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May 15, 2024

The Honorable Chuck Schumer Majority Leader United States Senate Washington, D.C. 20510 The Honorable Mitch McConnell Republican Leader United States Senate Washington, D.C. 20510

Dear Majority Leader Schumer, Minority Leader McConnell, and Honorable Members of the Senate:

The R Street Institute, a nonpartisan public policy research organization, opposes the Combating Illicit Xylazine Act (H.R. 1839/S. 993), currently filed as an amendment to the FAA Reauthorization Act of 2024.ⁱ

This legislation would place xylazine on the Controlled Substances Act (CSA) alongside Schedule III drugs, and would criminalize the unauthorized human use and distribution of xylazine – a veterinary sedative known colloquially as "tranq."ⁱⁱ However, doing so would bypass relevant scientific and medical evaluations and recommendations, and thus may have unintended consequences, such as hindering research and increasing overdose risk.

Why Scientific Assessment of Xylazine Matters

Last year, more than 112,000 people in the United States died of a drug overdose.ⁱⁱⁱ Although this crisis is currently driven by fentanyl, the core culprit is an unstable and opaque unregulated drug market that is contaminated by increasingly dangerous adulterants. Xylazine is one such adulterant that has begun to spread across the country, causing increased and understandable alarm. Xylazine can complicate overdoses and overdose response, and often leads to difficult-to-treat soft tissue wounds among people who inject drugs.^{iv} However, because xylazine is not typically used by or to treat humans, the scientific and medical communities have much to learn about this substance in order to understand the most effective ways to help people who take xylazine.

The eight-factor analysis conducted by the Department of Health and Human Services (HHS) as part of our typical drug scheduling process is a key step in gathering this initial knowledge.^v The process ensures a scientific evaluation of a given drug's true potential for misuse (a key criterion

for scheduling decisions) and pharmacological effects, among other things. To our knowledge, HHS has not yet made a recommendation to schedule xylazine or criminalize its use on par with Schedule III substances. However, evidence-based information should continue to be a fundamental part of any drug scheduling decision, whether it happens via the relevant agencies or Congress.

For example, the vast majority of people who use drugs do not know whether xylazine is in their supply nor do they seek it out.^{vi} It is estimated that 99.5% of xylazine-involved deaths in 2021 also involved illicitly manufactured fentanyl or fentanyl analogues, substances that are already criminalized.^{vii} In fact, many actively try to avoid it due to concerns about excessive sedation and soft tissue injury.^{viii} These factors suggest that xylazine likely has low misuse potential on its own, and it would be important for that to be considered in any scheduling decisions.

Overcriminalization and Overdose

We all want our communities and our loved ones to be safe; however, criminalizing substances is not an effective way to prevent drug deaths. For example, despite the 2018 emergency class-wide scheduling of fentanyl related substances, fentanyl-involved overdoses have continued to climb.^{ix} Similarly, 2,727 people died of an overdose in Florida in 2018, the same year it placed xylazine on Schedule I of the state CSA; by 2023, that number had more than doubled, to 7,465.^x

Furthermore, increased criminalization of drug use may increase overdose risk in the short- and long-term. Faced with stigma and the threat of law enforcement interactions, individuals are more likely to use alone and less likely to practice harm reduction or call for emergency services.^{xi} In addition, while prohibition of individual substances may reduce their production and distribution, it has been shown to lead to an increasingly potent and opaque drug supply over time, a process often referred to as the "Iron Law of Prohibition."^{xii} These consequences are likely to have a disproportionate effect on people with substance use disorder (SUD). Nearly 9 of 10 individuals at the lowest levels of the drug distribution chain report using drugs, and almost half meet the criteria for a SUD.^{xiii}

Because scheduling substances is not an effective way to stop or even substantially slow overdoses, and overcriminalization comes with additional risks to people who use drugs, there is no benefit to moving forward without thorough scientific evaluation.

Scheduling Can Hinder Research

Rushing to schedule xylazine ahead of a scientific and medical evaluation of the substance may inadvertently create research restrictions just when we need more research to better understand xylazine's effects on humans. Such barriers could delay the development of xylazine-specific antidotes and treatment medications, for example.

Although Schedule III substances are not as tightly controlled as those on Schedule I, scientists still face logistical and time-related barriers to studying them.^{xiv} If our goal is to keep our communities and loved ones as safe and healthy as possible, researchers should be able to swiftly study xylazine to expand available prevention, harm reduction, and recovery-oriented tools. Furthermore, once a drug is placed on the CSA, "down-scheduling," though not unheard of, is a slow and potentially arduous process that can further delay scientific research (as is evidenced by the process of moving cannabis from Schedule I to Schedule III).^{xv}

Policy Solutions

We share Congress' concerns about the spread of xylazine (and other, emerging adulterants) in the illicit drug supply and applaud the intention of preventing overdose deaths and improving the safety of our communities and our loved ones. Toward that end, we urge this body to prioritize efforts that facilitate rather than hinder research into potentially harmful substances and improve access to evidence-based health interventions for people who use drugs and who suffer from substance use disorder.

