U.S. Department of JUSTICE

Review of the Federal Execution Protocol Addendum and Manner of Execution Regulations

January 2025

Office of Legal Policy

Introduction

On July 1, 2021, the Attorney General issued a memorandum instituting a moratorium on federal executions pending the Department of Justice's (Department) review of certain policies and procedures.[1] This review consists of three prongs: first, a review of the federal execution protocol addendum; second, a review of the manner of execution regulations;[2] and third, a review of the relevant Justice Manual provisions. In the memorandum, the Attorney General noted that "the Department of Justice must ensure that everyone in the federal criminal justice system is not only afforded the rights guaranteed by the Constitution and laws of the United States, but is also treated fairly and humanely." The memorandum directed the Office of Legal Policy (OLP), under the supervision of the Deputy Attorney General, to coordinate the first two prongs of the review.[3]

Regarding the review of the federal execution protocol addendum, which provides that an injection of a single drug – pentobarbital – is the sole manner of federal execution, the memorandum stated in part:

> Although some medical experts have concluded that the use of pentobarbital may risk inflicting painful pulmonary edema, the Supreme Court found that this risk was insufficient "to justify last-minute intervention by a Federal Court" shortly before an execution was scheduled to occur. *Barr v. Lee*, 140 S. Ct. 2590, 2591 (2020) (per curiam). A risk need not meet the Court's high threshold for such relief, or violate the Eighth Amendment, to raise important questions about our responsibility to treat individuals humanely and avoid unnecessary pain and suffering.

Regarding the review of the manner of execution regulations, the memorandum noted that they had last been amended on November 27, 2020, to reflect the provisions of the Federal Death Penalty Act, 18 U.S.C. § 3596. This statute expanded the permissible methods of execution to include any manner prescribed by the "law of the State in which the sentence was imposed," and also permitted the federal government to use state facilities and personnel in federal executions. Additionally, the amendments to the manner of execution regulations added procedural provisions regarding the Attorney General's capacity to make exceptions to the regulations, as well as to delegate relevant duties within the Department. The memorandum directed a review to consider modification, rescission, or any other changes to the regulations.

This document summarizes the reviews of the federal execution protocol addendum and the manner of execution regulations in two parts. Part 1 addresses the review of the federal execution protocol: After an extensive review of available

[1] Memorandum from the Attorney General, *Moratorium on Federal Executions Pending Review of Policies and Procedures* (July 1, 2021), https://www.justice.gov/opa/file/1557511/dl?inline.
[2] *See* 28 C.F.R. § 26 (2020).
[3] On January 30, 2023, the Deputy Attorney General issued a memorandum adopting changes to Title 9, Chapter 10 of the Justice Manual, which addresses capital crimes. *See* Memorandum from the Deputy Attorney General, *Changes to the Justice Manual's Provisions Regarding Capital Crimes* (January 30, 2023) https://www.justice.gov/d9/2023-01/2023.01.30%20DAG%20Memo%20re%20JM%20Edits.pdf.

scientific, medical, and legal research; recent autopsies of individuals who have received lethal injections of pentobarbital; consultation with experts within and outside the Department; and solicitation and consideration of public comments, OLP concludes that there remains significant uncertainty about whether the use of pentobarbital as a single-drug lethal injection causes unnecessary pain and suffering. In the face of such uncertainty, the Department should err on the side of humane treatment and avoidance of unnecessary pain and suffering, and therefore halt the use of pentobarbital unless and until that uncertainty is resolved. Part 2 addresses the review of the manner of execution regulations: Because the amendments made in 2020 largely reflect statutory law, there is no present reason to modify or rescind them. However, if the federal government were required to conduct an execution in a manner other than lethal injection of pentobarbital, the Department should undertake an analysis of that manner like the one engaged in here with regard to pentobarbital before it may be used.

