision of the Federal Alcohol Administration Act banning the display of alcohol content on beer labels in part because "it allows the exact opposite in the case of wines and spirits").

370 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 509–10 (1996) (opinion of Stevens, J.).

371 *See, e.g.*, *id.* at 514 ("[A] 'vice' label that is unaccompanied by a corresponding prohibition against the commercial behavior at issue fails to provide a principled justification for the regulation of commercial speech about that activity.").

372 Crazy Ely W. Vill., LLC v. City of Las Vegas, 618 F. App'x 904, 907 (9th Cir. 2015).

373 This proposition is reflected in prong one of the *Central Hudson* test.

374 ROBERT J. MACCOUN & PETER REUTER, DRUG WAR HERESIES: LEARNING FROM OTHER VICES, TIMES, AND PLACES 11 (2001).

375 *See* Coyote Publ'g, Inc. v. Miller, 598 F.3d 592, 606 (9th Cir. 2010) ("The state's dual approach does not make its asserted interest in limiting commodification of sex any less substantial than in the states that ban commercial sex transactions entirely.").

based process, to be an *inadequate* alternative for protecting public health.[376]

None of these arguments is a silver bullet, of course, but each gives plausible grounds to defend the constitutionality of restrictions on the speech of drug manufacturers and sellers — grounds that either would not exist or would be substantially weaker if the restrictions were imposed outside the CSA's scheduling system. Importantly, advertising and lobbying controls under the CSA could also be made modular, with a fallback option to safeguard the overall regulatory structure in the event of judicial invalidation of controls on commercial speech. For instance, Schedule B could require separate registration by for-profit and nonprofit entities; and then a severability clause could provide that in the event of judicial invalidation of restrictions on advertising or lobbying, the entire for-profit registration option would be eliminated, resulting in a schedule in which only nonprofit entities could manufacture and sell.[377] Such a fallback option would ensure that legalization does not amount to deregulation. It might also have the collateral benefit of discouraging constitutional challenges to advertising and lobbying restrictions by for-profit firms who fear that, should the challenges succeed, they would be triggering their own removal from the marketplace.

CONCLUSION

This Article has argued that an institutional design perspective can shed light on drug policy's past disappointments, present dilemmas, and future possibilities. Looking backward, we show how the CSA's unintended consequences can be traced to the prohibition, pharma, and

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[376] For this reason, expanding access through Schedules A and B — rather than simply legalizing certain drugs outright — would also give the United States a stronger claim to compliance with existing international drug control treaties. Professors Antonia Eliason and Robert Howse, notably, have argued that under Article 38 of the Single Convention on Narcotic Drugs, states may permit otherwise prohibited nonmedical, nonscientific uses of controlled substances to the extent that they do so in the service of "prevention of abuse of drugs." *See* Antonia Eliason & Robert Howse, *A Higher Authority: Canada's Cannabis Legalization in the Context of International Law*, 40 MICH. J. INT'L L. 327, 339, 336–44 (2019) (quoting Single Convention on Narcotic Drugs art. 38(1), Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 204, *as amended by* Protocol Amending the Single Convention on Narcotic Drugs, Mar. 25, 1972, 26 U.S.T. 1439, 976 U.N.T.S. 3 (entered into force Aug. 8, 1975)). As discussed in Part III, Schedules A and B would be crafted specifically toward that end, both in their controls on advertising, lobbying, selling, and the like and in their recognition of the prohibition problem as rendering criminal bans a counterproductive means of prevention.

[377] Prohibitions against for-profit entities engaging in activities that are lawful or potentially lawful for nonprofits receive only rational basis review and are routinely upheld by courts. Recent examples include laws exempting nonprofit private clubs from bans on smoking in bars and restaurants, *see* Liebes v. Guilford Cnty. Dep't of Pub. Health, 724 S.E.2d 70, 73, 79 (N.C. Ct. App. 2011); City of Wausau v. Jusufi, 2009 WI App 17, ¶ 17, 315 Wis. 2d 780, 763 N.W.2d 201, a Washington law permitting gambling establishments run only by nonprofits, *see* Paradise, Inc. v. Pierce County, 102 P.3d 173, 183 (Wash. Ct. App. 2004), laws limiting control over the practice of medicine to nonprofit hospitals, *see, e.g.*, People v. Cole, 135 P.3d 669, 672, 686 (Cal. 2006), and even a Rhode Island law (to return to the home of *44 Liquormart*) prohibiting for-profit pet stores, *see* Perfect Puppy, Inc. v. City of East Providence, 98 F. Supp. 3d 408, 420 (D.R.I. 2015).

pluralism problems. Looking forward, we suggest that the best hope of alleviating these problems lies in a pragmatic regulatory approach that facilitates democratization without domination and legalization without laissez faire. More concretely, we sketch a reform agenda that retains the CSA's basic scheduling framework but removes the DEA's decisionmaking authority, broadens participation and evaluation, and creates new schedules for managed access along with new administrative controls. By shifting the focus from particular drugs to the processes and structures through which drug policy decisions are made, this approach has the potential to facilitate political compromise, quell constitutional anxieties, and rekindle a legalization movement that has stalled out.

When it comes to human choices, self-help experts advise, "[y]ou do not rise to the level of your goals. You fall to the level of your systems."[378] The same could be said of the nation's drug policy choices. Fifty years of lofty goals and moral panics have brought fifty years of failure. It is time to shift focus to drug regulatory systems.

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[378] JAMES CLEAR, ATOMIC HABITS: AN EASY & PROVEN WAY TO BUILD GOOD HABITS & BREAK BAD ONES 28 (2018).