

United States Senate

WASHINGTON, DC 20510

May 21, 2024

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

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

Dear Commissioner Califf and Administrator Milgram:

We are writing to express deep concern about correctional facilities' methods for securing unsafe and unregulated drugs for use in capital punishment. These practices contribute to botched executions, undermine the integrity of the supply chain for the drugs, and endanger the U.S. patient population. The Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) are responsible for enforcing federal drug laws in order to keep Americans safe and prevent drug diversion. We are writing to urge the FDA and DEA to properly regulate drugs used for lethal injections in order to meet those obligations.

Lethal injection is the most common method of execution: in 2023, twenty-four people were executed, all by lethal injection.¹ However, the drugs used in lethal injections were not developed for this purpose. Instead, corrections officials use ordinary medicines developed to treat pain, seizures, and more,² but in lethal combinations and quantities. Though these are ordinary medicines, in the lethal injection context the FDA typically has not exercised its regulatory authority over the drugs — even when their use may clearly violate requirements related to supply chain security, prescriptions, branding, adulteration, and more.³ Lethal injection drugs also include controlled substances (such as fentanyl and pentobarbital) regulated by the DEA,⁴

¹ Death Penalty Information Center, “State-by-State Execution Protocols,” <https://deathpenaltyinfo.org/executions/methods-of-execution/state-by-state-execution-protocols>; U.S. Department of Justice, “Capital Punishment, 2021 – Statistical Tables,” November 2023, pp. 7, [https://bjs.ojp.gov/document/cp21st.pdf#:~:text=In%202021%2C%20all%2030%20states%20with%20a,\(3\)%2C%20nitrogen%20hypoxia%20\(3\)%2C%20and%20hanging%20\(2\).](https://bjs.ojp.gov/document/cp21st.pdf#:~:text=In%202021%2C%20all%2030%20states%20with%20a,(3)%2C%20nitrogen%20hypoxia%20(3)%2C%20and%20hanging%20(2).); Death Penalty Information Center, “Execution List 2023,” <https://deathpenaltyinfo.org/executions/2023>.

² See, e.g., Death Penalty Information Center, “State-by-State Execution Protocols,” <https://deathpenaltyinfo.org/executions/methods-of-execution/state-by-state-execution-protocols>; National Library of Medicine, “Pentobarbital,” Anna B. Johnson and Nazia M. Sadiq, February 9, 2022, <https://www.ncbi.nlm.nih.gov/books/NBK545288/#:~:text=Pentobarbital%20is%20a%20medication%20used,anesthetic%20in%20the%20operating%20room.>

³ Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Neither Party at 5-6, *Bucklew v. Precythe* (2018) https://www.supremecourt.gov/DocketPDF/17/17-8151/55132/20180723152845334_17-8151%20ac%20Association%20for%20Accessible%20Medicines.PDF.

⁴ Drug Enforcement Administration, “Drugs of Abuse,” 2022, pp. 28-29, https://www.dea.gov/sites/default/files/2022-12/2022_DOA_eBook_File_Final.pdf.

but the DEA likewise at times takes a hands-off approach when the drugs are used for lethal injections.⁵

Over the past decade, states' access to lethal injection drugs has plummeted.⁶ Pharmaceutical companies have prohibited using their drugs in executions, and have even sued states for doing so.⁷ States' access via foreign suppliers has also dwindled; in the 2010s, the European Union banned the export of drugs used for capital punishment,⁸ and a federal court required the FDA to block imports of unapproved sodium thiopental (which multiple states had purchased from an overseas pharmacy operating out of the back room of an unrelated establishment).⁹

Since then, departments of corrections have turned to increasingly questionable suppliers willing to sell concoctions designed to kill.¹⁰ Some have imported the drugs from foreign suppliers in violation of federal law, such as Nebraska's attempt to obtain execution drugs from an India-based businessman without a pharmaceutical background.¹¹ Others have purchased the drugs from compounding pharmacies,¹² which mix or alter drugs, operate with less FDA oversight, and often produce compounds of questionable quality with a higher risk of dangerous contamination.¹³ But as many compounding pharmacies also refuse to supply lethal injection