Part 1 – The Federal Execution Protocol

I. Background

a. Capital Punishment and the Eighth Amendment of the Constitution

While the Supreme Court has a robust jurisprudence addressing the "cruel and unusual punishment" clause of the Eighth Amendment,[4] it has never held that a method of execution adopted by a state or the federal government, and challenged in litigation, violates the Eighth Amendment.[5] The Court's caselaw thus does not provide definitive guidance on what is unconstitutionally cruel and unusual in the capital punishment context, although the Court has

[4] *See, e.g.*, Wilkerson v. Utah, 99 U.S. 130, 136 (1878) (finding it "safe to affirm that punishments of torture...and all others in the same line of unnecessary cruelty, are forbidden."); *In re* Kemmler, 136 U.S. 436, 446 (1890) (stating that "if the punishment prescribed for an offense against the laws of the state were manifestly cruel and unusual, as burning at the stake, crucifixion, breaking on the wheel, or the like, it would be the duty of the courts to adjudge such penalties to be within the constitutional prohibition"); Weems v. United States, 217 U.S. 349 (1910) (prohibiting a sentence of 12 years in chains and hard labor); Trop v. Dulles, 356 U.S. 86 (1958) (prohibiting expatriation); Robinson v. California, 370 U.S. 660 (1962) (prohibiting the imprisonment for narcotics addition); Estelle v. Gamble, 429 U.S. 97 (1976) (prohibiting incarceration without medical care); Atkins v. Virginia, 536 U.S. 304 (2002) (finding the death penalty is unconstitutional for people with intellectual disabilities); Roper v. Simmons, 543 U.S. 551 (2005) (finding the death penalty is unconstitutional for people who were under 18 when they committed a crime); Kennedy v. Louisiana, 554 U.S. 407, 447 (2008) (reserving the imposition of the death penalty to "crimes that take the life of the victim").

[5] *See, e.g.*, *Wilkerson*, 99 U.S. 130 (regarding the use of a firing squad); *In re Kemmler*, 136 U.S. 436 (regarding the use of the electric chair); Gary v. Lucas, 463 U.S. 1237 (1983) (denying certiorari to a challenge to a state's use of a gas chamber); Baze v. Rees, 553 U.S. 35, 48 (2008) (upholding Kentucky's lethal injection procedure, finding that the plaintiff did not demonstrate that the execution procedure imposed a substantial risk of serious harm or a feasible alternative that reduces the a substantial risk of severe pain); Barr v. Lee, 591 U.S. 979 at 981 (2020) (vacating a district court's preliminary injunction against the federal government and permitting the federal execution to proceed using pentobarbital, finding that plaintiffs "have not made the showing required to justify last-minute intervention by a Federal Court"); *see also* United States v. Aquart, 912 F.3d 1, 62 (2d Cir. 2018) (finding that "the Court has not drawn 'precise distinctions between cruelty and unusualness' or clearly indicated that the two words bear qualitatively different meanings" (citing *Trop*, 356 U.S. at 100 n.32)).

said more generally that "wanton and unnecessary infliction of pain" offends the Eighth Amendment.[6]

In 1972, in the landmark case of *Furman v. Georgia*, the Supreme Court held in a one-paragraph per curiam decision that "the imposition and carrying out of the death penalty in these cases constitute cruel and unusual punishment in violation of the Eighth and Fourteenth Amendments."[7] The petitioners before the Court had been convicted and sentenced to death by juries in state courts, but the manner of execution was not at issue: the concerns in the case centered on the arbitrary and discriminatory application of the death penalty. The five justices in the majority each filed separate opinions in support of the judgment, providing independent justifications for the decision. Three of those five justices noted their view that the death penalty could be constitutional if greater procedural safeguards were in place, such that the jury would be required to adhere to standards for determining that the death penalty was appropriate. While the case effectively invalidated the prevailing state death penalty statues at the time, the decision left room for state and federal legislators to rewrite statutes to address the concerns about the arbitrary imposition of the death penalty.[8]

