

United States Senate

WASHINGTON, DC 20510

August 6, 2024

The Honorable Merrick Garland
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530

The Honorable Anne Milgram
Administrator
United States Drug Enforcement
Administration
8701 Morrisette Drive
Springfield, VA 22152

The Honorable Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Attorney General Garland, Commissioner Califf and Administrator Milgram:

We write to express continued concern about the lack of rigorous federal oversight of lethal injection drugs. On May 22, 2024, we wrote to you to highlight concerns about the hands-off regulatory approach the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) appear to have taken regarding drugs intended for executions.¹ We requested that the Department of Justice immediately rescind the Office of Legal Counsel's (OLC) Trump-era memorandum opining that the FDA lacks jurisdiction over drugs intended for executions,² and we urged the FDA to exercise its authority to regulate these drugs. Since then, new reports have confirmed ongoing abuses, reinforcing the need for enhanced regulatory scrutiny of lethal injection drugs.³

The supply chains for lethal injection drugs are shrouded in secrecy.⁴ The clandestine nature of the supply makes it difficult to ensure that the drugs meet necessary safety standards. The drugs themselves are often poor quality and compounded, resulting in shorter shelf lives and a higher potential for contamination.⁵ The combination of illicit drug procurement, poor-quality drugs mixed

¹ Office of U. S. Senator Elizabeth Warren, "Warren, Booker, Senators Call On Federal Agencies to Regulate Lethal Injection Drugs," press release, May 22, 2024, <https://www.warren.senate.gov/newsroom/press-releases/warren-booker-senators-call-on-federal-agencies-to-regulate-lethal-injection-drugs>.

² Letter from Senator Elizabeth Warren to U.S. Attorney General Merrick Garland, May 21, 2024, <https://www.warren.senate.gov/imo/media/doc/52124finaldojoletter.pdf>; Department of Justice, Office of Legal Counsel, "Opinion: Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions," May 3, 2019, <https://www.justice.gov/olc/opinion/file/1162686/dl?inline>.

³ National Public Radio, "Unmarked cars and secret orders: How a pharmacy prepared drugs for Texas' executions," Chiara Eisner, July 10, 2024, <https://www.npr.org/2024/07/10/g-s1-9016/unmarked-cars-and-secret-orders-how-a-pharmacy-prepared-drugs-for-texas-executions>.

⁴ The Hill, "Black death row inmates suffer more botched lethal injections than white inmates: Report," Cheyanne M. Daniels, April 18, 2024, <https://thehill.com/homenews/race-politics/4602507-black-death-row-inmates-botched-lethal-injections/>.

into untested cocktails, and expedited procedures contributes to botched executions⁶ — which Black people on death row have faced at an approximately 220% higher rate than their White counterparts.⁷

A new investigation released last month has demonstrated why it is critical for the DEA and FDA to promptly increase their enforcement of regulations regarding dangerous drugs used in lethal injections.⁸ Texas resorted to sourcing lethal injection drugs from a compounding pharmacy in San Antonio, the Rite-Away Pharmacy, after major pharmaceutical companies refused to sell such drugs to the state. National Public Radio (NPR) revealed troubling practices at the Rite-Away.⁹ The pharmacy has a history of citations for safety and cleanliness violations, including a failure to maintain sterile conditions and improper record-keeping, among other infractions.¹⁰ Employees delivered the drug ingredients in unmarked vehicles to avoid attracting attention.¹¹ Another branch of the same pharmacy had previously been sued by the federal government for dispensing medications without valid prescriptions, falsifying records, and providing high doses of fentanyl without a legitimate medical purpose¹² — suggesting a pattern of wrongdoing by the pharmacy that Texas selected as its lethal injection supplier.

⁵ Texas Defender Service, “BREAKING: Texas Supplies its Execution Drugs from a Pharmacy That Has Been Sanctioned by the DEA,” Texas Defender, July 10, 2024, <https://www.texasdefender.org/texas-execution-drugs-pharmacy-sanctioned-dea/>.

⁶ Death Penalty Information Center, “Behind the Curtain: Secrecy and the Death Penalty in the United States,” Robin Konrad, Robert Dunham, and Ngozi Ndulue, November 20, 2018, <https://deathpenaltyinfo.org/facts-and-research/dpic-reports/in-depth/behind-the-curtain-secrecy-and-the-death-penalty-in-the-united-states>; USA Today, “State try to obscure execution details as drug makers hinder lethal injection,” Renuka Rayasam, March 29, 2023, <https://www.usatoday.com/story/news/health/2023/03/29/states-obscure-execution-details-drugmakers-hinder-lethal-injection/11550570002/>; North Carolina Law Review, “The Sound of Death and ‘Shroud of Secrecy’: The Ninth Circuit’s Inconsistent Application of the History and Logic Test in *First Amendment Coalition of Arizona, Inc. v. Ryan*,” Isabela Palmieri, September 1, 2021, https://scholarship.law.unc.edu/nclr/vol99/iss6/5/?utm_source=scholarship.law.unc.edu%2Fncclr%2Fvol99%2Fiss6%2F5&utm_medium=PDF&utm_campaign=PDFCoverPages; Reprieve, “Everything you didn’t know about lethal injections: they’re cruel, unusual and racist,” April 18, 2024, <https://reprieve.org/uk/2024/04/18/everything-you-didnt-know-about-lethal-injections-theyre-cruel-unusual-and-racist/>.