⁵ See, e.g., Letter from the ACLU of Nebraska to DEA Acting Assistant Administrator Demetra Ashley, et al., March 12, 2018, https://www.aclunebbraska.org/sites/default/files/dea_letter_on_lethal_injections_2018_03_12.pdf; ABC News, "DOJ Tells Arizona it Illegally Obtained Death Penalty Drug," May 24, 2011, <https://abcnews.go.com/Politics/Controversial-arizona-execution-set/story?id=13679827>; Texas Tribune, "Lawyers Allege Texas Executes Prisoners With Illegally Obtained Drugs," Brandi Grissom, March 30, 2011, <https://www.texastribune.org/2011/03/30/lawyers-allege-texas-illegally-obtains-death-drugs/>.

⁶ The Marshall Project, "How the Drug Shortage Has Slowed the Death-Penalty Treadmill," Maurice Chammah and Tom Meagher, April 12, 2016, <https://www.themarshallproject.org/2016/04/12/how-the-drug-shortage-has-slowed-the-death-penalty-treadmill>.

⁷ The New Yorker, "The End of the Open Market for Lethal Injection Drugs," Lincoln Caplan, May 21, 2016, <https://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs/>; Courthouse News Service, "Drugmaker Sues to Block Nebraska From Using Execution Drug," Ted Wheeler, August 8, 2018, <https://www.courthousenews.com/drugmaker-sues-to-block-nebraska-from-using-execution-drug/>; The New York Times, "Danish Company Blocks Sale of Drug for U.S. Executions," David Jolly, July 1, 2011, <https://www.nytimes.com/2011/07/02/world/europe/02execute.html>; *Glossip v. Gross*, 576 U.S. 863, 870 (2015).

⁸ European Parliament Regulation (EU) 2019/125 concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment, Art. 3, January 31, 2019, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0125>; see also European Commission, "Commission extends control over goods which could be used for capital punishment or torture," press release, December 20, 2011, https://ec.europa.eu/commission/presscorner/detail/en/IP_11_1578.

⁹ Death Penalty Information Center, "State-by-State Execution Protocols," <https://deathpenaltyinfo.org/executions/methods-of-execution/state-by-state-execution-protocols>; *Beatty v. Food & Drug Admin.*, 853 F. Supp. 2d 30, 35 (D.D.C. 2012)

¹⁰ Brief of Amici Curiae Pharmacy, Medicine, And Health Policy Experts in Support of Petitioner at 17-20, *Bucklew v. Precythe* (2018) (No. 17-8151), https://www.supremecourt.gov/DocketPDF/17/17-8151/55113/20180723140325323_17-8151%20tsac%20PharmacyMedicineHealthPolicyExperts.pdf.

¹¹ BuzzFeed News, "This Is The Man In India Who Is Selling States Illegally Imported Execution Drugs," Chris McDaniel and Tasneem Nashrulla, October 29, 2015, <https://www.buzzfeednews.com/article/chrismdaniel/this-is-the-man-in-india-who-is-selling-states-illegally-imp>.

¹² The Guardian, "Tulsa pharmacy faces questions over lethal drug to be used in execution," Ed Pilkington, January 28, 2014, <https://www.theguardian.com/world/2014/jan/28/tulsa-compounding-pharmacy-lethal-injection-execution>.

drugs,¹⁴ corrections officials have resorted to less reputable sellers. For example, Louisiana, Missouri, and possibly other states obtained execution drugs from a pharmacy that was placed on probation after admitting to almost 2,000 violations of state pharmacy guidelines.¹⁵ Meanwhile, Texas obtained execution drugs from a compounder placed on probation after use of its drugs led to several children being hospitalized.¹⁶

Corrections departments have also employed dishonest and secretive practices to secure execution drugs: officials in Louisiana obfuscated the purpose of the drug when obtaining it from a hospital;¹⁷ Texas officials purchased the drugs using a DEA registration number for a non-existent hospital;¹⁸ and Idaho officials took a private plane with tens of thousands of dollars in cash to buy the drugs from out-of-state pharmacies.¹⁹