Four years later, after thirty-five states enacted revised death penalty laws, the Court upheld the constitutionality of the death penalty statutes considered in *Gregg v. Georgia* and several companion cases.[9] The Court ruled that death penalty statues that included safeguards to guide juror discretion and to require jurors to make special findings or to weigh "aggravating" versus "mitigating" circumstances withstood constitutional scrutiny.[10]

Since the 1970s, the Court has largely left questions about the method and implementation of capital punishment to legislative bodies, juries, and executive branch officials, but has placed limits on the instances in which the death penalty may be appropriate.[11] In *Kennedy v. Louisiana*, the Court stated that the "evolving standards of decency" principle "requires that use of the death penalty be restrained."[12] The Court said that "[i]n most cases justice is not better served by terminating the life of the perpetrator," and it held that use of the death penalty "must be reserved for the worst of crimes and limited in its instances of application."[13] Using the "evolving standards of decency" test, the Court has found unconstitutional the execution of certain categories of offenders, including juveniles, individuals

---

[6] *See* Ingraham v. Wright, 430 U.S. 651, 670 (1977) (quoting *Estelle*, 429 U.S. at 103).
[7] Furman v. Georgia*,* 408 U.S. 238, 239-40 (1972).
[8] Carol S. Steiker & Jordan M. Steiker, *Little* Furmans *Everywhere: State Court Intervention and the Decline of the American Death Penalty*, 107 Cornell L. Rev. 1621, 1626 (2022).
[9] Gregg v. Georgia, 428 U.S. 153, 875 (1976) (plurality opinion); Proffitt v. Florida, 428 U.S. 242 (1976); Jurek v. Texas, 428 U.S. 262 (1976); Woodson v. North Carolina 428 U.S. 280 (1976); Roberts v. Louisiana, 428 U.S. 325 (1976).
[10] *Id.* at 153. On the same day *Gregg* was decided, the Court decided Woodson v. North Carolina, 428 U.S. 280, 303 (1976), in which the Court held that the mandatory imposition of the death penalty is unconstitutional and that a "particularized consideration of relevant aspects of the character and record of each convicted defendant" is necessary "before the imposition upon him of a sentence of death."
[11] *See* James C. Feldman, *Nothing Less than the Dignity of Man: The Eighth Amendment and State Efforts to Reinstitute Traditional Methods of Execution,* 90 Wash. U.L. Rev. 1313 (2015).
[12] *Kennedy*, 554 U.S. at 446.
[13] *Id.* at 447.

with an intellectual disability, and individuals convicted of offenses other than homicide.[14] While the Court has held that certain forms of corporal punishment violate the Eighth Amendment, such as the use of excessive force in physical restraints,[15] it has never found specific methods of execution to violate the Constitution.[16]

In *Baze v. Rees*, the Court considered the constitutionality of Kentucky's lethal injection procedure and held that it did not violate the Eighth Amendment. The plurality opinion begins with the assertion that if capital punishment is constitutional, then it "necessarily follows that there must be a means of carrying it out."[17] Under *Baze*, for a petitioner to succeed on an Eighth Amendment challenge, he or she must demonstrate, first, that an execution procedure imposes a "substantial" or "objectively intolerable" risk of serious harm; and second, that there is a "feasible, readily implemented" alternative that "in fact significantly reduce[s] a substantial risk of severe pain."[18] Later, in *Bucklew v. Precythe*, the Court further articulated that the Eighth Amendment "does not guarantee a prisoner a painless death."[19] The Court held that the Eighth Amendment permits methods of execution, like hanging, that involved a significant risk of pain, while forbidding as cruel only those methods that intensified the death sentence by "'superadding' terror, pain, or disgrace" as compared to a viable alternative method.[20]

Taken together, the Court's recent decisions require petitioners who are challenging the method of execution to establish that a State's chosen method cruelly "superadds" pain to the death sentence, that there is a feasible and readily implemented alternative method that would significantly reduce a substantial risk of severe pain, and that the State has refused to adopt that method without a legitimate penological reason.[21] The Court has stated that the Constitution affords a "measure of deference to a State's choice of execution procedures," and does not authorize courts to serve as "boards of inquiry charged with determining 'best practices' for executions."[22]