Efforts such as funding for xylazine test strips are a start, but they are not enough.^{xvi} Lawmakers should also focus on supporting evidence-based education and prevention efforts, expanding overdose prevention resources–including naloxone access and community drug checking– improving Good Samaritan Laws, and reducing barriers to evidence-based drug treatment such as methadone.

Given the concerns outlined in this letter, we strongly urge Congress to seek and diligently consider scientific and medical assessments before placing xylazine or any other substance on the CSA. Scheduling alone does not curb deaths, and it comes with potentially serious consequences that must be weighed against any hoped-for benefits.

Thank you for taking the time to consider our position on this matter. Please let us know if you have any questions or wish to discuss our views further.

Sincerely,

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ⁱ S. 993, Combating Illicit Xylazine Act, 118th Congress, <u>https://www.congress.gov/bill/118th-congress/senate-bill/993/text</u>; "Cortez Masto Pushes Amendment to Must-Pass FAA Reauthorization to Pass her Combating Illicit Xylazine Act," Catherine Cortez Masto, May 2, 2024. <u>https://www.cortezmasto.senate.gov/news/press-</u>

releases/cortez-masto-pushes-amendment-to-must-pass-faa-reauthorization-to-pass-her-combating-illicit-xylazineact.

ⁱⁱⁱ Brian Mann and Aneri Pattani, "In 2023 fentanyl overdoses ravaged the U.S. and fueled a new culture war fight," NPR, Dec. 28, 2023. <u>https://www.npr.org/2023/12/28/1220881380/overdose-fentanyl-drugs-</u>

^{iv} "What You Should Know About Xylazine," Centers for Disease Control and Prevention, Feb. 22, 2024.

https://www.cdc.gov/drugoverdose/deaths/other-drugs/xylazine/faq.html.

^v German Lopez, "The federal drug scheduling system explained," *Vox,* August 11, 2016, <u>https://www.vox.com/2014/9/25/6842187/drug-schedule-list-marijuana</u>.

^{vi} David T. Zhu, "Public health impact and harm reduction implications of xylazine-involved overdoses: a narrative review," *Harm Reduction Journal*, 20: 131, (Sept. 12, 2023).

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10498612.

^{vii} *Fentanyl Adulterated or Associated with Xylazine Response Plan,* Office of National Drug Control Policy, The White House, July 2023. <u>https://www.whitehouse.gov/wp-content/uploads/2023/07/FENTANYL-ADULTERATED-OR-</u>ASSOCIATED-WITH-XYLAZINE-EMERGING-THREAT-RESPONSE-PLAN-Report-July-2023.pdf.

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^{ix} Synthetic Opioids: Considerations for the Class-Wide Scheduling of Fentanyl-Related Substances, U.S. Government Accountability Office, GAO-21-499, April 12, 2021. <u>https://www.gao.gov/products/gao-21-499</u>; National Center for Health Statistics, "Provisional Drug Overdose Counts," *National Vital Statistics System*, Centers for Disease Control and Prevention, Last accessed May 8, 2024. <u>https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm</u>.

* "CHAPTER 2018-13." Committee Substitute for Committee Substitute for House Bill No. 21, March 19, 2018.
 https://laws.flrules.org/files/Ch_2018_013.pdf; National Center for Health Statistics.

^{xi} Joseph G. Rosen et al., "Safety in solitude? Competing risks and drivers of solitary drug use among women who inject drugs and implications for overdose detection," *Addiction*, 118: 5, (May 2023), pp. 847-854.

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<u>https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2023.307291</u>; Jeffrey A. Singer, "The Iron Law of Prohibition: Introducing 'Tranq,'" Cato Institute, Feb. 13, 2023. <u>https://www.cato.org/blog/iron-law-prohibition-introducing-</u>

ⁱⁱ "What You Should Know About Xylazine," Centers for Disease Control and Prevention, Feb. 22, 2024. <u>https://www.cdc.gov/drugoverdose/deaths/other-drugs/xylazine/faq.html</u>.

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^{xiv} Michael H. Andreae et al., "An ethical exploration of barriers to research on controlled drugs," *American Journal of Bioethics*, 16: 4, (April 2016), pp. 36-47. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4849133</u>.

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^{xvi} "FACT SHEET: Biden-Harris Administration Launches the White House Challenge to Save Lives from Overdose," The White House, March 13, 2024. <u>https://www.whitehouse.gov/briefing-room/statements-</u>

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