Meanwhile, states are making it increasingly difficult to determine the sources of their lethal injection drugs. Twenty states have restricted access to information about the suppliers of lethal injection drugs.²⁰ These laws shield lethal drug supply chains from oversight by the FDA, DEA, and state boards of pharmacy, creating a “regulatory vacuum [that] endangers public health.”²¹

¹³ U.S. Food and Drug Administration, “Compounding and the FDA: Questions and Answers,” <https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers>; Brief of Amici Curiae Pharmacy, Medicine, And Health Policy Experts in Support of Petitioner at 17-20, *Bucklew v. Precythe* (2018) (No. 17-8151), https://www.supremecourt.gov/DocketPDF/17/17-8151/55113/20180723140325323_17-8151%20tsac%20PharmacyMedicineHealthPolicyExperts.pdf.

¹⁴ AP News, “Pharmacist group says members shouldn’t aid in executions,” Julie Watson, March 31, 2015, <https://apnews.com/article/business-health-united-states-executions-small-business-15bdf3d9ad854905ab0f9e5c0eed4c5f>.

¹⁵ BuzzFeed News, “Pharmacy That Mixed Executions Drugs Is Being Sold After Admitting Numerous Violations,” Chris McDaniel, April 21, 2016, <https://www.buzzfeednews.com/article/chrismcDaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc>; The Guardian, “Tulsa pharmacy faces questions over lethal drug to be used in execution,” Ed Pilkington, January 28, 2014, <https://www.theguardian.com/world/2014/jan/28/tulsa-compounding-pharmacy-lethal-injection-execution>; Brief of Amici Curiae Pharmacy, Medicine, and Health Policy Experts in Support of Petitioner at 17-20, *Bucklew v. Precythe* (2018) (No. 17-8151), https://www.supremecourt.gov/DocketPDF/17/17-8151/55113/20180723140325323_17-8151%20tsac%20PharmacyMedicineHealthPolicyExperts.pdf.

¹⁶ BuzzFeed News, “Inmates Said The Drug Burned As They Died. This Is How Texas Gets Its Execution Drugs,” Chris McDaniel, November 28, 2018, <https://www.buzzfeednews.com/article/chrismcDaniel/inmates-said-the-drug-burned-as-they-died-this-is-how-texas>.

¹⁷ The Lens, “In rush to find lethal injection drug, prison officials turned to a hospital,” Della Hasselle, August 6, 2014, <https://thelensnola.org/2014/08/06/lake-charles-memorial-hospital-sold-execution-drug-to-state/>; The New Yorker, “The End of the Open Market for Lethal Injection Drugs,” Lincoln Caplan, May 21, 2016, <https://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs>.

¹⁸ Letter from Professors Maurie Levin and Sandra Babcock to Attorney General Eric H. Holder, Jr., March 30, 2011, <https://dpic-cdn.org/production/legacy/TXHolderLetter.pdf>.

¹⁹ Idaho Capital Sun, “Cash buys, private flights, changing rules: How Idaho hides from execution oversight,” Kevin Fixler, January 16, 2022, <https://idahocapitalsun.com/2022/01/16/cash-buys-private-flights-changing-rules-how-idaho-hides-from-execution-oversight/>.

²⁰ Lethal Injection Information Center, “Respecting Corporate Contracts: State-By-State Risk Index, Fourth Edition,” May 2, 2024, <https://lethalinjectioninfo.org/state-by-state-risk-index-fourth-edition/>; Death Penalty Information Center, “Behind the Curtain: Secrecy and the Death Penalty in the United States,” November 20, 2018, p. 29, <https://dpic-cdn.org/production/documents/pdf/SecrecyReport-2.f1560295685.pdf?dm=1683576587>.