---

[14] *See Atkins*, 536 U.S. 304; *Roper*, 543 U.S. 551; *Kennedy*, 554 U.S. 407.
[15] In *Hope v. Pelzer*, 536 U.S. 730 (2002), the Supreme Court characterized the gratuitous handcuffing of a shirtless inmate to a hitching post for hours at a time as an "obvious" Eighth Amendment violation.
[16] *See* Glossip v. Gross, 576 U.S. 863 (2015) ("While methods of execution have changed over the years, '[t]his Court has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment.'" (quoting *Baze*, 553 U.S. at 48 (2008))).
[17] *Baze*, 553 U.S. at 47.
[18] *Id.* at 47-52 (noting that the Court's "broad framework of the Eighth Amendment" and its "approval of a particular method in the past has not precluded legislatures from taking the steps they deem appropriate, in light of new developments, to ensure humane capital punishment").
[19] Bucklew v. Precythe, 587 U.S. 119, 132 (2019).
[20] *Id.* at 138 (citing *Baze*, 553 U.S. at 48; *Glossip*, 576 U.S. 863); *see also Wilkerson*, 99 U.S. at 135 (in which the Court noted cases in England in which "terror, pain, or disgrace were sometimes superadded" to the sentence").
[21] *Bucklew*, 587 U.S. at 134.
[22] *Baze*, 553 U.S. at 51-52.

b. History of Federal Executions

In the last 100 years, the federal government's implementation of capital punishment has been limited: 34 people were executed between 1927 and 1963; 3 were executed between 2001 and 2003, and 13 were executed in 2020 and 2021.[23]

Until 1937, federal law prescribed hanging as the method of execution.[24] In 1937, Congress mandated that each federal execution be carried out in the manner prescribed by the laws of the State within which the sentence was imposed,[25] which at time also included the use of the electric chair and gas chamber. In 1988, Congress passed the Anti-Drug Abuse Act of 1988, which made the death penalty available for certain drug-related offenses but did not specify a method of execution.[26] The Justice Department issued regulations providing for lethal injection to be the federal method of execution in 1993.[27]

Subsequently, through the Violent Crime Control and Law Enforcement Act of 1994, Congress expanded the number of offenses for which the death penalty could be imposed and established general statutory procedures for seeking and imposing capital sentences.[28] The statute also included the Federal Death Penalty Act, which requires that federal executions be implemented "in the manner prescribed by the law of the State in which the sentence is imposed" and gives the Attorney General discretion to use "appropriate State or local facilities" and officials to implement a sentence of death in the manner prescribed.[29]

Between 2001 and 2003, the federal government carried out three executions using a three-drug cocktail, including sodium thiopental (a barbiturate), pancuronium bromide, and potassium chloride.[30] In January 2011, the sole American manufacturer of sodium thiopental stopped production after it faced pressure to guarantee that the drug would not be used in capital punishment.[31] The federal government announced that it did not have any reserves of sodium thiopental for lethal injections,[32] and federal courts prevented the importation of sodium thiopental from foreign manufacturers without approval from the Food and Drug Administration

[23] *Capital Punishment*, Federal Bureau of Prisons, https://www.bop.gov/about/history/federal_executions.jsp (last visited Dec. 30, 2024).
[24] *See* Crimes Act of 1790, ch. 9 § 33, 1 Stat. 112, 119.
[25] An Act of June 19, 1937, ch. 367, 50 Stat. 304, 304.
[26] Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, 102 Stat. 4181.
[27] 28 C.F.R. Part 26.
[28] Violent Crime Control and Law Enforcement Act of 1994, Pub. L. No. 103-322, 108 Stat. 1796 (1994).
[29] *See* 18 U.S.C. §§ 3596-3597.
[30] *BOP Execution Protocol*, Federal Bureau of Prisons (undated version prior to 2004 update,) (on file).
[31] *Statement from Hospira regarding its halt of production of Pentothal (sodium thiopental)* (Jan. 21, 2011), https://dpic-cdn.org/production/legacy/HospiraJan2011.pdf (last visited Dec. 30, 2024); *see also* Erik Eckholm & Katie Zezima, *States Face Shortage of Key Lethal Injection Drug*, N.Y. Times (Jan. 21, 2011) https://www.nytimes.com/2011/01/22/us/22lethal.html.
[32] *See* Roane v. Leonhart, 741 F.3d 147, 149 (2014); *see also* Letter from Attorney General Eric Holder to the National Association of Attorneys General (Mar. 4, 2011), https://files.deathpenaltyinfo.org/legacy/documents/2011.03.04.holder.letter.pdf (last visited Dec. 30, 2024).

