NOTE

A SITE TO SAVE A LIFE: THE CASE FOR LOBBYING CONGRESS TO RESTRICT THE DEPARTMENT OF JUSTICE FROM TARGETING SUPERVISED DRUG CONSUMPTION SITES

Trevor Thompson†

INTRODUCTION

Guy Felicella was not exaggerating when he told me that he owes his life to staff members of a Canadian supervised drug consumption site.[1] Guy overdosed on heroin four times in one of these sites, and when a person overloads their body with a potent opioid such as heroin, the opioid can cause their respir-

† J.D., Cornell Law School, 2022; B.A. Columbia University, 2018. Thank you to the hardworking members of the Cornell Law Review for their terrific edits and suggestions. Special thanks to Professor Kristen Underhill for inspiring this Note and for providing essential feedback throughout the writing process. This Note is dedicated to all those who have lost loved ones to drugs and alcohol and to the harm reduction groups working tirelessly to soften the blow of America's drug crisis.

1 Email Interview with Guy Felicella, Harm Reduction Advocate (Apr. 5, 2022) [hereinafter Email Interview with Guy Felicella] (on file with author). This Note will primarily use the term supervised consumption site, but this term is interchangeable with safe injection site, safe injection facility, safe consumption site, and overdose prevention site. Each term describes facilities that allow people to consume drugs under professional supervision, and each has the same goal: preventing users of illicit drugs from overdosing and dying on the streets.

atory system to reduce breathing to a dangerously slow rate.[2] This slow and shallow breathing—known as opioid-induced respiratory depression—can be fatal without intervention.[3] Each time that Guy used heroin in a drug consumption site, staff members at the site closely observed him for signs of what is known as opioid-induced respiratory depression.[4] And each time that Guy did exhibit any of these signs, staff members gave him naloxone, a medicine that rapidly reverses an opioid overdose by blocking the opioid's effects, to stop the poison from shutting down his body's vital functions.[5] Guy is certain that without staff members supervising him, he would be dead.[6]

Guy estimates that he used heroin over 4,000 times at a supervised consumption site.[7] He told me that the staff members always treated him with kindness, and that he always felt safe using the facility.[8] Guy is now in recovery from opioid addiction.[9] He is happily married and has two children, and he devotes his life to lifting the stigma of harm reduction and drug addiction.[10] Guy has even given a Ted Talk on his experience to inspire other addicts who are struggling.[11] He is confident that none of what he enjoys today would be possible without access to a supervised consumption site.[12]

Supervised consumption sites are lawful in Canada.[13] Health Canada reviews applications for supervised consumption sites, and it grants the requisite medical exemptions to operate a site under section 56.1 of Canada's Controlled Drug

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2 *See What Happens to the Body During Opioid Overdose*, MINUTES MATTER, https://minutesmatter.upmc.com/what-happens-to-the-body-during-opioid-overdose/ [https://perma.cc/3GHY-DNA9] (last visited Apr. 24, 2023).

3 Email Interview with Guy Felicella, *supra* note 1; Iris Bachmutsky, Xin Paul Wei, Eszter Kish & Kevin Yackle, *Opioids Depress Breathing Through Two Small Brainstem Sites*, 9 ELIFE 1, 1 (2020).

4 Email Interview with Guy Felicella, *supra* note 1.

5 *Id.*

6 *Id.*

7 *Id.*

8 *Id.*

9 *Id.*

10 *Id.*

11 TEDx Talks, *I Died Six Times . . . Let's End the Stigma of Harm Reduction*, YOUTUBE (July 18, 2018), https://www.youtube.com/watch?v=5uQxbh5mSPs [https://perma.cc/BKD2-H7JG].

12 Email Interview with Guy Felicella, *supra* note 1.

13 *Apply to Run a Supervised Consumption Site: Overview*, GOV'T OF CAN., https://www.canada.ca/en/health-canada/services/substance-use/supervised-consumption-sites/apply.html [https://perma.cc/3HXC-VFTV] (last visited June 26, 2023).

and Substances Act.[14] As of January 2021, there are thirty-seven supervised consumption sites that hold valid exemptions under Canada's Controlled Drugs and Substances Act.[15]

No such exemption exists in the United States. Here, supervised consumption sites operate on tenuous legal ground. The Third Circuit, the only federal court of appeals to weigh in on the legality of supervised consumption sites, held that operating a supervised consumption site would violate the Controlled Substances Act.[16] But because the Supreme Court denied certiorari in the case, and because another court of appeals may arrive at a different interpretation of the statute that governs supervised consumption sites, the sites arguably remain legal in other parts of the nation.[17] As of March 2023, there are two sites operating in New York City's East Harlem and Washington Heights neighborhoods, and Rhode Island plans to open one before the end of the year.[18]

Under Attorney General Merrick Garland, the Department of Justice ("DOJ") will likely leave supervised consumption sites alone.[19] In a statement to the Associated Press, the DOJ said it is "evaluating supervised consumption sites, including discussions with state and local regulators about appropriate guardrails for such sites, as part of an overall approach to harm reduction and public safety."[20] But the DOJ is not legally bound by this general statement of policy.[21] At any time, the DOJ could issue a memorandum and instruct the U.S. Attorney for the Southern District of New York to prosecute those operating the sites in New York City.[22] Although unlikely

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14 *Id.*

15 *A Review of Structural, Process, and Outcome Measures for Supervised Consumption Services*, ONTARIO HIV TREATMENT NETWORK (Mar. 2021), https://www.ohtn.on.ca/rapid-response-a-review-of-structural-process-and-outcome-measures-for-supervised-consumption-services/ [https://perma.cc/4RWT-QMR6].

16 United States v. Safehouse (*Safehouse II*), 985 F.3d 225, 243 (3rd Cir. 2021), *cert. denied*, Safehouse v. U.S. Dep't of Just., 142 S. Ct 345 (2021).

17 *See Safehouse v. U.S. Dep't of Just.*, 142 S. Ct. 345 (denying certiorari).

18 Noah Weiland, *As Overdoses Soar, Rhode Island Embraces a Daring Addiction Strategy*, N.Y. TIMES (Oct. 12, 2022), https://www.nytimes.com/2022/10/12/us/politics/rhode-island-overdoses.html [https://perma.cc/K5EW-4LXU].

19 *See* Jennifer Peltz & Michael Balsamo, *Justice Dept. Signals it May Allow Safe Injection Sites*, AP NEWS (Feb. 8, 2022), https://apnews.com/article/business-health-new-york-c4e6d999583d7b7abce2189fba095011 [https://perma.cc/SY3F-FCGN].

20 *Id.*

21 JARED P. COLE & TODD GARVEY, CONG. RSCH. SERV., R44468, GENERAL POLICY STATEMENTS: LEGAL OVERVIEW 7 (2016).

22 When Jeff Sessions became Attorney General ("AG"), he issued a memorandum on federal marijuana enforcement policy that rescinded previous guidance

under Attorney General Garland, this sequence of events could very well unfold under subsequent administrations, such as a Republican administration.[23]

For the reasons above, those who operate supervised consumption sites should not rely on the prosecutorial discretion of the DOJ. Instead, they should lobby congressional representatives who support these sites to include in the federal appropriations bill a policy rider—a provision of a bill that "rides" on top of a high-stakes bill—that would restrict the DOJ from using its budget to prosecute those who operate the sites.

This Note will begin with an overview of fentanyl's role in exacerbating the opioid crisis that has now claimed over a million American lives.[24] It will then offer a partial explanation for why the crisis has gotten worse over the past few years: the Food and Drug Administration's ("FDA") refusal to initiate a prescription to over-the-counter ("OTC") switch of at least one naloxone product. In addition to demonstrating why the FDA's refusal to initiate an OTC switch has made the crisis worse, this Note will also explore how it highlights administrative law's failure to provide Americans with meaningful recourse for agency inaction. This Note will then argue that the FDA has the legal authority to unilaterally initiate a prescription-to-OTC switch for at least one naloxone product and that its delay in making this switch emphasizes the urgent need for widespread adoption of supervised consumption sites throughout the United States. Finally, it will explore what is likely the most promising avenue for shielding those who operate supervised consumption sites from federal criminal liability: the addition of a policy rider to an appropriations bill that restricts the DOJ from using its budget to prosecute them. It will explore the

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documents. In the memorandum, he directed all U.S. Attorneys to enforce the laws that Congress had enacted and to follow well-established principles when pursuing prosecutions related to marijuana activities. To substantially alter federal policy, all AG Sessions had to do was issue a memorandum directing the U.S. Attorneys he supervised to follow "well-established principles." *See, e.g.*, Press Release, U.S. Dep't of Just., Justice Department Issues Memo on Marijuana Enforcement (Jan. 4, 2018), https://www.justice.gov/opa/pr/justice-department-issues-memo-marijuana-enforcement [https://perma.cc/2FG3-P7EB].

23 *See, e.g.*, Jeremy Roebuck & Aubrey Whelan, *U.S. Attorney Sues to Stop Supervised Injection Sites in Philadelphia*, PHILA. INQUIRER (Feb. 6, 2019), https://www.inquirer.com/news/supervised-injection-sites-philadelphia-stop-safehouse-us-attorney-opioid-crisis-20190206.html [https://perma.cc/NDD7-ARRT].

24 Brian Mann, *More Than a Million Americans Have Died From Overdoses During the Opioid Epidemic*, NPR (Dec. 30, 2021), https://www.npr.org/2021/12/30/1069062738/more-than-a-million-americans-have-died-from-overdoses-during-the-opioid-epidemic [https://perma.cc/RX3M-A8SP].

obstacles harm reductionists may encounter if they pursue this avenue. However, it will ultimately argue that for those who devote their lives to giving drug users a second shot at life, it represents the most promising path to immunization from federal prosecution.

I
THE DRUG OVERDOSE CRISIS

In October 2017, President Trump took the dramatic step of directing Acting Health and Human Services Secretary Eric D. Hargan to formally designate the opioid crisis as a nationwide public health emergency.[25] The designation did not provide federal agencies with additional funds to deal with the crisis that had claimed more than 59,000 lives in 2016 but perhaps it did signal to opioid-ravaged communities throughout the nation that the government was prepared to act.[26] Sadly, Secretary Hargan's designation did not meaningfully reduce the damage done by the drug overdose crisis.[27] In fact, the crisis has only gotten worse since then. According to the Centers for Disease Control's ("CDC") provisional data, an estimated 107,622 people died of drug overdoses from December 2020 to December 2021.[28] Never before have so many Americans died of drug overdoses in a 12-month period of time.[29] Most alarmingly, even drug overdose deaths among teenagers have risen sharply over the last two years.[30]

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25 Press Release, U.S. Dep't of Health & Human Servs., HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis (Oct. 26, 2017), https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html [https://perma.cc/XQP9-QURU].

26 *Id.*

27 *See* Press Release, Nat'l Ctr. For Health Stat., Ctrs. for Disease Control & Prevention, U.S. Overdose Deaths in 2021 Increased Half as Much as in 2020 – But Are Still Up 15% (May 11, 2022), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm#:~:text=provisional%20data%20from%20CDC's%20National,93%2C655%20deaths%20estimated%20in%202020 [https://perma.cc/E9GF-6YXZ].

28 F.B. Ahmad, J.A. Cisewski, L.M. Rossen & P. Sutton, Nat'l Ctr. For Health Stat., *Provisional Drug Overdose Death Counts*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 15, 2023), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm [https://perma.cc/GD6C-77PE].

29 Deidre McPhillips, *In 2021, US Drug Overdose Deaths Hit Highest Level on Record, CDC Data Shows*, CNN HEALTH (May 11, 2022), https://www.cnn.com/2022/05/11/health/drug-overdose-deaths-record-high-2021/index.html [https://perma.cc/JUF2-2H45].

30 Aria Bendix, *Fentanyl Drives Spike in Teen Overdose Deaths, Even as Drug Use Falls to New Low*, NBC NEWS (Apr. 12, 2022), https://www.nbcnews.com/health/health-news/teen-overdose-deaths-spiked-low-drug-use-rcna23103 [https://perma.cc/7PY7-4NXL].