²¹ Brief of Amici Curiae Pharmacy, Medicine, And Health Policy Experts in Support of Petitioner at 11, 18, *Bucklew v. Precythe* (2018) (No. 17-8151), <https://www.supremecourt.gov/DocketPDF/17/17->

For example, an Oklahoma-based lethal injection drug supplier committed regulatory violations, such as improper sterilization and storage of medications, for years without being uncovered, partly because of the state's secrecy law.²²

In this unregulated and opaque environment, states execute people using drugs of unknown origin and dubious quality. Sometimes, the drugs are misbranded or unlabeled, shipped in "unmarked jars and boxes"²³ and with shipment invoices falsely describing the contents as "harmless medicine."²⁴ Other times, the drugs are expired, degraded, improperly stored, or contaminated. In one case, a clear solution was discovered to have turned yellow and cloudy shortly before an execution.²⁵

These unregulated, poor-quality drugs contribute to botched executions. For example, botched executions have resulted from states using sub-potent drugs that cause needless pain, long-expired drugs that could obstruct IV lines, drugs in untested doses, and drugs delivered in unmarked boxes that turn out to be the wrong drug altogether.²⁶ One sedative commonly used in executions, midazolam, frequently fails to adequately anesthetize individuals; in 2017, for example, over 60 percent of executions involving midazolam were botched.²⁷ Individuals who face botched executions are often left "gasping, heaving, [and] writhing" for upwards of 45 to 60

[8151/55113/20180723140325323_17-8151%20tsac%20PharmacyMedicineHealthPolicyExperts.pdf](https://www.supremecourt.gov/DocketPDF/17/17-8151/55113/20180723140325323_17-8151%20tsac%20PharmacyMedicineHealthPolicyExperts.pdf) (quotation marks omitted).

²² Brief of Amici Curiae Pharmacy, Medicine, And Health Policy Experts in Support of Petitioner at 26, *Bucklew v. Precythe* (2018) (No. 17-8151), https://www.supremecourt.gov/DocketPDF/17/17-8151/55113/20180723140325323_17-8151%20tsac%20PharmacyMedicineHealthPolicyExperts.pdf; BuzzFeed News, "Pharmacy That Mixed Executions Drugs Is Being Sold After Admitting Numerous Violations," Chris McDaniel, April 21, 2016, https://www.buzzfeednews.com/article/chrimcdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc#_ycDLE46a1.

²³ The Guardian, "Revealed: Republican-led states secretly spending huge sums on execution drugs," Ed Pilkington, April 9, 2021, <https://www.theguardian.com/world/2021/apr/09/revealed-republican-led-states-secretly-spending-huge-sums-on-execution-drugs>.

²⁴ BuzzFeed News, "Nebraska Bought 300 Executions' Worth Of Illegal Execution Drugs From A Foreign Supplier," Chris McDaniel, June 8, 2015, <https://www.buzzfeednews.com/article/chrimcdaniel/nebraska-bought-300-executions-worth-of-illegal-execution-dr>.

²⁵ Journal of the American Pharmacists Association, "When government agencies turn to unregulated drug sources: Implications for the drug supply chain and public health are grave," Parshant Yadav, Rebecca Lynn Weintraub, and Andy Stergachis, August 1, 2018, p. 479, [https://www.japha.org/article/S1544-3191\(18\)30336-4/abstract](https://www.japha.org/article/S1544-3191(18)30336-4/abstract).

²⁶ Death Penalty Information Center, "Behind the Curtain: Secrecy and the Death Penalty in the United States," November 20, 2018, p. 46, <https://dpic-cdn.org/production/documents/pdf/SecrecyReport-2.f1560295685.pdf?dm=1683576587>; Newsweek, "Robert Fratta Fears Expired Drugs Will Lead to Another Botched Execution," Khaleda Rahman, January 10, 2023, <https://www.newsweek.com/robert-fratta-fears-expired-drugs-botched-execution-1772687>; The New York Times, "A Botched Execution in Idaho Renews Scrutiny of Lethal Injection," Mike Baker, February 28, 2024, <https://www.nytimes.com/2024/02/28/us/idaho-death-penalty-thomas-creech.html>; The Frontier, "State officials' 'paranoia' over execution secrecy paved way for drug mixups," Ziva Branstetter and Cary Aspinwall, May 20, 2016, <https://www.readfrontier.org/stories/paranoia-led-to-execution-drug-mixups/>; Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Neither Party, *Bucklew v. Precythe* (2018), pp. 8-10, https://www.supremecourt.gov/DocketPDF/17/17-8151/55132/20180723152845334_17-8151%20ac%20Association%20for%20Accessible%20Medicines.PDF.

