

United States Senate
WASHINGTON, DC 20510

May 21, 2024

The Honorable Merrick B. Garland
Attorney General
U.S. Department of Justice
Office of the Attorney General
950 Pennsylvania Ave., NW
Washington, DC 20530

Dear Attorney General Garland:

We respectfully request that you immediately rescind the Office of Legal Counsel’s (OLC) May 3, 2019, memorandum entitled “Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions” (“OLC opinion”). The Department of Justice’s (DOJ) OLC opinion incorrectly found that the Food and Drug Administration (FDA) lacks jurisdiction to regulate drugs intended for use in executions.¹ The opinion is deeply flawed — both legally and morally — and has posed unnecessary risks for individuals on death row, including the risk of suffering a botched execution. You have the authority to reverse the opinion without waiting for the DOJ Office of Legal Policy’s (OLP) ongoing review of the federal death penalty protocol. We urge you to do so immediately.

The OLC issued its opinion after the FDA blocked Texas’ attempts in 2015 to import 1,000 vials of unapproved sodium thiopental for use in lethal injections.² The FDA confiscated the vials at the airport in Houston after U.S. Customs and Border Protection agents seized the shipment pursuant to the federal Food, Drug, and Cosmetic Act (FDCA), which requires that drugs that are forbidden, adulterated, misbranded, or unapproved “be refused admission.”³ The FDA was also complying with a 2012 court order by the United States District Court for the District of Columbia mandating that the agency refuse admission of unapproved or misbranded sodium thiopental into the country;⁴ the D.C. Circuit Court of Appeals subsequently upheld the decision.⁵ Despite the established precedent, in 2019, the OLC found that the FDA lacked jurisdiction not only to block the import of foreign lethal injection drugs, but to regulate those drugs altogether.

¹ Dep’t 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>.

² See Jolie McCullough, *In a Nod to Texas, U.S. Department of Justice Says FDA Can’t Regulate Execution Drugs*, THE TEXAS TRIBUNE (May 14, 2019). Also see the factual record as provided in *Beaty v. Food & Drug Admin.*, 853 F. Supp. 2d 30, 37 (D.D.C. 2012).

³ *Beaty*, 853 F. Supp. 2d at 37.

⁴ *Id.*

⁵ See *Cook v. Food & Drug Admin.*, 733 F.3d 1 (D.C. Cir. 2013) (holding that “the FDCA imposes mandatory duties upon the agency charged with its enforcement. The FDA acted in derogation of those duties by permitting the importation of thiopental, a concededly misbranded and unapproved new drug . . .”).

The OLC opinion is flawed in several regards. First, the plain language of the FDCA authorizes the FDA to regulate “drugs,” which are defined to include “articles . . . intended to affect the structure or any function of the body of man or other animals.” In its opinion, OLC conceded that “[a]rticles used in capital punishment do literally ‘affect the structure or any function of the body’ by causing all bodily functions to cease.”⁶

Despite the statutory language, the OLC reasoned that the FDA could not possibly be allowed to regulate lethal injection drugs because they are inherently unsafe (and indeed are designed to kill). Thus, the FDA would be required to ban them altogether, yet capital punishment has for centuries been permitted by state and federal law.⁷ We note, as an initial matter, that the OLC appeared to presume the death penalty must persist, even as use of the practice has plummeted and judicial skepticism of its constitutionality has risen.⁸ That aside, the OLC’s argument also ignores the possibility that remedies beyond a ban on lethal injections could be available to the FDA. The FDA could seek to minimize the risk of a botched or needlessly painful execution⁹ — just as it does when regulating animal euthanasia drugs.¹⁰ Furthermore, the reasoning implies that states or the federal government would need to rely on drugs in order to carry out the death penalty, despite the fact that the majority of executing states have alternative means of carrying it out that don’t involve the use of drugs.¹¹

Instead, the OLC’s opinion leaves individuals on death row with no regulatory protection from “an unnecessary risk that they will not be anesthetized properly prior to execution”¹² or will face “a painful and prolonged dying process.”¹³ A new study reveals that the unregulated nature of execution drugs — which are sometimes expired, contaminated, sub-potent, or otherwise degraded — contributes to botched executions, often resulting in individuals writhing in pain for an hour or more.¹⁴ Such risks of “severe and gratuitous pain” undermine the FDCA’s goals,¹⁵ and as the Supreme Court has instructed, the FDCA must “be given a liberal construction consistent with the Act’s overriding purpose to protect the public health.”¹⁶

⁶ OLC opinion citing 21 U.S.C. § 321(g)(1)(C), (h)(3). Unlike other forms of execution such as electric chairs or firing squads that also technically affect the function of the body, lethal injection drugs are chemical agents squarely within the FDA’s regulatory expertise and indeed are already regulated by the FDA when used for other purposes. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8561201/>.