The biggest driver behind the rising number of drug overdose deaths—and especially behind the sharp uptick in opioid overdose deaths—is fentanyl.[31] Joel Bomgar, vice chairman of the Medicaid Committee in Mississippi House of Representatives, said that "for every life we save from a prescription overdose, . . . four more are dying from switching to heroin and fentanyl."[32] Pharmaceutical fentanyl is a synthetic opioid.[33] It is about 100 times more potent than morphine as an analgesic (pain reliever), so doctors typically prescribe it to patients for severe pain and especially for advanced cancer pain.[34] Patients most commonly consume fentanyl in the form of transdermal patches or transmucosal lozenges; these lozenges are typically referred to as the fentanyl "lollipops."[35] The drug can also be administered intravenously, intramuscularly, spinally, epidurally, or, in tablet form, orally.[36] And it is ripe for abuse.

Fentanyl is a powerful drug.[37] It produces intense euphoric effects in its users, and it does so at smaller doses than those an experienced user would require from heroin.[38] Guy told me that, for this reason, most opioid users in British Columbia today do not want heroin; they want fentanyl.[39] After all, he said, "once the drug supply changes and becomes more potent . . . going back to heroin doesn't really work."[40] He speculates that heroin is no longer sold on the streets of Vancouver today.

Opioid users can abuse fentanyl in its prescribed form by removing the gel contents from patches and injecting or ingesting these contents.[41] They can also freeze the patches, cut them into pieces, and orally ingest pieces of the patches, or they can divert fentanyl lollipops and fentanyl injectables from

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31 *Drug Overdoses*, NSC INJURY FACTS, https://injuryfacts.nsc.org/home-and-community/safety-topics/drugoverdoses/data-details/ [https://perma.cc/8LVL-P39M] (last visited Apr. 24, 2023).

32 Zachary Siegel, *The Opioid Epidemic Is Changing Too Fast for Any Solutions to Stick*, THE CUT (Oct. 18. 2017), https://www.thecut.com/2017/10/the-opioid-epidemic-is-changing-too-fast-to-be-tamed.html [https://perma.cc/ZL87-NQXC].

33 *Fentanyl*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/opioids/basics/fentanyl.html [https://perma.cc/4JTN-SVQL] (June 1, 2022).

34 DRUG & CHEM. EVALUATION SECTION, U.S. DEP'T OF JUST., FENTANYL (2023), https://www.deadiversion.usdoj.gov/drug_chem_info/fentanyl.pdf [https://perma.cc/G7NL-JF7S].

35 *Id.*

36 *Id.*

37 *Id.*

38 *Id.*

39 Email Interview with Guy Felicella, *supra* note 1.

40 *Id.*

41 DRUG & CHEM. EVALUATION SECTION, U.S. DEP'T OF JUST., *supra* note 34.

their diverted form and abuse them as well.[42] The Drug Enforcement Administration ("DEA") estimates that doctors prescribed the drug about five million times in 2017, and Jannsen Pharmaceuticals, a major manufacturer of fentanyl, boasts more than forty thousand employees in labs and offices around the world.[43] However, illicit fentanyl has primarily driven the drug overdose crisis over the past few years.[44]

China is the principal source of illicit U.S. fentanyl.[45] Before 2018, Chinese manufacturers of fentanyl routinely sold the drug on the Internet and shipped it to the United States via the United States Postal Service ("USPS").[46] Today, the drug does not as easily make its way into our borders, in part because Congress passed the Synthetics Trafficking and Overdose Prevention Act ("STOP Act") in 2018.[47] The STOP Act requires the USPS to collect information on all mail sent from China, including details on the sender and on the package's contents.[48] Following passage of the STOP Act, the Chinese government also began cracking down on manufacturers of illicit fentanyl.[49] In May 2019, the Chinese government placed the entire class of fentanyl-type drugs and two fentanyl precursors under a controlled regulatory regime and now more strictly monitors outgoing mail to the United States.[50] Still, China remains the primary source of fentanyl in the United States; it just gets here through a less direct route.[51]

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42 *Id.*

43 *Id.*

44 *Overdose Death Investigations Challenge DEA Agents to Bring Justice*, U.S. DRUG ENF'T ADMIN. (Feb. 8, 2023), https://www.dea.gov/stories/2023/2023-02/2023-02-08/overdose-death-investigations-challenge-dea-agents-bring-justice [https://perma.cc/U7FQ-SL9T].

45 Vanda Felbab-Brown, *China and Synthetic Drugs Control: Fentanyl, Methamphetamines, and Precursors*, BROOKINGS (Mar. 2022), https://www.brookings.edu/research/china-and-synthetic-drugs-control-fentanyl-methamphetamines-and-precursors/ [https://perma.cc/WKH4-Y6YZ].

46 *See* Sanya Mansoor, *Trump Urges USPS and FedEx to Crackdown on Fentanyl Trafficking From China. They've Been Trying for Years*, TIME (Aug. 24, 2019), https://time.com/5660390/trump-china-fentanyl-mail-drug-trafficking/ [https://perma.cc/G3KZ-C7NX].

47 *See id.*

48 *Id.*

49 Gerry Shih, *China Touts Its Crackdown on Fentanyl, Urged by Trump, as Drug-ring Members are Sentenced*, WASH. POST (Nov. 7, 2019), https://www.washingtonpost.com/world/asia-pacific/china-touts-crackdown-on-fentanyl-urged-by-trump-as-it-sentences-drug-ring-members/2019/11/07/d72c2196-010c-11ea-8341-cc3dce52e7de_story.html [https://perma.cc/Q9C4-XQWE].

50 Felbab-Brown, *supra* note 45.

51 *See id.*

Mexican transnational criminal organizations ("TCOs") are "largely responsible for the production of U.S.-consumed illicit fentanyl."[52] These TCOs source the chemical inputs or precursors for fentanyl production from China, and then manufacture the drug Mexico.[53] The groups then traffic fentanyl into the United States in low concentration, high volume loads; a seizure of one kilogram of Mexican fentanyl, for example, may only contain less than a 10% concentration of fentanyl.[54] Some of the laboratories in which Mexican TCOs produce fentanyl are highly sophisticated and even stocked with advanced processing methods such as grade glassware, chemicals, and industrial size tablet presses.[55] The DEA has dismantled numerous operations that met this level of sophistication.[56] Mexican TCOs also produce wholesale quantities of illicit fentanyl pills for trafficking into the United States.[57] These counterfeit pills have caused countless fatal overdoses, and many dealers convicted of distributing counterfeit fentanyl pills have been sentenced to lengthy and harsh prison terms.[58] Because six out of ten fentanyl-laced pills contain a potentially

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52 SUSAN V. LAWRENCE, LIANA W. ROSEN & RICARDO BARRIOS, CONG. RSCH. SERV., IF10890, CHINA PRIMER: ILLICIT FENTANYL AND CHINA'S ROLE (2022).

53 *Id.*

54 U.S. DRUG ENF'T ADMIN., U.S. DEP'T OF JUST., FENTANYL FLOW TO THE UNITED STATES 3 (2020), https://www.dea.gov/sites/default/files/2020-03/DEA_GOV_DIR-008-20%20Fentanyl%20Flow%20in%20the%20United%20States_0.pdf [https://perma.cc/5DN6-X9CC].

55 *Id.*

56 *See id.*

57 *Id.*

58 *See, e.g.*, Press Release, U.S. Dep't of Just., Fentanyl Dealer Sentenced To Eight Years In Overdose Death (Apr. 5, 2022), https://www.justice.gov/usao-ndca/pr/fentanyl-dealer-sentenced-eight-years-overdose-death [https://perma.cc/G5BD-E4KH]; Press Release, Multnomah County, Two Teens Die from Overdose of Suspected Counterfeit Pills Containing Fentanyl (Mar. 8. 2022), https://www.multco.us/multnomah-county/news/two-teens-die-overdose-suspected-counterfeit-pills-containing-fentanyl [https://perma.cc/KQ5L-ASPV]; Press Release, U.S. Dep't of Just., Boston Man Pleads Guilty to Possessing Over 200 Pressed Fentanyl Pills Disguised as Oxycodone (Mar. 25, 2022), https://www.justice.gov/usao-ma/pr/boston-man-pleads-guilty-possessing-over-200-pressed-fentanyl-pills-disguised-oxycodone [https://perma.cc/D8ZY-5JD3]; Press Release, U.S. Dep't of Just., Chula Vista Man Sentenced for Distributing Fentanyl-laced Pills that Caused Overdose Death of 20-year-old (Mar. 29, 2022), https://www.justice.gov/usao-sdca/pr/chula-vista-man-sentenced-distributing-fentanyl-laced-pills-caused-overdose-death-20 [https://perma.cc/9XML-MCPU]; Press Release, U.S. Dep't of Just., Fresno Fentanyl Pill Dealer Sentenced to 6 Years in Prison for Illegal Possession of Counterfeit M30 Pills and a Loaded Firearm (Apr. 18, 2022), https://www.justice.gov/usao-edca/pr/fresno-fentanyl-pill-dealer-sentenced-6-years-prison-illegal-possession-counterfeit-m30 [https://perma.cc/68LV-BFMX].

lethal dose of fentanyl, the DEA now warns users that just "One Pill Can Kill."[59]

Today, fentanyl appears in more than just counterfeit oxycodone pills and heroin; the drug has been increasingly contaminating illicit stimulants such as cocaine and methamphetamine.[60] A comprehensive study of overdose deaths involving cocaine and methamphetamine in Ohio found that, between 2014 and 2018, the number of cocaine-involved deaths tripled (from 3,822 to 14,666) and the number of methamphetamine-involved deaths increased by 275% (from 4402 to 12,092).[61] The study found that these stimulant-involved deaths were associated with exposure to fentanyl.[62] A CDC report arrived at the same conclusion.[63] The CDC found that approximately 80% of U.S. deaths from overdoses of cocaine involved opioids, and three of those four deaths involved illicitly manufactured fentanyls.[64] Heroin users may "unknowingly purchase fentanyl or a drug mixture of unpredictable strength and composition."[65] Regardless, unintentional fentanyl overdoses frequently occur throughout the nation. In January 2019, for example, three patients arrived at an emergency hospital in California after ingesting what they thought was cocaine; in reality, they had just snorted fentanyl.[66] One of the patients was pronounced brain-dead three days later, while the other two required frequent doses of naloxone to escape

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59 *One Pill Can Kill*, U.S. DRUG ENF'T ADMIN., U.S. DEP'T OF JUST., https://www.dea.gov/onepill [https://perma.cc/8VP8-K2A5] (last visited Apr. 24, 2023).

60 *See New Study: Supply of Illicit Fentanyl – Not Illicit Stimulants – Associated with Increasing Overdose Deaths Involving Cocaine, Methamphetamine*, RTI INT'L (Feb. 3, 2022), https://www.rti.org/news/fentanyl-associated-with-increasing-cocaine-meth-overdose-deaths [https://perma.cc/8ZAU-8BYC]; Zachary Siegel, *The Drug Supply is Contaminated!*, SUBSTANCE SUBSTACK (Mar. 13, 2022), https://tanag.substack.com/p/the-drug-supply-is-contaminated?s=W [https://perma.cc/V86U-S4LV].

61 Jon E. Zibbell et al., *Association Between Law Enforcement Seizures of Illicit Drugs and Drug Overdose Deaths Involving Cocaine and Methamphetamine, Ohio, 2014–2019*, 232 DRUG & ALCOHOL DEPENDENCE 1, 1 (2022).

62 *See id.* at 6.

63 *CDC See Increased Drug Overdose Fatalities Due to Cocaine and Fentanyl*, CWLA, https://www.cwla.org/cdc-see-increased-drug-overdose-fatalities-due-to-cocaine-and-fentanyl/ [https://perma.cc/4PNS-J7HM] (last visited Apr. 24, 2023).