²⁷ Death Penalty Information Center, "Behind the Curtain: Secrecy and the Death Penalty in the United States," November 20, 2018, p. 54, <https://dpic-cdn.org/production/documents/pdf/SecrecyReport-2.f1560295685.pdf?dm=1683576587>.

minutes.²⁸ The risk of facing a botched execution is not evenly distributed: according to a new report by the organization Reprieve, Black people on death row have faced “220% higher odds of suffering a botched lethal injection than white people.”²⁹

Even when functioning as intended, execution drugs often cause extreme pain, and untested, experimental drug cocktails have unpredictable effects.³⁰ For example, pentobarbital, the most common execution drug, has been found to cause the sensation of drowning and suffocation, contrary to officials’ claims that such executions are quick and painless.³¹ And common lethal injection drug combinations have been described as the “chemical equivalent of being burned alive,”³² and have led people to exclaim during their executions that they could feel their bodies burning from the inside out.³³ While lethal injection is perceived as more humane than methods like the electric chair or firing squad,³⁴ this practice often results in an “excruciatingly painful death hidden behind a veneer of medication,”³⁵ and has the highest botch rate of any method of execution.³⁶

Furthermore, the ways in which lethal injection drugs are obtained compromise the drug supply chain and introduce needless health risks for the broader public. As public health experts have warned, “[o]nce an illicit supply channel is established with a supplier, it is extremely challenging to control which drug products move through it, and which customers they reach.”³⁷

²⁸ Death Penalty Information Center, “Behind the Curtain: Secrecy and the Death Penalty in the United States,” November 20, 2018, p. 54, https://dpic-cdn.org/production/documents/pdf/SecrecyReport-2_f1560295685.pdf?dm=1683576587; see also Reprieve, “Lethal injection in the modern era: cruel, unusual and racist,” April 2024, p. 5, https://reprieve.org/wp-content/uploads/sites/2/2024/04/2024_04_17_PUB-Botched-lethal-injection-report-FINAL.pdf.

²⁹ Reprieve, “Lethal injection in the modern era: cruel, unusual and racist,” April 2024, p. 2, https://reprieve.org/wp-content/uploads/sites/2/2024/04/2024_04_17_PUB-Botched-lethal-injection-report-FINAL.pdf.

³⁰ Washington Law Review, “Experimental Execution,” Seema K. Shah, March 1, 2015, p. 154, <https://digitalcommons.law.uw.edu/cgi/viewcontent.cgi?article=4864&context=wlr>; Slate, “Nevada’s Plan to Bring Back Executions With an Untested Drug Cocktail,” Austin Sarat, July 30, 2021, <https://slate.com/news-and-politics/2021/07/nevada-death-penalty-drug-fentanyl-ketamine.html>; Reprieve, “Lethal injection in the modern era: cruel, unusual and racist,” April 2024, pp. 7-8, https://reprieve.org/wp-content/uploads/sites/2/2024/04/2024_04_17_PUB-Botched-lethal-injection-report-FINAL.pdf.

³¹ NPR, “Gasping for Air: Autopsies Reveal Troubling Effects of Lethal Injection,” Noah Caldwell, Ailsa Chang, and Jolie Myers, September 21, 2020, <https://www.npr.org/2020/09/21/793177589/gasping-for-air-autopsies-reveal-troubling-effects-of-lethal-injection>; In re Fed. Bureau of Prisons’ Execution Protocol Cases, 980 F.3d 123, 131 (D.C. Cir. 2020).

³² *Glossip v. Gross*, 576 U.S. 863, 974 (2015) (Sotomayor, J., dissenting).