⁷ OLC opinion at 11.

⁸ *Glossip v. Gross*, 576 U.S. 863, 949 (2015) (Sotomayor, J., dissenting); Annette Choi & Dakin Andone, *Executions in the US are in Decline – but Some Jurisdictions Lead the Rest*, CNN (Oct. 6, 2023); Laura Bazelon, *An ‘Execute-Them-At-Any-Cost Mentality’: The Supreme Court’s New, Bloodthirsty Era*, POLITICO (Jan. 21, 2024).

⁹ Patricia J. Zettler and Seema K. Shah, *Broader Implications of Eliminating FDA Jurisdiction Over Execution Drugs*, Am. J. Pub. Health (Oct. 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8561201/#bib3>.

¹⁰ OLC opinion at 15 n.9.

¹¹ Death Penalty Information Center, “Authorized Methods by State,” <https://deathpenaltyinfo.org/executions/methods-of-execution/authorized-methods-by-state>; Death Penalty Information Center, “State by State,” <https://deathpenaltyinfo.org/states-landing>.

¹² *Beatty*, 853 F. Supp. 2d at 43.

¹³ *In re Fed. Bureau of Prisons’ Execution Protocol Cases*, 980 F.3d 123, 139 (D.C. Cir. 2020).

¹⁴ *Reprieve*, *Report: Lethal Injection in the Modern Era* (Apr. 17, 2024) at 10.

¹⁵ 980 F.3d at 142.

¹⁶ *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798, 89 S. Ct. 1410, 1418, 22 L. Ed. 2d 726 (1969).

The OLC opinion endangers not only individuals facing execution but also patients across the United States who depend on the FDA to ensure the safety of medications. The opinion effectively strips the FDA’s ability to ensure that drug products imported into the country are safe and effective. As prominent public health scholars have noted, once an illicit supply chain opens, there is a serious risk of diversion into the patient market.¹⁷ Experts including former FDA Commissioner Margaret A. Hamburg have warned this could lead to a product safety emergency.¹⁸ Among many concerns, this could also create a new and dangerous supply chain for fentanyl, which is used by some states for lethal injection.¹⁹

Beyond contradicting the language and purpose of the FDCA, the OLC opinion also conflicts with federal court precedent. In decisions rendered before and after the OLC opinion, the D.C. Circuit has applied the FDCA to drugs intended for use in executions. A year after the OLC opinion, the court noted that “binding precedent in this circuit” establishes that the FDA has jurisdiction over the drugs used in lethal injections.²⁰ Prior cases held that FDA was legally obligated to block the import of unapproved, foreign drugs intended for executions, in order to protect public health.²¹ The OLC opinion’s reasoning fails to square with this well-established precedent. Instead, the OLC relied heavily on the Supreme Court’s 2000 decision in *Food & Drug Administration v. Brown & Williamson Tobacco Corporation*, which found that the FDA lacked jurisdiction to regulate tobacco.²² Putting aside that decision’s weaknesses, discussed by four dissenting Justices, *Brown* is distinguishable; the OLC pointed to the fact that Congress enacted several federal statutes addressing the health issues related to tobacco without expressly granting the FDA the authority to regulate tobacco, as evidence that the FDA did not have jurisdiction to regulate it. There are no analogous federal laws addressing lethal injection drugs.²³

The death penalty in America has long been plagued by intolerable racial injustices and disparities.²⁴ As of 2022, Black and Hispanic Americans represented 53% of people on death row despite making up only 31% of the U.S. population.²⁵ And new findings show that Black people

¹⁷ See John Hertig et. al., Current Threats to Maintaining a Secure Pharmaceutical Supply Chain in an Online World, *Hosp. Pharm.* (Apr. 2020).