⁷ Reprieve, “Lethal Injection in the Modern Era,” Apr. 17, 2024, https://reprieve.org/wp-content/uploads/sites/2/2024/04/2024_04_17_PUB-Botched-lethal-injection-report-FINAL.pdf.

⁸ National Public Radio, “Unmarked cars and secret orders: How a pharmacy prepared drugs for Texas’ executions,” Chiara Eisner, July 10, 2024, <https://www.npr.org/2024/07/10/g-s1-9016/unmarked-cars-and-secret-orders-how-a-pharmacy-prepared-drugs-for-texas-executions>.

⁹ *Id.*

¹⁰ *Id.*; News Nation, “Texas bought execution drug from compound pharmacy: Report,” Casey Buchman, July 11, 2024, <https://www.newsnationnow.com/us-news/southwest/texas-bought-execution-drug-compound-pharmacy-report/#:~:text=Inspection%20documents%20revealed%20that%20Rite.other%20violations%2C%E2%80%9D%20NPR%20wrote>.

¹¹ Austin Chronicle, “Texas’ Secret Supplier of Execution Drugs is Accused of Enabling Drug Dealing,” Brant Bingamon, July 19, 2024, <https://www.austinchronicle.com/news/2024-07-19/texas-secret-supplier-of-execution-drugs-is-accused-of-enabling-drug-dealing/>; National Public Radio, “Unmarked cars and secret orders: How a pharmacy prepared drugs for Texas’ executions,” Chiara Eisner, July 10, 2024, <https://www.npr.org/2024/07/10/g-s1-9016/unmarked-cars-and-secret-orders-how-a-pharmacy-prepared-drugs-for-texas-executions>.


¹² U.S. Drug Enforcement Administration, “Federal Court Orders San Antonio-Area Pharmacy and Pharmacist to Pay \$275,000 Civil Penalty in Case Alleging Unlawful Opioid Distribution,” press release, October 11, 2023, <https://www.dea.gov/press-releases/2023/10/11/federal-court-orders-san-antonio-area-pharmacy-and-pharmacist-pay-275000>; <https://www.justice.gov/opa/pr/justice-department-seeks-permanent-injunction-against-san-antonio-area-pharmacist-controlled>; https://www.documentcloud.org/documents/24776408-rite_away_complaint?responsive=1&title=1.

This is not the only disturbing recent report. Utah is currently considering using the dangerous anesthetic ketamine along with fentanyl in an upcoming execution, if it is unable to obtain the common lethal injection drug pentobarbital.¹³ Utah would be the first state in the country to use ketamine in an execution and would experimentally combine it with fentanyl and potassium chloride.¹⁴ The individual slated for execution has argued that this combination could cause severe pain, hallucinations, and “mental anguish.”¹⁵ Utah has revealed little about how the state is procuring fentanyl and ketamine, or about safeguards for preventing those dangerous drugs from leaking from the state’s supply chain and reaching the general public.¹⁶

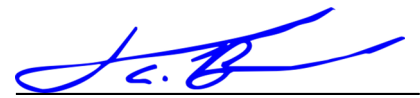
The FDA and DEA have the regulatory authority to prevent the procurement of dangerous, low-quality drugs from secretive suppliers with a history of regulatory infractions.¹⁷ We therefore reiterate our May 2024 request for information about the FDA’s and DEA’s plans to increase enforcement of their regulations in the context of lethal injection drugs, in order to ensure a secure supply chain for these dangerous drugs and to reduce the risk of needlessly painful botched executions. Furthermore, we again urge prompt revocation of the 2019 OLC opinion regarding the FDA’s jurisdiction over lethal injection drugs.

Thank you for your attention to this important matter.

Sincerely,



Elizabeth Warren
United States Senator



Cory A. Booker
United States Senator

¹³ Salt Lake Tribune, “Utah prison officials are abandoning the plan to use an untested drug combo in an upcoming execution. Here’s what they want to use instead,” Jessica Miller, July 17, 2024, <https://www.sltrib.com/news/2024/07/17/utah-officials-racing-get-proven/>.

¹⁴ *Id.*; Utah News Dispatch, “Utah could be first state to use ketamine in execution, but lawsuit warns of a ‘horrific death,’” Kyle Dunphey, July 12, 2024, <https://utahnewsdispatch.com/2024/07/12/death-row-inmate-taberon-honie-sues-utah-over-lethal-injection-drugs/>.

¹⁵ Utah News Dispatch, “With the clock ticking, Utah looking for new drug for lethal injection execution,” Kyle Dunphey, July 17, 2024, <https://utahnewsdispatch.com/2024/07/17/utah-drugs-for-taberon-honie-lethal-injection-execution/>; The Hill, “Death row gone rogue: It’s time to regulate lethal injection drugs,” Austin Sarat, May 28, 2024, <https://thehill.com/opinion/healthcare/4689097-death-row-gone-rogue-its-time-to-regulate-lethal-injection-drugs/>.

¹⁶ Salt Lake Tribune, “Utah’s lethal injection cocktail will include ketamine, fentanyl,” Paighen Harkins, June 7, 2024, <https://www.sltrib.com/news/2024/06/07/utahs-lethal-injection-cocktail/>; Utah Code § 64-13-27 (2024), https://le.utah.gov/xcode/Title64/Chapter13/64-13-S27.html?v=C64-13-S27_2024021620240501.

¹⁷ Congressional Research Service, “How FDA Approves Drugs and Regulates Their Safety and Effectiveness,” May 8, 2018, <https://crsreports.congress.gov/product/pdf/R/R41983>.