64 *Id.*

65 U.S. SENTENCING COMM'N, FENTANYL AND FENTANYL ANALOGUES: FEDERAL TRENDS AND TRAFFICKING PATTERNS 8 (2021), https://www.ussc.gov/sites/default/files/pdf/research-and-publications/research-publications/2021/20210125_Fentanyl-Report.pdf [https://perma.cc/2JKM-HUA3].

66 Patil Armenian et al., *Unintentional Fentanyl Overdoses Among Persons Who Thought They Were Snorting Cocaine—Fresno, California, January 7, 2019*, 68 MORBIDITY & MORTALITY WKLY. REP. 687, 687 (2019).

death.[67] In late February 2022, first responders found five people dead from overdoses in a suburban Denver apartment.[68] Those people thought they had purchased cocaine, but they were actually sold fentanyl.[69] Cocaine users often have no tolerance for fentanyl and may not have naloxone on hand.[70] Their deaths were thus all but certain. And just recently, a group of five U.S. Military Academy cadets in Florida overdosed on fentanyl which they thought was cocaine.[71]

In sum, the world's illicit drug supply is contaminated with fentanyl, and the contamination is unprecedented.[72] Drug users today can encounter the synthetic opioid in various, deadly ways. They might ingest it in counterfeit oxycodone tablets that drug traffickers produced in a lab in Mexico, China—or even the United States.[73] They might consume it in stimulants such as cocaine, methamphetamine, or counterfeit amphetamine tablets. They might even seek out fentanyl deliberately, as Guy told me, or they might assume it is in their heroin and use the heroin accordingly.[74] And, as is commonly and tragically the case, they may inject fentanyl thinking it was heroin, only to never wake up to discover that what they really consumed was the world's most deadly and potent opioid.

II
AN UNLIKELY DRIVER OF THE CRISIS

An obscure component of administrative law has contributed to the increasingly dire state of America's drug overdose crisis. The Administrative Procedure Act ("APA"), otherwise known as the statutory constitution of federal administrative government, establishes the default rules that govern how fed-

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67 *Id.*

68 *See* Siegel, *supra* note 60.

69 *Id.*

70 *Id.*

71 *Id.*

72 Zachary Siegel, *Teenagers Use Drugs Less, but More Are Dying From Overdoses*, SUBSTANCE SUBSTACK (Apr. 12, 2022), https://open.substack.com/pub/tanag/p/teenagers-use-drugs-less-but-more?utm_campaign=post&utm_medium=web [https://perma.cc/3U53-TA9Y].

73 *See, e.g.*, Press Release, U.S. Dep't of Just., Man Arrested After Federal Law Enforcement Seizes Fentanyl and "Pill Press" From Suburban Chicago Residence (Feb. 3, 2022), https://www.justice.gov/usao-ndil/pr/man-arrested-after-federal-law-enforcement-seizes-fentanyl-and-pill-press-suburban [https://perma.cc/ERQ7-GKRE]; *Sheriff: Commercial-Grade Pill Press, $1 Million in Illegal Drugs Seized*, KPLC NEWS (Jan. 12, 2022), https://www.kplctv.com/2022/01/12/calcasieu-sheriffs-office-hold-press-conference-narcotics-arrest-today/ [https://perma.cc/3UDX-AYQK].

74 Email Interview with Guy Felicella, *supra* note 1.

eral agencies act and how citizens can challenge their actions.[75] The APA also provides federal courts with instructions for when they should hold unlawful and set aside an agency's actions, findings, and conclusions.[76] Section 706(1) of the Administrative Procedure Act provides that reviewing courts shall compel an agency to act when it has unlawfully withheld or unreasonably delayed an action.[77] The APA elsewhere defines agency action as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[78] The Supreme Court offered an authoritative interpretation of § 706(1) in *Norton v. Southern Utah Wilderness Alliance.*[79]

At issue in *Norton* was whether the Bureau of Land Management ("BLM"), an agency within the Department of Interior, violated § 706(1) by allegedly failing to prevent off-road vehicles from eroding public wilderness lands in Utah.[80] Delivering the opinion for the Court, Justice Scalia reviewed the APA's definition of agency action.[81] He observed that the APA defines an agency action as an agency rule, order, license, sanction, or relief.[82] These categories, he reasoned, clearly refer to circumscribed, discrete agency actions.[83] To support this reading, he looked at how the APA elsewhere defines a rule, order, license, sanction, and relief.[84] After observing that the APA does not define what constitutes a "failure to act," he reasoned that it must mean a failure to take an agency action as the statute defines agency action in Section 551(13).[85] In short, Justice Scalia understood an agency's failure to act as the agency's failure to take one of the discrete actions listed in Section 551(13).[86]

The action must, moreover, be one that the agency is legally required to take because 706(1) authorizes courts to compel agency action only when the agency has unlawfully failed to

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75 Gillian Metzger, *The Administrative Procedure Act: An Introduction*, POVERTY & RACE RSCH. ACTION COUNCIL 1, 1 (2017), https://prrac.org/pdf/APA.summary.ProfMetzger.pdf [https://perma.cc/W8E9-E4SL].

76 5 U.S.C. § 706(2).

77 *Id.* § 706(1).

78 *Id.* § 551(13).

79 542 U.S. 55, 57 (2004).

80 *Id.* at 60.

81 *See id.* at 62.

82 *Id.*

83 *Id.*

84 *See id.*

85 *See id.* at 62–63.

86 *See id.* at 62.

act.[87] The Court rejected Southern Utah Wilderness Alliance's challenge to the Bureau of Land Management's refusal to regulate off-road vehicles.[88] In the opinion, Justice Scalia reviewed the statute that governed the BLM's activity, which mandated that the BLM "continue to manage [wilderness study areas] . . . in a manner so as not to impair the suitability of such areas for preservation as wilderness."[89] He reasoned that this provision of the statute gave the BLM a great deal of discretion in deciding how to manage wilderness study areas, and he asserted that the statute most certainly did not require the BLM to exclude off-road vehicles from them.[90] For Justice Scalia, then, there was no discrete agency action for which Section 706(1) required judicial enforcement.[91] Thus, under his reading of the APA and 43 U.S.C. § 1782(c), the Southern Utah Wilderness Alliance could not legally compel the BLM to prohibit people from operating off-road vehicles in Utah's wilderness.

Norton remains good law today. Thus, a claim under Section 706(1) can proceed only when a plaintiff asserts that an agency has failed to take a discrete agency action that it was required to take.[92] In other words, a plaintiff cannot obtain relief for inaction under the Administrative Procedure Act unless she demonstrates first that an agency actually has a legal obligation to take an action or adopt a rule.[93] So if Congress had imposed on the BLM a statutory obligation to pass rules that would prevent man-made devices from eroding natural wilderness areas to any appreciable degree, the Southern Utah Wilderness Alliance likely would have prevailed in its suit. Similarly, if Congress required the BLM to pass these rules and the BLM denied a petition for rulemaking from the Southern Utah Wilderness Alliance, the group likely could get relief. Petitions for rulemaking offer little in the way of recourse, however, because courts apply a very deferential form of review when evaluating an agency's decision to deny a rulemaking petition.[94]

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87 *See id.* at 64.

88 *See id.*

89 *Id.* at 65 (quoting 43 U.S.C. § 1782(c)).

90 *See id.* at 66.

91 *Id.*

92 *Id.* at 64.

93 Sidney A. Shapiro, *Rulemaking Inaction and the Failure of Administrative Law*, 68 DUKE L.J. 1805, 1818 (2019).

94 *See id.*

Professor Sidney A. Shapiro of Wake Forest University School of Law has described the judiciary's treatment of agency inaction as the failure of administrative law.[95] He argues that because judges reviewing agency inaction will likely conclude that agency priority-setting is above their pay grade, agencies can expect courts to almost always permit inaction.[96] Moreover, because regulatory beneficiaries can no longer sue agencies for inaction if Congress has not expressly mandated that the agency take a discrete action, the only recourse available to citizens is to petition the agency to promulgate a rule.[97] But beneficiaries run into an additional obstacle here because, as previously mentioned, federal courts are highly deferential to an agency's decision to deny a citizen's petition for rulemaking.[98]

To illustrate, FDA regulations require the FDA to respond to a citizen petition within 180 days of receipt.[99] FDA's response can take various forms. FDA can, for example, approve the petition, deny the petition, dismiss the petition if it has become moot, or, importantly, provide a tentative response to the petition if the agency has been unable to reach a decision on its underlying request.[100] Once FDA has issued a tentative response to a petition, it has met its obligation to respond under 21 C.F.R. § 10.30.[101] As a result, the Agency can sit on a petition for years before issuing a final response.[102] Indeed, an analysis of FDA's response rate to citizen petitions filed by non-governmental actors—ordinary citizens—found that the mean time to decision was 2.85 years.[103] Some petitions were still pending after 10 to 13 years.[104] For this reason, if an agency like the FDA has sat on a petition for years after issuing a tentative response or has delayed in developing a rule, judges will only compel agency action if the agency has acted without good faith, thus limiting the recourse available for citizens.[105]

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95 *Id.* at 1807–8.
96 *Id.* at 1816.
97 *Id.* at 1812.
98 *See id.* at 1816.
99 21 C.F.R. § 10.30(e)(2). The FDA is required to respond to citizen petitions subject to Section 505(q) of the FD&C Act within 150 days. 21 U.S.C. § 355(q)(1)(F).
100 21 C.F.R. § 10.30(e)(2).
101 *See id.*
102 *Id.*
103 Brian K. Chen et al., *Petitioning the FDA to Improve Pharmaceutical, Device, and Public Health Safety by Ordinary Citizens: A Descriptive Analysis*, 11 PLOSONE 5 (2016).
104 *Id.*
105 *See id.*

Although the APA requires agencies to respond to petitions within a "reasonable" amount of time, the statute does not define what is reasonable, and the multi-factor test that courts rely on to assess whether an agency's delay "is so egregious as to warrant mandamus" is also of little assistance.[106] That test, which the D.C. Circuit developed in *Telecommunications Research & Action Center v. FCC*, provides courts with a number of factors to consider when determining whether a delay is reasonable, but it does not make clear which factors are more important than the others, and it does not state how many factors must be met for a court to find a delay unreasonable.[107]

III
THE FDA'S ROLE

The FDA's delay in initiating a prescription-to-OTC switch for naloxone, the life-saving opioid agonist that rapidly reverses opioid overdoses, exemplifies just how devastating agency inaction can be for those it most affects. In other words, communities throughout the nation have suffered the consequences of FDA's delay in making naloxone an over-the-counter drug.

Harm reductionists have been urging the FDA to initiate a prescription-to-OTC switch of naloxone for over a decade. According to Eliza J. Wheeler, co-director of harm reduction group Remedy Alliance, the organized push dates back as far as 2008.[108] That year, Public Citizen, a non-profit consumer advocacy organization that "champions the public interest in the halls of power,"[109] reached out to the FDA inquiring into the steps a drug sponsor would have to take to make naloxone an over-the-counter drug.[110] Specifically, Public Interest asked FDA what data a sponsor would need to produce and

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106 Telecomms. Rsch. & Action Ctr. v. FCC, 750 F.2d 70, 72 (D.C. Cir. 1984). Section 706(1) of the APA authorizes a court to "compel agency action unlawfully held or unreasonably delayed." 5 U.S.C. § 706(1); *Telecomms. Rsch. & Action Ctr.*, 750 F.2d at 77.

107 750 F.2d at 80; *see* Shapiro, *supra* note 93, at 1820–21.