³³ University of Pennsylvania Law Review, “Reviewing Refusal: Lethal Injection, the FDA, and the Courts,” Andrew Shi, 2019, p. 247, https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=9684&context=penn_law_review#page=3

³⁴ Gallup, “Death Penalty,” <https://news.gallup.com/poll/1606/death-penalty.aspx>.

³⁵ *Glossip v. Gross*, 576 U.S. 863, 977 (2015) (Sotomayor, J., dissenting)

³⁶ Death Penalty Information Center, “Botched Executions,” February 2024, <https://deathpenaltyinfo.org/executions/botched-executions>.

³⁷ Brief of Amici Curiae Pharmacy, Medicine, and Health Policy Experts in Support of Petitioner at 11, *Bucklew v. Precythe* (2018) (No. 17-8151), https://www.supremecourt.gov/DocketPDF/17/17-8151/55113/20180723140325323_17-8151%20tsac%20PharmacyMedicineHealthPolicyExperts.pdf.

This risk is not hypothetical. For example, in 2006 it was revealed that a large quantity of lethal injection drugs went missing from a California prison because an employee was smuggling the drug out of the prison.³⁸ And in 2011 it emerged that unapproved drugs from an overseas lethal injection drug supplier ended up at a pharmacy in Georgia.³⁹ When these drugs fall into the wrong hands, they risk a “product safety emergency” for the wider patient population.⁴⁰

Further undermining public health, prisons frequently stockpile medications that are in short supply to use for executions, diverting those drugs from legitimate medical treatments.⁴¹ One 2017 study found that just four states with the death penalty were hoarding enough medication for over 11,000 surgeries, contributing to drug shortages for patients.⁴²

The FDA and DEA should begin to adequately regulate lethal injection drugs. Historically, these agencies have often declined to regulate drugs when they are used in executions.⁴³ However, the growing body of evidence demonstrating the avoidable health risks of lethal injection practices — both for individuals on death row and the general public — should compel the FDA and DEA to robustly exercise their jurisdiction in this area. Corrections departments and lethal injection drug suppliers may frequently violate the *Federal Food, Drug, and Cosmetic Act* (FFDCA), the *Controlled Substances Act* (CSA), and FDA and DEA regulations — including requirements related to supply chain security, prescriptions, manufacturing, compounding, registration and reporting, labeling, adulteration, misbranding, and foreign import approval.⁴⁴ Such violations contribute to needlessly painful and botched executions that undermine the FFDCA’s core objective of ensuring that drugs are “safe and effective.”⁴⁵ These violations also risk introducing poor-quality, unapproved controlled substances into the drug supply chain for patients — including schedule II drugs like fentanyl and pentobarbital — contrary to the CSA’s goals.⁴⁶

³⁸ Beatty v. Food & Drug Admin., 853 F. Supp. 2d 30, 43 n.8 (D.D.C. 2012); Morales v. Tilton, 465 F. Supp. 2d 972, 979 n.9 (N.D. Cal. 2006).

³⁹ Beatty v. Food & Drug Admin., 853 F. Supp. 2d 30, 43 n.8 (D.D.C. 2012).

⁴⁰ Journal of the American Pharmacists Association, “When government agencies turn to unregulated drug sources: Implications for the drug supply chain and public health are grave,” Parshant Yadav, Rebecca Lynn Weintraub, and Andy Stergachis, August 1, 2018, p. 480, [https://www.japha.org/article/S1544-3191\(18\)30336-4/abstract](https://www.japha.org/article/S1544-3191(18)30336-4/abstract); Beatty v. Food & Drug Admin., 853 F. Supp. 2d 30, 42-43 (D.D.C. 2012); NPR, “Georgia May Have Broken Law By Importing Drug,” Kathy Lohr, March 17, 2011, <https://www.npr.org/2011/03/17/134604308/dea-georgia-may-have-broken-law-by-importing-lethal-injection-drug>.

⁴¹ Brief for the Association for Accessible Medicines as Amicus Curiae in Support of Neither Party, Bucklew v. Precythe (2018), p. 14, https://www.supremecourt.gov/DocketPDF/17/17-8151/55132/20180723152845334_17-8151%20ac%20Association%20for%20Accessible%20Medicines.PDF.