(FDA).[33] No federal executions occurred after 2003, until the Department revised the execution protocol to use only a single drug, pentobarbital, and restarted executions in 2020.

c. Medically Approved Use of Pentobarbital

Pentobarbital is a barbiturate drug that the FDA has approved for use in humans as an emergency treatment for status epilepticus (seizures that occur in quick succession or that last longer than five minutes), as a short-term sedative to treat insomnia, or as a pre-anesthetic prior to surgery.[34] The therapeutic concentration of pentobarbital depends on the intended therapeutic effect. For example, the sedation dose is 1 to 5 mcg/mL. The standard injectable dose of pentobarbital is between 150 and 200 milligrams. Toxic doses of pentobarbital occur at approximately 1 gram in most adults, with death occurring at 2 to 10 grams.[35]

The FDA has approved the use of pentobarbital in animal euthanasia.[36] Typically, animal euthanasia products contain a combination of pentobarbital sodium and phenytoin sodium: the pentobarbital "produces rapid anesthetic action, unconsciousness, and depression of the respiratory and vasomotor centers," while the phenytoin "causes cardiovascular collapse and/or central nervous system depression."[37] According to the American Veterinary Medical Association, "[i]ntravenous injection of a barbituric acid derivative (e.g., pentobarbital, pentobarbital combination product) is the preferred method for euthanasia of dogs, cats, and other small companion animals," and veterinarians may also first use a sedative prior to administering the barbiturate.[38] The dosage of the drug is typically determined by the animal's body weight.

Pentobarbital has also been used in states with lawful medical aid in dying practices. Those states typically have developed a regulatory framework for physicians to prescribe lethal doses specific to the individual, often along with sedatives or other medications.[39] These prescriptions are all considered "off-label," as they are not uses approved by the FDA. Notably,

---

[33] In *Beaty v. Food & Drug Admin.*, 853 F. Supp.2d 30 (D.D.C. 2012), the district court considered an action brought by inmates on death row and held that that the FDA violated the APA by improperly allowing the shipment of drugs from abroad to states to use in capital punishment. The D.C. Circuit affirmed. Cook v. Food & Drug Admin., 733 F.3d 1 (D.C. Cir. 2013).

[34] *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (last visited Dec. 30, 2024).

[35] *See* Anna B. Johnson & Nazia M. Sadiq, *Pentobarbital*, StatPearls, National Library of Medicine (Feb. 25, 2024), https://www.ncbi.nlm.nih.gov/books/NBK545288/ (last visited Dec. 30, 2024).

[36] *Animal Drugs*, Food & Drug Admin., https://animaldrugsatfda.fda.gov/adafda/views/#/home/searchResult (search results for "animal euthanasia") (last visited Dec. 30, 2024).

[37] M. B. Forrester, *Human exposure to pentobarbital-phenytoin combination veterinary drugs*, Human & Experimental Toxicology (2017), https://journals.sagepub.com/doi/10.1177/0960327116661398 (last visited Dec. 30, 2024).

[38] *AVMA Guidelines for the Euthanasia of Animals: 2020 Edition*, American Veterinary Medical Association, at 57, https://www.avma.org/sites/default/files/2020-02/Guidelines-on-Euthanasia-2020.pdf.