108 Eliza J. Wheeler (@ejwheeler9), TWITTER (Mar. 25, 2022, 9:46 AM), https://twitter.com/ejwheeler9/status/1507353224696586250 [https://perma.cc/5KHZ-CA8F]. Eliza Wheeler is co-director of Remedy Alliance, a harm reduction group that was previously the Opioid Safety and Naloxone Network Buyers Club. *See also* Letter from Sharon Hertz, Deputy Dir. of the Div. of Anesthesia, Analgesia & Rheumatology Prods., U.S. Food & Drug Admin., and Andrea Leonard-Segal, Dir. of Div. of Nonprescription Clinical Evaluation, U.S. Food & Drug Admin., to Peter Lurie, Deputy Dir. of Public Citizen's Health Rsch. Grp. (June 16, 2009) [hereinafter Hertz Letter] (on file with author).

109 PUBLIC CITIZEN, ABOUT US, https://www.citizen.org/about/ [https://perma.cc/WT46-HLH3] (last visited July 25, 2023).

110 Hertz Letter, *supra* note 108.

what drug approval pathway the agency would advise a sponsor pursue.[111] In its response, the FDA acknowledged that it could "initiate a proceeding to switch the drug from prescription to OTC via rulemaking."[112] However, "the pathway most likely to adequately address all of the requirements for making naloxone available without a prescription would be through a sponsor willing to take on such a drug development and ultimately to submit a New Drug Application."[113] The FDA's response was disappointing, but the agency did note that an "interested outside party [could] bring a citizen petition requesting the FDA initiate the rulemaking route."[114] Several years later, Pharmacists Planning Service, Inc., a non-profit educational foundation focused on public health, did just that.[115] In 2014, it petitioned the FDA to adopt a modified treatment to its approach of naloxone.[116] The group requested that the FDA place naloxone into the class of drugs that only pharmacists can dispense.[117] Examples of these drugs include Mucinex-D, ipecac, needles, syringes, antihistamines with pseudoephedrine decongestants, along with many others.[118] The group highlighted the FDA's successful effort in making Sudafed a behind-the-counter drug, and it made clear to the FDA that only pharmacists licensed by their corresponding states could dispense naloxone if the FDA modified the drug's designation.[119] The FDA still would not budge; it denied the petition the following year.[120]

In 2019, the FDA released a statement acknowledging that making naloxone more widely available in every pharmacy as an OTC product would be an important public health advance-

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111 *Id.* at 1.

112 *Id.*

113 *Id.*

114 *Id.*

115 *See* Citizen Petition from Pharmacists Plan. Serv., Inc. to Documents Mgmt. Branch, U.S. Food & Drug Admin., No. FDA-2014-P-0752-0002 (May 27, 2014) [hereinafter Citizen Petition from Pharmacists Planning Serv.], https://pink.pharmaintelligence.informa.com/-/media/pmbi-old-site/supporting-documents/the-tan-sheet/23/14/14_ppsi_citizenpetitions.pdf [https://perma.cc/X3MW-66FJ].

116 *See id.* at 1.

117 *Id.*

118 *Id.* at 2; Sandy P. Bonfin, *What Medications Are Kept Behind the Pharmacy Counter?*, GOODRX HEALTH (Apr. 11, 2022), https://www.goodrx.com/healthcare-access/medication-education/whats-behind-the-counter [https://perma.cc/W89S-B9JN].

119 *See* Citizen Petition from Pharmacists Planning Serv. at 2–3.

120 *See* Christopher T. Creech, Comment, *Increasing Access to Naloxone: Administrative Solutions to the Opioid Overdose Crisis*, 68 ADMIN. L. REV. 517, 541 (2016).

ment.[121] It even designed, tested, and validated the key labeling requirements necessary for the FDA to approve an OTC version of naloxone.[122] Still, it implied that the change had to originate with the pharmaceutical industry.[123] And just recently in March 2022, the FDA stated that although it has heard the calls for broadening naloxone access by switching it to OTC, "the transition to OTC remains challenging" and the agency needs data to support safe and effective intranasal use before it could initiate a switch.[124] It also asserted that making syringe-injectable naloxone an OTC drug poses challenges for OTC development because many individuals have never injected drugs and lack the competence to administer injectable drugs with minimal instructions.[125] But it assured the public that it is nevertheless committed to increasing options for opioid overdose reversal and improving access to naloxone.[126]

The FDA did not deny or acknowledge in this statement that it has the legal authority to unilaterally initiate a prescription-to-OTC switch of naloxone. It suggested only that it would need data to support safe and effective OTC use of intranasal naloxone. However, the FDA did not indicate from where the data should come, and for that reason the statement rang hollow. The FDA has the legal authority to initiate a prescription-to-OTC switch of intranasal naloxone, and it ought to have done so much earlier in the opioid crisis. Consider first what the agency itself has done and said. In October 1982, the FDA took the then-unprecedented step of changing a popular inhaler's designation from prescription-only to over-the-counter.[127] Then, in 2003, the Director of the Office of New Drugs at the FDA's Center for Drugs and Evaluation stated

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121 Press Release, Norman E. Sharpless, Acting Comm'r of Food & Drugs, U.S. Food & Drug Admin., Statement on Continued Efforts to Increase Availability of All Forms of Naloxone to Help Reduce Opioid Overdose Deaths (Sep. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose [https://perma.cc/ZAY8-69AS].

122 *Id*

123 *See id.*

124 Patrizia Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Remarks by Patrizia Cavazzoni, M.D.: Naloxone Access Public Meeting (Mar. 29, 2022), https://www.fda.gov/drugs/news-events-human-drugs/remarks-patrizia-cavazzoni-md-naloxone-access-public-meeting [https://perma.cc/BN9T-8TPY].

125 *Id.*

126 *Id.*

127 Morton Mintz, *Over-the-counter Sale Draws Fire*, WASH. POST (Apr. 28, 1983), https://www.washingtonpost.com/archive/politics/1983/04/28/over-the-counter-sale-draws-fire/0a497ee4-6332-4efc-917c-91ed36ecfd5f/ [https://perma.cc/ZL6J-5M9M].

that the FDA had "the authority to determine whether or not a product is Rx or OTC."[128] FDA Commissioner Mark B. McClellan also confirmed that the agency had the legal and regulatory authority to require forced switches.[129]

The Food, Drug, and Cosmetic Act ("FD&C Act") regulates nearly every aspect of the prescription and OTC drug market, and it is the statutory basis for the FDA's ability to promulgate rules.[130] Section 503(b)(3) of the FD&C Act permits the FDA to exempt a drug from otherwise applicable requirements "when such requirements are not necessary for the protection of public health."[131] The FDA's own regulations are even more explicit about the FDA's authority to initiate an OTC switch, stating that "[a]ny drug limited to prescription use . . . shall be exempted from prescription-dispensing requirements when the [FDA] Commissioner finds such requirements are not necessary for the protection of the public health."[132] Thus, there is both a statutory and regulatory basis for the FDA's ability to change a drug's designation from prescription-only to over-the-counter.

Finally, the FDA can issue an administrative order establishing an OTC monograph for naloxone, facilitating greater access to the drug. An OTC monograph is a "rule book" for a therapeutic category of drugs and contains categories such as antacids, laxatives, analgesics, and stimulants.[133] The OTC monograph will list appropriate active ingredients, uses, doses, labeling, and testing procedures under which a certain category of OTC drug is generally recognized as safe and effective ("GRASE") and thus eligible for marketing without a New Drug Application.[134]

FDA has promulgated regulations establishing the procedure for classifying over-the-counter drugs as GRASE and not misbranded.[135] Under these regulations, an over-the-counter

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128 Marc Kaufman, *FDA Says It Can Take Away Drugs' Prescription Status*, WASH. POST (Apr. 26, 2003), https://www.washingtonpost.com/archive/politics/2003/04/26/fda-says-it-can-take-away-drugs-prescription-status/f1d0c726-594c-434f-8dec-9b4edc4b6989/ [https://perma.cc/NV29-MAR8].

129 *Id.*

130 *See generally* Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 321 – 399i.

131 21 U.S.C. § 353(b)(3); *see also* Corey S. Davis and Derek Carr, *Over The Counter Naloxone Needed To Save Lives in the United States*, 130 PREVENTIVE MED. 1, 2 (2020).

132 21 C.F.R. § 310.200(b) (2023).

133 *See OTC Drug Review Process — OTC Drug Monographs*, U.S. FOOD & DRUG ADMIN. (June 28, 2022), https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process [https://perma.cc/FY82-9EQK]; 21 C.F.R. § 330.5 (2023).

134 *Id.*

135 *See* 21 C.F.R. § 330.1 (2023).

drug will be classified as GRASE if it meets the conditions set forth under 21 C.F.R. § 330.1 and any condition contained in an applicable monograph.[136] Before Congress passed the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") in 2020, the FDA could only add, remove, or change an OTC monograph by notice-and-comment rulemaking, a cumbersome three-phase public process that prevented the FDA from quickly amending or adding new OTC monographs, even when significant safety concerns were at issue.[137] The CARES Act amended this process by adding Section 505G to the FD&C Act, which replaced the rulemaking process for establishing OTC monographs with an administrative order process.[138]

Now, under Section 505G(b), the FDA can issue an administrative order establishing or amending an OTC monograph for a drug that satisfies certain requirements under Section 505G(a)(1) or (2).[139] In particular, FDA may issue an administrative order determining that there are conditions under which a drug is GRASE and may be dispensed without a written prescription.[140] If a drug covered by such an administrative order meets the general requirements for nonprescription drugs, it will no longer be subject to Section 355 of the FD&C Act, which sets forth the requirements for the approval of new drugs.[141] In other words, a manufacturer could begin marketing the drug in conformity with the administrative order without seeking FDA approval.[142] Consider, then, how a manufacturer of a naloxone nasal spray or naloxone injectable could take advantage of this process. With an OTC monograph for naloxone in place, the manufacturer could begin marketing a nasal spray product as soon as it meets the conditions—such as active ingredients, indications, doses, routes of administration, labeling, and testing—under which the drug is GRASE for its intended use. FDA could also issue a subsequent administrative order adding conditions to the OTC monograph, such as

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136 *Id.*

137 *Id.*

138 Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No.116-136, § 3851, 134 Stat. 281, 435 (2020) (codified at 21 U.S.C. § 355h); Theresa M. Michele, *An Exciting New Chapter in OTC Drug History: OTC Monography Reform in the CARES Act*, U.S. FOOD & DRUG ADMIN. (Aug. 6, 2020), https://www.fda.gov/news-events/fda-voices/exciting-new-chapter-otc-drug-history-otc-monograph-reform-cares-act [https://perma.cc/7PR6-5R8D].

139 21 U.S.C. § 355h(b); Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3851.

140 21 U.S.C. § 355h(b)(1)(A).

141 *Id.* § 355h(b)(B).

142 *Id.*

an order recognizing that naloxone—under the conditions in the monograph—is GRASE for injectable use.[143]

As discussed above, the FDA retains the authority to unilaterally make naloxone—whether as an injectable or as a nasal spray—an over-the-counter the drug. Nevertheless, the agency has been unwilling to initiate the switch itself. To the FDA's credit, however, it has taken steps to encourage industry to submit applications for OTC naloxone, and recently even approved two naloxone nasal sprays for OTC use, a major step forward in the agency's approach to countering this public health crisis.[144]

In November 2022, the FDA issued a Federal Register notice announcing its assessment that certain naloxone drug products may be approvable as safe and effective for nonprescription use.[145] Specifically, the FDA announced its preliminary opinion that naloxone nasal spray and naloxone autoinjector for intramuscular ("IM") or subcutaneous ("SC") use have the potential to be safe and effective for use in nonprescription drug labeling without the supervision of a healthcare practitioner.[146] Months after announcing this preliminary opinion, the FDA sought the advice of a scientific advisory committee on whether the agency should approve Emergent BioSolutions' supplemental drug application for nasal naloxone as an over-the-counter product.[147] The FDA uses forty-nine scientific advisory committees to provide the agency with independent expert advice and recommendations.[148] The agency generally follows the committees' recommendations, but it is not legally obligated to follow them.[149] The advisory committee tasked with evaluating Emergent's nasal naloxone unani-

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143 *See supra* note 133.