⁴² The Guardian, “States are stockpiling lethal injection drugs that could be used to save lives,” Ed Pilkington, April, 20, 2017, <https://www.theguardian.com/world/2017/apr/20/states-stockpiling-lethal-injection-drugs-arkansas-execution>.

⁴³ Office of Legal Counsel, “Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions” May 3, 2019, p. 22, <https://www.justice.gov/olc/opinion/file/1162686/download/>.

⁴⁴ Federal Food, Drug, and Cosmetic Act of 1983, Public Law 97-414; Controlled Substances Act of 1970, Public Law 91-513; 21 C.F.R. chapter I; 21 C.F.R. chapter II.

⁴⁵ Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000).

⁴⁶ The Congressional Research Service, “The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress,” Joanna R. Lampe, January 19, 2023, pp. 2, 13, <https://sgp.fas.org/crs/misc/R45948.pdf>; U.S. Drug

The FDA and DEA have the necessary authority to act. We acknowledge that, in 2019, the Trump Administration’s Department of Justice issued an Office of Legal Counsel (OLC) opinion advising that the FDA lacked jurisdiction over lethal injection drugs.⁴⁷ That opinion was published shortly before the Trump Administration announced that it would resume federal executions, and was one of the uncommon OLC opinions ordered directly by the Attorney General.⁴⁸ It paved the way for President Trump to secure unregulated drugs via a secret supply chain in order to fast-track more federal executions during his last year in office than occurred during the previous 56 years combined.⁴⁹ But that OLC opinion was wrongly decided⁵⁰ and conflicts with both D.C. Circuit precedent⁵¹ — including caselaw postdating the OLC opinion — and the FDA’s own assertion that it has jurisdiction over lethal injection drugs.⁵² We urge the Biden Administration to reverse that OLC opinion and ensure that the FDA and DEA fulfill their public health responsibilities with respect to lethal injection drugs.

By enforcing the FFDCA, CSA, and implementing regulations, the FDA and DEA can secure the integrity of the supply chain for lethal injection drugs, minimizing the risk of botched executions and more broadly assuring the public health and safety of the drug supply chain. To help us understand how the FDA and DEA are fulfilling their obligations to protect public health and prevent drug diversion and misuse, we ask that you answer the following questions by June 5, 2024:

1. What steps is the FDA taking, or will the agency take, to investigate or pursue enforcement action against entities or individuals compounding drugs for use in lethal

Enforcement Administration, “DEA Mission Statement,” <https://www.dea.gov/about/mission>; ABC News, “DOJ Tells Arizona it Illegally Obtained Death Penalty Drug,” May 24, 2011,

<https://abcnews.go.com/Politics/Controversial-arizona-execution-set/story?id=13679827>; BBC, “Nebraska first in US to use opioid fentanyl in execution,” August 14, 2018, <https://www.bbc.com/news/world-us-canada-45185687>.

⁴⁷ Office of Legal Counsel, “Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions,” May 3, 2019, p. 26, <https://www.justice.gov/olc/opinion/file/1162686/download/>.

⁴⁸ The Washington Post, “The Justice Department boosts lethal injection in a big way,” Harry Litman, May 20, 2019, <https://www.washingtonpost.com/opinions/2019/05/20/justice-department-boosts-lethal-injection-big-way/>.

⁴⁹ AP News, “Trump administration carries out 13th and final execution,” Michael Tarm and Michael Kunzelman, January 16, 2021, [https://apnews.com/general-news-28e44cc5c026dc16472751bbde0ead50; U.S. Department of Justice, Office of Public Affairs, “Federal Government to Resume Capital Punishment After Nearly Two Decade Lapse,” press release, July 25, 2019, https://www.justice.gov/opa/pr/federal-government-resume-capital-punishment-after-nearly-two-decade-lapse](https://apnews.com/general-news-28e44cc5c026dc16472751bbde0ead50;U.S.DepartmentofJustice,OfficeofPublicAffairs,“FederalGovernmenttoResumeCapitalPunishmentAfterNearlyTwoDecadeLapse.”pressrelease,July25,2019,https://www.justice.gov/opa/pr/federal-government-resume-capital-punishment-after-nearly-two-decade-lapse).