¹⁸ See, e.g., Br. of *Amici Curiae* Pharmacy, Medicine, and Health Pol’y Experts in Supp. of Pet’r, *Bucklew v. Precythe*, Case No. 17-8151 (July 2018) and Br. of *Amici Curiae* Concerned Public Health Professionals, Scientists, Former Regulators, and Educators in Support of Respondents-Appellants, *Owens v. Stirling*, Appellate Case No. 2022-001280 (S.C.).

¹⁹ See Austin Sarat, *Nevada’s Plan to Bring Back Executions with an Untested Drug Cocktail*, SLATE (Jul. 30, 2021), 980 F.3d at 136.

²⁰ *Beaty*, 853 F. Supp. 2d at [?], *aff’d in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (holding that the Food and Drug Administration’s failure to apply the FDCA to lethal injection drugs “undermined the purpose of the [statute] and acted in a manner contrary to the public health,” with the consequence that “prisoners on death row have an unnecessary risk that they will not be anesthetized properly prior to execution”). See also *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (applying the FDCA’s regulation of drug imports to a lethal injection drug); *Chaney v. Heckler*, 718 F.2d 1174, 1179-1182 (D.C. Cir. 1983), *rev’d on other grounds*, 470 U.S. 821 (1985).

²¹ See *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

²² Andrew Shi, Reviewing Refusal: Lethal Injection, the FDA, and the Courts, 168 U. PA. L. REV. 245 (2019), available at https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=9684&context=penn_law_review.

²³ See generally David Keeys, *Race and the Death Penalty: The Legacy of McCleskey v. Kemp*. Lynne, Rienner Publishers, Inc., 2016.

²⁴ Ranya Shannon, *3 Ways the 1994 Crime Bill Continues to Hurt Communities of Color*, CENTER FOR AMERICAN PROGRESS (May 10, 2019).

sentenced to death had 220% higher odds of facing a botched execution than White people.²⁶ The use of unapproved and unsafe drugs for lethal injection further perpetuates the disproportionate impact capital punishment on people of color — this time through botched executions.²⁷

This misguided OLC opinion is inconsistent with the principles of fairness and justice, undermines drug safety, and facilitates legally dubious state execution methods. It blocks the FDA from intervening when states obtain unmarked vials from underground suppliers, inject their citizens with contaminated solutions, and cause needlessly painful deaths. And particularly when “the government argues that a lethal injection drug is legally and constitutionally permissible because it will ensure a ‘humane’ death, it cannot then disclaim a responsibility to comply with federal statutes enacted to ensure that the drugs operate humanely.”²⁸ As Justice Sotomayor recently posited about these “experiments with human life”: “the world is watching.”²⁹

We urge you to immediately rescind the 2019 OLC opinion on FDA jurisdiction over execution drugs. The DOJ under the current Administration has reversed previous OLC opinions that were legally unsound and should do so here.³⁰ President Biden committed this Administration to public health, racial justice, and human rights. While we are pleased that DOJ has imposed a moratorium on federal executions pending a review of policies and procedures, that deliberative process does not prohibit rescission of the OLC opinion.

Thank you for your prompt attention to this matter.

Sincerely,



Cory A. Booker
United States Senator



Elizabeth Warren
United States Senator

²⁶ Reprieve, *Report: Lethal Injection in the Modern Era* (Apr. 17, 2024).

²⁷ NACDL, *Race and the Death Penalty* (Dec. 7, 2022).

²⁸ *Matter of Fed. Bureau of Prisons’ Execution Protocol Cases*, 485 F. Supp. 3d 233, 240 (D.D.C.), vacated (Aug. 27, 2020), *aff’d but criticized sub nom. In re Fed. Bureau of Prisons’ Execution Protocol Cases*, 980 F.3d 123 (D.C. Cir. 2020).

²⁹ *Smith v. Hamm*, 144 S. Ct. 414, 415 (2024) (Sotomayor, J., dissenting).

³⁰ See, e.g., <https://www.justice.gov/olc/file/1419111/dl>.



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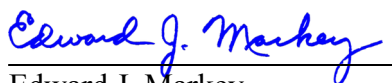
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