144 *FDA Approves Second Over-the-Counter Naloxone Nasal Spray Product*, U.S. FOOD & DRUG ADMIN. (July 28, 2023) [hereinafter *Second Naloxone Nasal Spray Approval*], https://www.fda.gov/news-events/press-announcements/fda-approves-second-over-counter-naloxone-nasal-spray-product [https://perma.cc/LMZ9-XL56].

145 *See* Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use, 87 Fed. Reg. 68,702, 68,702 (Nov. 16, 2022).

146 *Id.*

147 *See* Lev Facher, *FDA Advisers Recommend Approval of Over-the-counter Naloxone to Fight Opioid Overdose*, STAT (Feb. 15, 2023), https://www.statnews.com/2023/02/15/naloxone-otc-opioisa-fda-panel-recommends/ [https://perma.cc/MWW7-2KMJ].

148 *Advisory Committees Give FDA Critical Advice and the Public a Voice*, U.S. FOOD & DRUG ADMIN. (Sept. 21, 2022), https://www.fda.gov/consumers/consumer-updates/advisory-committees-give-fda-critical-advice-and-public-voice [https://perma.cc/3ZFA-YJM9].

149 *Id.*

mously voted in favor of making Emergent's product an OTC drug.[150] Despite minimal concerns with safety risks, the committee members echoed what harm reductionists have been arguing for over a decade: the urgency of the overdose crisis far outweighs the potential delays with gathering new data and running user-friendliness tests on new instructions for nasal naloxone in the OTC setting.[151] In March 2023, the FDA finally approved the first nasal naloxone spray for OTC use, a significant milestone in the Agency's efforts to combat the devastating effects of the opioid crisis.[152]

The FDA's mission is to protect the public health. In convening an advisory committee to provide it with a recommendation on Emergent's nasal spray and virtually guaranteeing that the agency would designate the spray as an OTC drug if the committee voted in favor of OTC status, the agency carried out its mission. It should be applauded for its efforts, and lives will doubtless be saved as a result. Still, the agency's refusal to unilaterally designate naloxone—and especially injectable naloxone—as an OTC drug reveals the harm that agency inaction can cause. Consider that the nasal spray version of naloxone costs as much as $75 per dose, making it inaccessible to many people who need it.[153] On the other hand, a nonprofit can purchase injectable naloxone from manufacturers at a heavily discounted price and then sell it to harm reduction groups for less than $2 per dose.[154] Emergent has not yet indicated how it will price its nasal spray if it receives FDA approval but even with insurance reimbursement it will far exceed this cost.[155] Not only is injectable naloxone cheaper, harm reduction communities have been safely using it for decades, and there are some circumstances in which a nasal spray is not feasible to administer.[156] According to Nabarun

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150 *See* Facher, *supra* note 147.

151 *Id.*

152 Jan Hoffman, *F.D.A. Approves Narcan for Over-the-counter Sales*, N.Y. TIMES (Mar. 29, 2023), https://www.nytimes.com/2023/03/29/health/narcan-over-the-counter.html [https://perma.cc/7M69-4U6K]. The FDA approved the second over-the-counter naloxone nasal spray in July of 2023, another indication that the agency recognizes the urgency of the crisis. *Second Naloxone Nasal Spray Approval*, *supra* note 144.

153 Leana S. Wen, *One Big Thing the FDA Can Do to Save Americans Overdoses*, WASH. POST (Feb. 15, 2023), https://www.washingtonpost.com/opinions/2023/02/15/fda-injectable-naloxone-opioid-overdose/ [https://perma.cc/PY7A-M8KR].

154 *See id.*

155 *Id.*

156 *See id.* (providing an example of when an overdosing patient's physical position makes a nasal spray difficult to administer).

Dasgupta, an epidemiologist who runs a nonprofit that distributes low-cost liquid naloxone to community groups, "over-the-counter status for the nasal spray doesn't replace the need for more liquid naloxone distribution."[157]

Nevertheless, the FDA is highly unlikely to approve injectable naloxone for OTC use—much less invoke its authority to make the switch itself. And because of administrative law's treatment of agency inaction, the only recourse will be persistent and aggressive lobbying to get the FDA to do the right thing. Short of this, there is virtually nothing harm reductionists can do. Suppose, for example, that a group of citizens sue the FDA in federal court for arbitrarily and capriciously denying their petition for the FDA to issue an administrative order to make injectable naloxone an OTC drug. Under the highly deferential standard of review by which federal courts review an agency's denial of rulemaking petitions, the FDA's decision would almost certainly withstand judicial scrutiny.[158] Suppose further that the FDA failed to respond to the petition and a group of plaintiffs sued the FDA for failing to act under Section 706(1). After *Norton*, the plaintiffs would have to show that the FDA failed to take a discrete action that it was legally required to take.[159] The plaintiffs would therefore have to locate that discrete action in an applicable statute. Now consider that, in *Norton,* the Court held that the following statutory language was insufficient to confer on the Bureau of Land Management a legal obligation to take the discrete action—prohibiting off-road vehicle use in Utah's wilderness—that the Southern Utah Wilderness Alliance wanted it to take: "[the Bureau of Land Management shall] continue to manage [wilderness study areas] . . . in a manner so as not to impair the suitability of such areas for preservation as wilderness."[160] The most similar statutory language here is from 21 U.S.C. § 353(b)(3). That provision of the statute states that the HHS Secretary "may by regulation remove drugs . . . from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health."[161] According to principles of statutory interpretation, the commonly repeated rule is that "may" is permissive, not

157 *Id.*
158 *See* Massachusetts v. EPA, 549 U.S. 497, 527–28 (2007).
159 *See* Norton v. S. Utah Wilderness All., 542 U.S. 55, 64 (2004).
160 *Id.* at 65 (quoting 43 U.S.C. § 1782(c)).
161 21 U.S.C. § 353(b)(3).

mandatory.[162] The plaintiffs would thus be hard-pressed to persuade a federal judge that the language in U.S.C. § 353(b)(3) imposes a legal obligation on the HHS Secretary to take a discrete action.

IV
THE SOLUTION AND THE OBSTACLES

Administrative law offers harm reductionists little recourse in their fight to give drug users a second shot at life. Although the FDA will likely approve naloxone nasal spray for over-the-counter use, the agency is far less likely to make injectable naloxone an OTC drug—and there is very little that anyone can do to force them. Furthermore, though the FDA's recent efforts to increase public access to naloxone are commendable, the agency's lengthy approval process for new drugs and drug indications will never meet the more urgent demands of the public health crisis that continues to plague the nation. The next step, then, is clear: harm reductionists must open supervised consumption sites in cities throughout the nation and make them as accessible as possible to drug users. But there is an additional obstacle here. It is likely a federal crime for anyone to operate one of these sites.

Judge Gerald A. McHugh of the Eastern District of Pennsylvania was the first federal judge to weigh in on the legality of supervised consumption sites.[163] In a declaratory judgment action brought by the United States seeking to enjoin the operation of a proposed supervised consumption site, Judge McHugh held that of 21 U.S.C. § 856(a) does not prohibit individuals from operating supervised consumption sites.[164] 21 U.S.C. § 856(a) is often inappropriately referred to as the "Crack House Statute" because it was initially passed to target those who operated houses and buildings where drugs were made and used in the 1980s.[165] The "Crack House Statute" states that it is a federal crime to do either of the following: (1) "knowingly open, lease, rent, use, or maintain any place . . . for

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162 ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 112 (2012).

163 *See* United States v. Safehouse (*Safehouse I*), 408 F. Supp. 3d 583 (E.D. Pa. 2019), *rev'd*, 985 F.3d 225 (3d Cir. 2021), *cert. denied*, Safehouse v. U.S. Dep't of Just., 142 S. Ct 345 (2021).

164 *See id.* at 587.

165 *See* Jeffrey A. Singer, *The "Crack House Statute" Is Hurting the Homeless When We Most Need Them Helped*, CATO INSTITUTE (Apr. 2, 2020), https://www.cato.org/commentary/crack-house-statute-hurting-homeless-when-we-most-need-them-helped [https://perma.cc/CT5C-DBCU].

the purpose of manufacturing, distributing, or using any controlled substance" or (2) "manage or control any place . . . either as an owner, lessee, agent, employee . . . and knowingly and intentionally rent, lease, profit from, or make available for use . . . the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance."[166]

In upholding the legality of the supervised consumption site at issue, Judge McHugh considered the kinds of projects that Congress had intended to criminalize when it passed the statute.[167] After surveying the legislative history behind the statute, Judge McHugh concluded that supervised consumption sites were clearly beyond the comprehension of Congress when it passed the bill.[168] He read the statute to conclude that the purpose at issue under Section 856 "must be a significant purpose to facilitate drug use, and that allowance of some drug use as one component of an effort to combat drug use will not suffice to establish a violation of Section 856(a)(2)."[169] Under this reading of the statute, then, parents could not be held criminally liable for encouraging their child to use heroin in their garage instead of on the streets.

A divided Third Circuit reversed Judge McHugh's decision.[170] The panel majority's decision also rested on its reading of Section 856(a)(2)'s last phrase: "for the purpose of . . ." Writing for the panel majority, Judge Stephanos Bibas held that the only actors who need to have the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance are those who visit the place at issue.[171] Those who operate the place, on the other hand, need only open it to these visitors knowing that they will use drugs there.[172] Under this interpretation of the statute, those who operate a supervised consumption need only "knowingly and intentionally" open the site's doors to those who would come for the purpose of using drugs inside.[173] Thus, under Third Circuit law, the only purpose that matters is the third party's purpose, not the operator's.[174] Although Judge Bibas was sympathetic to Safehouse's mission,

166 21 U.S.C. § 856(a).
167 *Safehouse I*, 408 F. Supp. 3d at 592.
168 *Id.*
169 *Id.* at 618.
170 United States v. Safehouse (*Safehouse II*), 985 F.3d 225, 243 (3d Cir. 2021).
171 *See id.* at 232.
172 *Id.*
173 *Id.* at 232–33.
174 *See id.* at 232.

he found that the text of Section 856(a) clearly bans supervised consumption sites, and that if this ban undermines Congress's efforts to address the opioid crisis, Congress should step in and amend the statute.[175]

The Supreme Court denied Safehouse's petition for certiorari, so the Third Circuit's opinion is binding only on those under its jurisdiction.[176] Moreover, the opinion prompted Judge Jane Roth to write a lengthy and thoroughly reasoned dissent that echoed and agreed with Judge McHugh's reading of the statute,[177] so it is fair to say that federal judges throughout the nation will disagree on whether operating a supervised consumption site is a federal crime under Section 856(a)(2). Thus, if the DOJ prosecuted operators of supervised consumption sites located outside of the Third Circuit's jurisdiction, it is plausible that several circuits would split on the issue. A circuit split would likely then encourage harm reductionists to open and operate sites only in those parts of the country where the governing circuits had declared them legal.

If harm reductionists want to save as many lives as they can, they should not rely on federal courts to help them accomplish this laudable goal. Nor should they rely on the DOJ to adhere to its statement that it is "evaluating . . . appropriate guardrails for [supervised consumption] sites . . . as part of an overall approach to harm reduction and public safety."[178] Although the DOJ did not issue this statement as a formal guidance document, its effect is similar: it signals to those who fall within the agency's regulatory scope—those who operate supervised consumption sites—how the agency will exercise its discretion to enforce the law and prosecute those who violate it. The problem with a guidance statement like this one is that it is not legally binding.[179] An agency cannot invoke a general statement of policy when enforcing the law because these statements merely indicate what the agency seeks to establish as policy.[180] Here, for example, the DOJ is not bound by this

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175 *See id.*

176 Safehouse v. Dep't of Just., 142 S. Ct. 345 (2021) (denying cert.); *see* Matthew L. Schafer, *Federal Law, Federal Courts, and Binding and Persuasive Authority*, WRITING CTR. AT GEO. U. L. CTR., https://www.law.georgetown.edu/wp-content/uploads/2018/07/Matthew-Schafer-FederalLawFederalCourtsandBindingandPersuasiveAuthority.pdf [https://perma.cc/U8BH-WGFX].