⁵⁰ Letter from Senator Cory Booker, et al., to Attorney General Merrick Garland, <https://www.booker.senate.gov/imo/media/doc/52124finaldojolcletter.pdf>.

⁵¹ In 2019 under the Trump Administration, the FDA said it would follow the OLC opinion, but only “to the extent permissible by” an applicable court order, *see* Regulatory News, “FDA to Follow DOJ Memo on Limiting its Regulation of Execution Drugs,” Zachary Brennan, May 15, 2019, <https://www.raps.org/news-and-articles/news-articles/2019/5/fda-to-follow-doj-memo-on-limiting-its-regulation>, given the binding effect of federal court decisions over OLC opinions, *see* Stanford Law and Policy Review, “‘Law and’ The OLC’s Article II Immunity Memos,” Kimberly L. Wehle, February 2021, p. 17-20, <https://law.stanford.edu/wp-content/uploads/2021/03/2020-32-Stan.-L.-Poly.-Rev.-1-1.pdf>.

⁵² U.S. Food and Drug Administration, “Notice of FDA Action,” April 21, 2017, p. 10, <https://www.fda.gov/media/106199/download>; *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013); *In re Fed. Bureau of Prisons’ Execution Protocol Cases*, 980 F.3d 123, 136 (D.C. Cir. 2020).

injection executions in violation of the FDCA or Drug Supply Chain Security Act⁵³ (DSCSA)?

2. What steps is the DEA taking, or will the agency take, to investigate and pursue enforcement actions against entities or individuals that intentionally import, manufacture, distribute or dispense controlled substances for use in lethal injections in violation of the CSA?
3. How is the DEA ensuring it retains oversight of the importation, manufacture, distribution, possession and use of controlled substances, including opioids such as Fentanyl, where states are using expansive secrecy laws or policies to hide their execution drug procurement practices?
4. How are the FDA and DEA enforcing, and how will the agencies enforce, federal reporting requirements under the FFDCSA, DSCSA and CSA in the context of lethal injection executions and secrecy laws and practices?
5. Have the FDA and DEA communicated with DOJ about the need to revisit the previous Administration's OLC opinion effectively deregulating the supply of execution drugs?
6. What actions are the FDA and DEA taking to ensure that the combination of the OLC opinion, state secrecy practices, and FFDCSA and CSA violations by states or entities involved in the supply of execution drugs do not expose the public to unsafe and improperly labeled drugs, or increase the availability of substandard and/or illicit controlled substances on the domestic market?

We thank you for your attention to this important matter.

Sincerely,

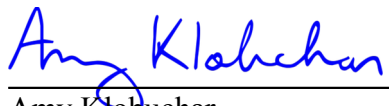


Elizabeth Warren
United States Senator

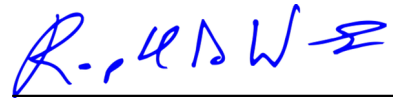


Cory A. Booker
United States Senator

⁵³ Drug Quality and Security Act of 2013, Title II of Public Law 113–54.



Amy Klobuchar
United States Senator



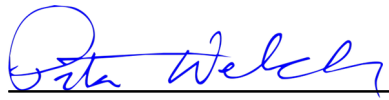
Raphael Warnock
United States Senator



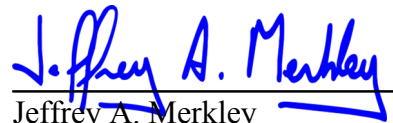
Alex Padilla
United States Senator



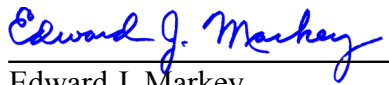
Mazie K. Hirono
United States Senator



Peter Welch
United States Senator



Jeffrey A. Merkley
United States Senator



Edward J. Markey
United States Senator