177 *See Safehouse II*, 985 F.3d at 243.

178 Peltz & Balsamo, *supra* note 19.

179 *See* Alexander Nabavi-Noori, *Agency Control and Internally Binding Norms*, 131 YALE L.J. 1278, 1301 (2022).

180 Pac. Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33, 38 (D.C. Cir. 1974).

statement, made to an AP News reporter. Instead, the DOJ could file criminal charges against those operating New York City's two consumption sites at any given moment. However, there is a promising alternative that does not rely on the DOJ's prosecutorial discretion.

V
CONGRESS AND THE ROHRABACHER-FARR AMENDMENT

Harm reductionists should lobby select Congressional representatives to include a policy rider in spending legislation that would restrict the DOJ from using congressionally allocated funds to prosecute those who operate supervised consumption sites. A proper assessment of the strengths and weaknesses of this strategy requires some background information.

Federal agencies need money. Without money, they are toothless: they cannot pass rules, conduct investigations, enforce the law, and carry out their statutory missions. Congress funds federal agencies, and it does so through appropriations of money.[181] Thus, as Professor Gillian Metzger has persuasively written, "[a]ppropriations lie at the core of the administrative state."[182] The two appropriations committees in each chamber of Congress are responsible for determining how much money to allocate to federal agencies, and they make these decisions with guidance from the president and the House and Senate Budget committees.[183] The president kicks off the federal budgeting process by submitting a detailed budget request for the upcoming fiscal year, which begins on the first of October.[184] In this request, the president advises Congress on how much they recommend for overall federal fiscal policy, such as how much money the federal government should spend and how much of a deficit it should run.[185] The House and Senate budget committees, using the president's proposed budget as a benchmark, then propose budget resolu-

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181 ALLEN SCHICK, THE FEDERAL BUDGET: POLITICS, POLICY, PROCESS 106 (3d ed. 2007).

182 Gillian E. Metzger, *Taking Appropriations Seriously*, 121 COLUM. L. REV. 1075, 1075 (2021).

183 *Policy Basics: Introduction to the Federal Budget Process*, CTR. ON BUDGET & POL'Y PRIORITIES (Oct. 24, 2022), https://www.cbpp.org/research/introduction-to-the-federal-budget-process [https://perma.cc/TGH7-5YAC].

184 *Id.*

185 *Id.*

tions that set targets for spending and tax revenue.[186] With the budget resolutions in hand, the House Appropriations Committee and Senate Appropriations Committee get to work.

The appropriations committees in the House and Senate are split up into twelve subcommittees.[187] Each subcommittee holds hearings to discuss budget requests and needs for any federal agency that falls under its jurisdiction.[188] The Subcommittee on Commerce, Justice, Science, and Related Agencies, for example, is responsible for funding the DOJ.[189] Each subcommittee chair then issues a "mark" recommending amounts for the agencies under his or her jurisdiction, and the full subcommittee follows suit by preparing a subcommittee bill, drafting a report explaining why it allocated funds the way it did, and providing guidance to the agencies it governs.[190] The full appropriations committee then reviews the subcommittee's bill, and it typically makes only minor changes to the bill. The subcommittee's bill must then pass the House and Senate, and the president must sign it by the start of the fiscal year on the first of October.[191]

Congress can also allocate funds to agencies outside of the formal appropriations process. Consider, for example, President Biden's Build Back Better Act. Although that bill died in the Senate, the House passed it by a slim margin.[192] Subtitle D(a)(1) of Title II of the Build Back Better Act states that "in addition to amounts otherwise available, there are appropriated to the Secretary for fiscal year 2022, out of any money in the Treasury not otherwise appropriated, to remain available until September 30, 2031 . . . $1,800,000,000 for hazardous fuels reduction projects . . . within the wildland-urban inter-

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186 Karen Yourish & Laura Stanton, *A Guide to the Federal Budget Process*, WASH. POST, https://www.washingtonpost.com/wp-srv/special/politics/federal-budget-process/budgetprocess.pdf [https://perma.cc/FH8J-48ZY].

187 JAMES V. SATURNO, CONG. RSCH. SERV., RL31572, APPROPRIATIONS SUBCOMMITTEE STRUCTURE: HISTORY OF CHANGES FROM 1920 TO 2023 1, 11–12 (2021).

188 *See id.* at 1.

189 *Subcommittees*, HOUSE APPROPRIATIONS COMM., https://appropriations.house.gov/subcommittees/commerce-justice-science-and-related-agencies/commerce-subcommittee-jurisdiction [https://perma.cc/A853-PW9T].

190 SCHICK, *supra* note 181, at 234 tbl. 9-6.

191 Metzger, *supra* note 182, at 1090. The subcommittee bills can then be consolidated into a consolidated appropriations act that includes the 12 regular appropriations bills that fund federal agencies for a fiscal year. *See, e.g.*, Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, 136 Stat. 49 (2022).

192 *House Votes to Advance "Build Back Better Act" with Historic Affordable Housing Investments*, NAT'L LOW INCOME HOUS. COAL. (Nov. 22, 2021), https://nlihc.org/resource/house-votes-advance-build-back-better-act-historic-affordable-housing-investments [https://perma.cc/W65S-RCPL].

face."[193] Unlike appropriations bills, which still stand a chance of surviving a divided Senate,[194] these pieces of legislation are unlikely, in today's highly polarized climate, to get sixty votes. For this reason, both parties have resorted to the process of budget reconciliation.

Budget reconciliation is a creature of the Congressional Budget Act of 1974.[195] It is a special legislative procedure that allows for expedited consideration of certain tax, spending, and debt limit legislation.[196] Congress originally intended to use the procedure as a means of reconciling revenue streams and direct spending under existing laws with new levels of spending that it set forth in a budget resolution.[197] But because bills passed through budget reconciliation need only pass a simple majority in the Senate, the procedure has since emerged as a tactic for both parties to advance controversial legislation.[198] Democrats used reconciliation to pass some health care changes in 2010, and Republicans used it to pass the Tax Cuts and Jobs Act of 2017.[199] Congress may not, however, use budget reconciliation to pass any kind of bill.[200] Any legislation Congress attempts to pass through the procedure is subject to the Byrd Rule, which disqualifies legislative provisions from a reconciliation bill if they produce no budgetary effects or have effects only incidental to the policy change.[201] The Senate parliamentarian is responsible for monitoring compliance with the

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193 Inflation Reduction Act of 2022, Pub. L. No. 117-169, tit. I, § 23001(a) 136 Stat. 1818, 2023 (2022).

194 The appropriations bill for fiscal year 2022 passed the Senate by a vote of sixty-eight to thirty-one. *President Biden Signs into Law FY22 Spending Bill with Increased Funding for Housing*, NAT'L LOW INCOME HOUS. COAL. (May 14, 2022), NAT'L LOW INCOME HOUS. COAL., https://nlihc.org/resource/president-biden-signs-law-fy22-spending-bill-increased-funding-housing [https://perma.cc/P7RG-JC9Z].

195 *See* Congressional Budget and Impoundment Control Act of 1974, Pub. L. No. 93-344, § 310, 88 Stat. 297, 315–16 (1974) (codified as amended at 2 U.S.C. § 641).

196 Richard Kogan & David Reich, *Introduction to Budget "Reconciliation,"* CTR ON BUDGET & POL'Y PRIORITIES (May 6, 2022), https://www.cbpp.org/research/federal-budget/introduction-to-budget-reconciliation [https://perma.cc/2RYY-3AHN].

197 SCHICK, *supra* note 181, at 142.

198 *See* Eric McDaniel & Kelsey Snell, *A $1.5 Trillion Question: What is Budget Reconciliation? Here's an Explainer*, NPR (Nov. 4, 2021), https://www.npr.org/2021/09/14/1026519470/what-is-budget-reconciliation-3-5-trillion [https://perma.cc/5TLA-HMXF].

199 *Id.*

200 *See id.*

201 *What Is Budget Reconciliation?*, PETER G. PETERSON FOUND. (July 14, 2021), https://www.pgpf.org/budget-basics/what-is-budget-reconciliation [https://perma.cc/5QQ2-LMRR].

Byrd Rule.[202] Just recently, for example, the Senate parliamentarian determined that a provision for immigration reform that Democrats placed in the Build Back Better Act violated the Byrd Rule because it would create a new class of 6.5 million eligible individuals.[203] It was thus a "substantial policy change[ ] with lasting effects [that would] outweigh [its] budgetary impact."[204]

Another way for Congressional representatives to strategically enact substantive, non-budgetary policies is through the use of appropriations riders. Appropriations riders are provisions that members of Congress place in appropriations legislation to restrict agencies from using their funds for purposes that the agency would otherwise be statutorily authorized to undertake.[205] Riders thus change governmental policy because they impede the executive branch from pursuing particular agency initiatives that might be unpopular with a representative's constituents or the country as a whole.[206] For this reason, scholars have referred to them as limitation riders because they limit bureaucratic decision making.[207] Members of Congress often include—or attempt to include—riders in spending bills because they expect their colleagues to compromise on the bill's contents.[208] Delaying passage of an appropriations bill can, after all, shut the government down. When the government shuts down, federal agencies must discontinue all non-essential discretionary functions.[209]

Consider the following limitation rider from H.R. 2471-Consolidated Appropriations Act, 2022, the appropriations bill that President Biden signed in March of this year. It states, in relevant part, that "[n]one of the funds made available under this Act to the Department of Justice may be used, with respect to any of the States . . . to prevent any of them from implementing their own laws that authorize the use, distribution, posses-

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202 *See* McDaniel & Snell, *supra* note 198.

203 Marianne Levine, *Senate Parliamentarian Rejects Latest Dem Proposal on Immigration*, POLITICO (Dec. 16, 2021), https://www.politico.com/news/2021/12/16/senate-parliamentarian-rejects-latest-dem-proposal-on-immigration-525195 [https://perma.cc/P5QQ-9CYZ].

204 *Id.*

205 Metzger, *supra* note 182, at 1093.

206 *Id.*

207 *See* Jason A. MacDonald, *Limitation Riders and Congressional Influence over Bureaucratic Policy Decisions*, 104 AM. POL. SCI. REV. 766, 766 (2010).

208 *See id.* at 774.

209 *Q&A: Everything You Should Know About Government Shutdowns*, COMM. FOR A RESPONSIBLE BUDGET (Dec. 12, 2022) https://www.crfb.org/papers/qa-everything-you-should-know-about-government-shutdowns [https://perma.cc/TDV9-A9UU].

sion, or cultivation of medical marijuana."[210] This limitation rider is known as the Rohrabacher-Farr Amendment or the Rohrabacher-Blumenauer Amendment because former U.S. Representative Dana Rohrabacher introduced the amendment in 2014.[211] Its history is illustrative. Representative Rohrabacher and the amendment's original sponsor, Representative Maurice Hinchey, tried—but failed—to add the amendment to spending legislation many times before 2014. When Congressman Rohrabacher finally succeeded, Congressman Hinchey had retired, and Congressman Sam Farr of California joined him as co-sponsor. By that time many more members of Congress represented places where people were lawfully using medical marijuana under their states' laws.[212] By a vote of 219 to 189 in the House, Congressman Rohrabacher and Congressman Farr finally succeeded in adding the amendment to the final spending bill in 2014.[213] Congress has since renewed the amendment in its appropriations bills for every fiscal year since then.[214] Thus, for the fiscal year of 2022, the DOJ is prohibited from using any of the funds it receives from Congress to prosecute, say, an owner of a marijuana dispensary in Colorado for giving out medical marijuana.[215] It is as if Congress enacted substantive legislation making medical marijuana legal.

VI
A LIMITATION RIDER FOR SUPERVISED CONSUMPTION SITES

Administrative law offers harm reductionists no legal recourse, and prosecutorial discretion is an unreliable protection from federal criminal liability. Harm reductionists should thus lobby a member of Congress to place an amendment modeled on the Rohrabacher-Farr Amendment in the appropriations bill for fiscal year 2023. As it turns out, a member of Congress has already introduced such an amendment.

In 2019, U.S. Representative Pramila Jayapal offered the following amendment in advance of the DOJ's budget hearing

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210 Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 531, 136 Stat. 49, 150–51 (2022).

211 Tom Angell, *Federal Medical Marijuana Amendment Author Dies At 79*, MARIJUANA MOMENT (Nov. 24, 2017), https://www.marijuanamoment.net/federal-medical-marijuana-amendment-author-dies-79/[https://perma.cc/STF8-VZB7].

212 *Id.*

213 *Id.*

214 *Id.*

215 Consol. Appropriations Act § 531. The text of the amendment applies only to medical marijuana, but it has, in effect, restricted the DOJ from targeting dispensaries of recreational marijuana as well.

for the fiscal year of 2020: "[n]one of the funds made available by this Act may be used to prohibit States and localities from establishing or implementing safe consumption sites."[216] The Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies did not add the amendment to its subcommittee appropriation bill for that year, and Representative Jayapal has not offered it again since.[217] Unfortunately, the amendment is now more urgent than ever.

U.S. Representative Matt Cartwright is the chairman of the Commerce, Justice, and Science ("CJS") Subcommittee of the House Appropriations Committee for the 117th Congress.[218] In this capacity, he oversees more than $70 billion in annual federal spending on matters of economic development, law enforcement, science, and innovation. Of course, he is also responsible for funding the DOJ.[219] Representative Cartwright represents Pennsylvania's 8th Congressional District, which encompasses all of Wayne, Pike, and Lackawanna counties, along with portions of Luzerne and Monroe counties.[220]

Lackawanna County, like most counties throughout the nation, is no stranger to the drug overdose crisis. Indeed, overdose deaths from pure fentanyl have doubled in the county since 2020, and the drug was involved in 92% of overdose deaths in the county for 2021.[221] The chief of police in Scran-

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216 PRAMILA JAYAPAL, AMENDMENT TO DIVISION A OF RULES COMMITTEE PRINT 116-18 (COMMERCE, JUSTICE, SCIENCE AND RELATED AGENCIES APPROPRIATIONS DIVISION) (2019); The Editorial Board, *As Philadelphia Stalls on Supervised Injection, Other Places Take up the Debate. Even Congress.*, PHILA. INQUIRER (June 17, 2019), https://www.inquirer.com/opinion/editorials/safe-supervised-injection-consumption-sites-department-justice-amendment-pramila-jayapal-20190617.html [https://perma.cc/Z5Z7-SCUL].

217 *See H.R. 3055 - Commerce, Justice, Science, Agriculture, Rural Development, Food and Drug Administration, Interior, Environment, Military Construction, Veterans Affairs, Transportation, and Housing and Urban Development Appropriations Act, 2020*, Comm. on Rules, https://rules.house.gov/bill/116/hr-3055 [https://perma.cc/SBW9-D23D] (last visited July 13, 2023).

218 Press Release, Matt Cartwright, U.S. Representative, House of Representatives, Cartwright Officially Named Chairman of Powerful Appropriations Subcommittee (Jan. 25, 2021), https://cartwright.house.gov/news/documentsingle.aspx?DocumentID=391504 [https://perma.cc/4KNX-7DRR].

219 *Id.*

220 *See District*, CARTWRIGHT FOR CONG., https://cartwrightcongress.com/district/ [https://perma.cc/KP3G-PFH2] (last visited July 13, 2023).

221 Caroline Foreback, *Scranton Aims to Reduce OD Deaths, Considers Decriminalizing Fentanyl Testing Strips*, PA HOMEPAGE (Sept. 21, 2021), https://www.pahomepage.com/top-stories/scranton-aims-to-reduce-od-deaths-considers-decriminalizing-fentanyl-testing-strips/ [https://perma.cc/XM4Z-RMCY]; Elizabeth Worthington, *New Trends in Opioid Crisis Alarming Lackawanna County Officials*, WNEP (Sept. 7, 2021), https://www.wnep.com/article/news/local/lackawanna-county/new-trends-in-opioid-crisis-alarming-lackawanna-county-

ton, the county's largest city, said that the opioid crisis is worse than he has ever seen it.[222] Fortunately, the county is also no stranger to the benefits of harm reduction. Scranton's mayor, Paige Cognetti, proposed an ordinance that would prevent police from arresting people for possessing or distributing fentanyl test trips for harm reduction purposes.[223] The city's council did not pass the ordinance, but it was a step in the right direction. For these reasons, Representative Cartwright is a prime target for lobbying efforts to put a rider in his subcommittee's appropriations bill. With a rider in place, Scranton's city council members might feel emboldened to open a supervised consumption site knowing that they would escape federal prosecution. At the very least, they might stop their city's police force from arresting people who take matters into their own hands by testing their drugs for fentanyl. Immunizing harm reductionists in Lackawanna County from federal prosecution would be especially meaningful because the county falls under the Third Circuit's jurisdiction.

Representative Jayapal's district in Washington state has fared no better since she introduced the supervised consumption site amendment in 2019. Her district encompasses King County, Washington, where Seattle is based.[224] In 2021, there were 388 fentanyl-involved deaths in King County, a more than double increase from the number of fentanyl-involved deaths in 2020.[225] The county also set a record in 2021 for total drug and alcohol overdose deaths, with 709 people dying. University of Washington researcher Caleb Banta-Green said that in her 20 years of experience, "fentanyl's growth is the biggest, fastest shift we've ever seen—and also the most lethal."[226] Seattle actually came close to opening a supervised consumption site.[227] In 2021, Seattle's city council included in its annual

officials/523-8b60823e-8bf0-492a-b116-e6b944298304 [https://perma.cc/NEV2-EJ6C].

222 *See* Worthington, *supra* note 221.

223 Foreback, *supra* note 221.

224 *See Our District*, CONG. PRAMILA JAYAPAL, https://jayapal.house.gov/our-district/ [https://perma.cc/C8VE-BCAF] (last visited July 13, 2023).

225 Daniel Beekman, *UW Survey of Drug Users Shows Fentanyl Surge as King County Sets Record for Overdose Deaths*, SEATTLE TIMES (Mar. 10, 2022), https://www.seattletimes.com/seattle-news/uw-survey-of-drug-users-shows-fentanyl-surge-as-king-county-sets-record-for-overdose-deaths/ [https://perma.cc/3D8F-5N5F].

226 *Id.*

227 *See* Jake Goldstein-Street, *Amid Record Spike in Overdoses and with Money to Spend, Seattle and County Still Working on Plan for 'Supervised Consumption,'* CAPITOL HILL SEATTLE BLOG (Jan. 21, 2021), https://www.capitolhillseattle.com/2021/01/amid-record-spike-in-overdoses-and-with-

budget $1.12 million for health services for drug users. But the money was never spent, and the project appears to have stalled. If Representative Jayapal re-introduces and successfully includes the amendment in the appropriations bill for 2023 or any year thereafter, harm reductionists just might get the boost they need to open that site in Seattle. And even if momentum on the project remains stalled, she will have done more than just remain passive as people in her district die on the streets of the cities and towns she represents.

Surveying the damage done by the drug overdose crisis in every congressional district in the nation is beyond the scope of this note. Preliminary research into each of these districts would likely reveal that the drug overdose crisis has left its mark in one devastating way or another. Harm reductionists thus need to marshal all available resources and begin a lobbying campaign to get a member of Congress—Representative Jayapal is a promising start—to insert the same limitation rider Representative Jayapal once proposed in the appropriations bill for fiscal year 2023. The amendment may—and likely will—fail on its first attempt, and it may even fail the year after that. For instance, the Rohrabacher-Farr amendment failed five more times after Congressmen Rohrabacher and Hinchey introduced it in 2003.[228] But eventually that amendment succeeded, and due to political momentum and a nationwide shift in tolerance for marijuana, it has made its way into our annual appropriations bills every year since. Harm reductionists need to get the ball rolling so that a limitation rider for supervised consumption sites can undergo the same fate.

VII
THE OBSTACLES

A limitation rider would provide harm reductionists with far more security than a non-binding statement from the DOJ that it will not bring federal criminal charges against them.

And since the FDA appears unwilling to initiate an prescription-to-OTC switch for injectable naloxone—a life-saving drug that is already notoriously difficult for poorly funded

money-to-spend-seattle-and-county-still-working-on-plan-for-supervised-consumption/ [https://perma.cc/2QB4-YWGR].

228 *See* Michelle Rutter, *Appropriations and Cannabis (Part 2): Why It Matters*, NAT'L CANNABIS INDUSTRY ASS'N (Sept. 25, 2018), https://thecannabisindustry.org/tag/hinchey-rohrabacher-amendment/ [https://perma.cc/YCL8-THJS].

groups to obtain[229]—a rider would also ensure that drug users can find a place where the drug will be adequately stocked. Nevertheless, if harm reductionists succeed in getting a rider passed, they must remain vigilant. For example, even if Congress manages to pass an appropriations bill that contains a rider preventing the DOJ from going after supervised consumption sites, there is no guarantee that it will renew the rider the following fiscal year. Moreover, if the government shuts down because Congress has failed to pass a spending bill, so too will the rider expire. And finally, harm reductionists must grapple with the possibility that some federal judges will uphold a DOJ prosecution even with the rider in place.

Consider the Hyde Amendment, a legacy rider that has appeared in the annual subcommittee appropriations bill for the Department of Health and Human Services in every fiscal year since 1976.[230] The Hyde Amendment blocks federal Medicaid funding for abortion services. In H.R. 2471, the appropriations bill for fiscal year 2022, the amendment states that "[n]one of the funds appropriated in this Act . . . shall be expended for any abortion," and "none of the funds appropriated in this Act . . . shall be expended for health benefits coverage that includes coverage of abortion."[231] When President Biden was campaigning for the presidency, he promised to remove the amendment from his budget proposal if he were elected.[232] He fulfilled his campaign promise by omitting the amendment from the budget plan that he released in May 2021,[233] and the House followed suit by passing a spending bill the following month that also excluded the amendment.[234] But conservative lawmakers were staunchly opposed to passing a spending bill

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229 *See* Nabarun Dasgupta, Oral Comments Made During the Reagan-Udall Foundation for FDA Meeting on Naloxone Access (Mar. 29, 2022), https://cdr.lib.unc.edu/concern/scholarly_works/rr172678t?locale=EN [https://perma.cc/R2ZQ-GTHZ].

230 *See Hyde Amendment*, PLANNED PARENTHOOD, HTTPS://WWW.PLANNEDPARENTHOODACTION.ORG/ISSUES/ABORTION/FEDERAL-AND-STATE-BANS-AND-RESTRICTIONS-ABORTION/HYDE-AMENDMENT [https://perma.cc/D96S-GB88] (last visited Apr. 24, 2023).

231 Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, §§ 506(a), 202–203, 136 Stat. 49, 131, 496 (2022).

232 *See* Sarah McCammon, *Biden's Budget Proposal Reverses a Decades-long Ban on Abortion Funding*, NPR (May 31, 2021), https://www.npr.org/2021/05/31/1001881788/bidens-budget-proposal-reverses-a-decades-long-ban-on-abortion-funding [https://perma.cc/PX8E-49M2].

233 *Id.*

234 *See* Brent D. Griffiths, *Biden Will Be Forced to Sign a Restriction on Abortion Funding after Democrats Caved to Republican Demands*, INSIDER (Mar. 9, 2022), https://www.businessinsider.com/biden-hyde-amendment-repeal-house-spending-plan-ukraine-2022-3 [https://perma.cc/9CE6-VSAV].

without the Hyde Amendment included, so Democrats compromised and added it to the bill that is now H.R. 2471, Consolidated Appropriations Act, 2022.[235] But for the second year in a row, President Biden has excluded the controversial amendment from his budget proposal.[236] The amendment will likely make its way back into the appropriations bill for fiscal year 2023, but the exclusion is, for now, promising to those who want women on Medicaid to have better access to abortion.

The battle over the Hyde Amendment illustrates how limitation riders operate on shaky political ground. If Democrats controlled both the House and the Senate with more commanding majorities, the Hyde Amendment would likely have disappeared from the appropriations bill for fiscal year 2022. This should certainly give harm reductionists pause, because even if the rider makes its way into a bill under President Biden, it could easily be omitted from his successor's budget proposal. If Republicans then control both houses of Congress, the rider might vanish, and supervised consumption sites would be at risk. Still, the battle over the Hyde Amendment does show that riders build up political momentum. Republicans were steadfast in their refusal to sign the bill without the amendment included.[237] Indeed, once Congress adds a rider to an appropriations bill, it often remains embedded in spending bills year after year.[238] And unlike bills passed through budget reconciliation, spending bills need sixty votes, so both parties must come to the bargaining table and make tough concessions.

Government shutdowns also place limitation riders in peril. Government shutdowns have a constitutional basis. Article I, Section 9, clause 7 of the Constitution states that "[n]o money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law."[239] In other words, federal agencies cannot spend their funds unless Congress has, by law, appropriated that money to them. Scholars refer to this clause as the appropriations clause.[240] So when Congress fails to fund agencies on time for the new fiscal year, the govern-

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235 *See id.*

236 *See id.*

237 *See id.*

238 Lisa Gilbert, *Harmful Legacy Riders Must Stay Out of the Annual Spending Package*, THE HILL (Nov. 8, 2021), https://thehill.com/blogs/congress-blog/economy-budget/580653-harmful-legacy-riders-must-stay-out-of-the-annual-spending/ [https://perma.cc/MUX4-KV9N].

239 U.S. CONST. art. 1, § 9, cl. 7.

240 *See Metzger*, *supra* note 182, at 1078.

ment shuts down.[241] Because limitation riders do not exist unless there is spending legislation in place that funds the government, riders expire when the government shuts down, and a window conceivably opens for, say, the DOJ to prosecute people who run medical marijuana dispensaries. Indeed, when Jeff Sessions was AG, cannabis law practitioners paid close attention to the prospect of a looming government shutdown and the attendant reality that the Rohrabacher-Farr Amendment would expire.[242] Nevertheless, employees of federal agencies are statutorily prohibited from spending money without an appropriations bill,[243] and in the 1980s the Attorney General issued two opinions that made abundantly clear that agencies cannot spend any money unless Congress has passed an appropriations bill.[244] If the DOJ thus tried to prosecute operators of a supervised consumption site while the government was shut down, they would be, strictly speaking, violating the law. It is also unlikely that an agency like the DOJ would expend its finite resources on an enforcement action if it knew that Congress could pass a spending bill at any time that would immediately bring the investigation to a halt.

Harm reductionists also cannot overlook the reality that federal judges can be quite creative with how they interpret statutes. Two judges can arrive at radically different readings of statutory language by employing different canons of statutory interpretation, assigning varying degrees of weight to legislative history, and, in some cases, considering only how a reading of the language will achieve the policy result they think is best. Limitation riders are statutory text, so judges can easily expand or restrict what riders cover by using these interpre-

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241 Vox, *Why the US Government is Always Shutting Down*, YOUTUBE (Nov. 29, 2021), https://www.youtube.com/watch?v=kdv07eIC8Wg [https://perma.cc/42SC-2ZN5].

242 *See, e.g.*, *Protection against DoJ Interference with State Medical Cannabis Programs Extended until Dec. 8*, THOMPSON COBURN LLP (Sept. 18, 2017), https://www.thompsoncoburn.com/insights/blogs/tracking-cannabis/post/2017-09-18/protection-against-department-of-justice-interference-with-state-medical-cannabis-programs-extended-until-dec.-8 [https://perma.cc/SNB8-Z8AY] (analyzing the impact of a short-term funding deal on medical cannabis programs); *Rohrabacher-Farr Amendment Renewed*, GREEN LIGHT LAW GROUP (May 4, 2017), https://greenlightlawgroup.com/blog/rohrabacher-farr-amendment-renewed [https://perma.cc/Z7KS-Z8XF] (analyzing risk to cannabis businesses); John Schroyer, *Rohrabacher-Blumenauer Amendment Extended until December*, MJBIZDAILY (Sept. 8, 2017), https://mjbizdaily.com/rohrabacher-blumenauer-amendment-extended-december/ [https://perma.cc/A4CE-N2EU] (describing extension of Rohrabacher Amendment).

243 31 U.S.C. § 1341.

244 Vox, *supra* note 241.

tive moves. In *United States v. McIntosh*, for example, the Ninth Circuit held that the DOJ could not use funds to prosecute individuals charged with a federal crime for distributing marijuana in California if they were complying with California's medical marijuana laws.[245] The panel divined the ordinary meaning of the language used in the Rohrabacher-Farr amendment to support its holding.[246] But a different Ninth Circuit panel might have relied more on legislative history to narrow the scope of the rider and affirm a prosecution. Moreover, this panel only remanded the case to the district court to determine whether the defendants had actually complied with state law.

More recently, the First Circuit held that the DOJ had lawfully prosecuted a group of Maine residents for violations of the Controlled Substances Act because these prosecutions were consistent with Maine's medical marijuana regulations.[247] The Rohrabacher-Farr Amendment, it reasoned, only prohibits the DOJ from prosecuting people if doing so prevents a state from giving practical effect to its medical marijuana laws.[248] It upheld the DOJ's indictment because the defendants used their medical marijuana licenses to cultivate and distribute hundreds of pounds of marijuana to people who were not qualifying patients under Maine law.[249] This conduct, it held, was plainly at odds with Maine's marijuana regulations, which expressly state that a cardholder cannot sell, furnish, or give marijuana to a person who is not allowed to possess it.[250] The First Circuit thus reasoned that immunizing this conduct from federal prosecution would "stretch the rider's language beyond its ordinary meaning."[251]

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245 833 F.3d 1163, 1177–79 (9th Cir. 2016), *remanded to* No. 14-CR-00016, 2017 WL 2695319 (N.D. Cal. Mar. 20, 2017); John Hudak, *McIntosh Decision Limits DOJ Powers, but Medical Marijuana Advocates Should Worry*, BROOKINGS (Aug. 19, 2016) https://www.brookings.edu/blog/fixgov/2016/08/19/mcintosh-decision-limits-doj-powers-but-medical-marijuana-advocates-should-worry/ [https://perma.cc/L4DX-JJQD].

246 *McIntosh*, 833 F.3d at 1177–1178.

247 United States v. Bilodeau, 24 F.4th 705, 708 (1st Cir. 2022), *cert. denied*, 142 S. Ct. 2875 (2022); Michael H. Sampson, *First Circuit's Recent Decision Allowing Federal Prosecutions Despite "Rohrabacher-Blumenauer" Far from Red Flag for Legitimate Cannabis Businesses*, LEECH TISHMAN FUSCALDO & LAMPL (Feb. 2, 2022), https://www.leechtishman.com/insights/blog/first-circuits-recent-decision-allowing-federal-prosecutions-despite-rohrabacher-blumenauer-far-from-red-flag-for-legitimate-cannabis-businesses/ [https://perma.cc/R7ZT-U5WK].

248 *Bilodeau*, 24 F.4th at 712–13.

249 *Id.* at 715.

250 *Id.*

251 *Id.* at 714.

In sum, even with a rider in the appropriations bill, harm reductionists would have to pay close attention to how federal judiciary interpreted its mandate. The DOJ might decide to roll the dice and prosecute, hoping to draw a favorable panel or appear before a favorable dtrict judge. And depending on a number of other factors, such as the judge's ideology and policy preferences, she might uphold that prosecution. Nevertheless, harm reductionists already must pay close attention to how the federal judiciary interprets the "Crack House Statute," which lends itself to more creative statutory interpretation than an appropriations rider. Additionally, if the rider's language is sufficiently clear and the scope of what it covers adequately broad (Representative Jayapal's amendment serves as a good model), federal judges would have little wiggle room to expand or narrow the scope of the amendment. The lobbying campaign is thus worthwhile despite the risk that a federal judge might find a way to make the rider less reliable.

CONCLUSION

There are two supervised consumption sites operating in upper Manhattan's East Harlem and Washington Heights is-neighborhoods.[252] As of this writing, these sites have prevented more than 150 overdoses in roughly 9,500 visits.[253] More than 800 people have used the sites, and some have done so more than once.[254] We can estimate, then, that the sites have saved over a 100 lives, because some users may have overdosed twice.[255] The scope of the opioid crisis is so widespread today that it is easy for scholars, doctors—and even addicts—to become numb to the death toll. But although more than 100 people die from drug overdoses every day in this country, saving 100 lives is no insignificant feat.[256] It gives 100

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252 *See* Jeffrey C. Mays & Andy Newman, *Nation's First Supervised Drug-injection Sites Open in New York*, N.Y. TIMES (Nov. 30, 2021), https://www.nytimes.com/2021/11/30/nyregion/supervised-injection-sites-nyc.html [https://perma.cc/JQH2-UKKA].

253 Peltz & Balsamo, *supra* note 19.

254 *Id.*

255 The sites have likely saved more than 100 lives. Guy injected heroin at a supervised consumption site over 4,000 times, and he overdosed at the site four times. Using his experience as a model, we can assume a 0.1% overdose rate. At this rate, the odds that twenty–five people who visited New York's sites overdosed more than once opened are low. But a safe estimate serves the purpose of this note.

256 *See Drug Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE (Feb. 9, 2023) https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates [https://perma.cc/SE4G-W5B2].

more people an opportunity to escape the grip of addiction and discover what else life has to offer. It gives 100 more people an opportunity to educate future generations about the perils of drug use and the importance of using alcohol and prescription medication responsibly. And it gives 100 more people a chance to prove to skeptics that harm reduction—not harsh criminal sanctions, shame, and death—is the most effective strategy at reducing the damage that the drug overdose crisis has done to our nation.

Guy Felicella is a living, breathing embodiment of what supervised consumption sites can do. Without them, he would be dead. Instead, just recently, Guy spoke to medical students at the University of British Columbia about the consequences homelessness has on a person's health. Guy can speak on this topic because Guy lived this topic; he offers a perspective that no textbook or pamphlet can adequately cover. He also attends school districts and universities to educate students on addiction.[257] He devotes his spare time to raising his children and collecting rare National Hockey League hockey cards. In short, he lives a purpose-driven, rich, fulfilling life. None of it would be possible without the compassion that supervised consumption sites showed him and the Canadian government's progressive embrace of harm reduction.[258]

A limitation rider will not solve the overdose crisis—it will not rid the drug supply of fentanyl, prevent people from consuming counterfeit pills, or resolve the mental health crisis that drives so many to use drugs in the first place.[259] What it will do is simply reduce the damage that the overdose crisis can do. It will prevent a less progressive attorney general from marshalling all the resources of the DOJ to prosecute "heroin shooting galleries,"[260] and it will make it more challenging for federal judges to uphold their prosecutions based on their preferred reading of the governing statute. This country does not need more people to die. Enough have already lost their lives to drugs and alcohol, and enough families have suffered for it. The lobbying campaign for a limitation rider must begin today,

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257 Email Interview with Guy Felicella, *supra* note 1.

258 *Id.*

259 *See, e.g.*, *The State of Mental Health in America*, MENTAL HEALTH AM., https://www.mhanational.org/issues/state-mental-health-america [https://perma.cc/UA2F-4C5L].

260 *See* Georgett Roberts & Julia Marsh, *De Blasio Opening First Legal Shooting Galleries for Drug Users in the US*, N.Y. POST (Nov. 30, 2021), https://nypost.com/2021/11/30/de-blasio-opening-supervised-injection-sites-for-drug-users-in-nyc/ [https://perma.cc/V8BA-FLR7].

and it must persist even if the amendment fails for fiscal year 2023 and fiscal year 2024. The lives of those currently caught in addiction's grip depend on it.