[39] *See, e.g.*, *Oregon Death with Dignity Act: 2023 Data Summary*, Oregon Health Authority (2024), https://www.oregon.gov/oha/ph/providerpartnerresources/evaluationresearch/deathwithdignityact/documents/year26.pdf.

a 2019 opinion from the Office of Legal Counsel concluded that the FDA did not have jurisdiction to regulate drugs used in executions.[40]

While several states have used pentobarbital in executions as a single-drug injection,[41] the FDA has not reviewed or approved of the use of pentobarbital in high doses or for the purpose of causing death. In addition, the primary manufacturer of injectable pentobarbital that has been approved by the FDA, the Danish company Lundbeck, has restricted the use of the drug in capital punishment.[42] As a result, states and the federal government have not purchased injectable pentobarbital from drug manufacturers, but instead have found chemical companies that provide powdered active pharmaceutical ingredient (API) pentobarbital in bulk and then used compounding pharmacies to create an injectable solution.[43] According to the FDA, "[c]ompounded drugs are not FDA approved, which means the agency does not verify their safety, effectiveness or quality before they are marketed."[44] Pharmacies that compound drugs in bulk, such as those typically contracted to produce lethal injection drugs, are required to register as Human Drug Compounding Outsourcing Facilities under Section 503B of the Food, Drug, and Cosmetic Act.[45] These facilities are advised by the FDA to comply with "current good

---

[40] *Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions*, Office of Legal Counsel, Dept. of Justice, 43 Op. *1 (May 2, 2019). *But see In re* Federal Bureau of Prisons' Execution Protocol, 980 F.3d 123, 136 (D.C. Cir. 2020) ("There is no dispute that pentobarbital is a drug regulated under the FDCA… . Nor is there any dispute that pentobarbital is the type of drug that the FDCA requires to be dispensed only through a prescription issued by a licensed medical professional… . There likewise is no question that prisoners are generally entitled to the protections of the FDCA's prescription requirement." (citations omitted)).

[41] On the state level, 194 individuals in 8 states have been executed using pentobarbital as the sole lethal substance beginning in 2011: Arizona (11 executions between 2/29/12 - 10/23/13 and 5/11/22 - 11/16/22), Georgia (25 executions between 2/21/13 - 3/20/24), Idaho (1 execution on 6/12/12), Missouri (32 executions between 11/20/13 - 9/24/24), Ohio (10 executions between 3/10/11 - 9/25/13), South Carolina (2 executions between 9/20/24 - 11/1/24), South Dakota (4 executions between 10/15/12 - 11/04/19), and Texas (109 executions between 7/18/12 - 10/01/24). In total, 14 states have used pentobarbital in executions. Five other states plan to use pentobarbital: Kentucky, Louisiana, Montana, North Carolina, and Tennessee. *See State-by-State Execution Protocols*, Death Penalty Information Center, https://deathpenaltyinfo.org/state-lethal-injection (last visited Dec. 30, 2024).

[42] David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions,* N.Y. Times (Jul. 1, 2011), https://www.nytimes.com/2011/07/02/world/europe/02execute.html.

[43] Recent reporting described the compounding pharmacy working with the Texas Department of Criminal Justice to provide pentobarbital between 2019 and 2023. The reporting found that the pharmacy was "cited more than a dozen times over the past decade" by the Texas State Board of Pharmacy for "fail[ing] to maintain clean and sterile facilities and fail[ing] to keep complete and correctly labeled records and drugs in stock, among other violations." Chiara Eisner, *Unmarked cards and secret orders: How a pharmacy prepared drugs for Texas' executions*, NPR (Jul. 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. The report also noted that a pharmacy owned by the same family was sued by the Department of Justice for "dispensing powerful opioids to people without valid prescriptions, falsifying hundreds of prescriptions for controlled substances and ignoring serious red flags that indicated people intended to abuse their medications." *Id.*; *see also* Hayley Bedard, *NPR Investigation Reveals Supplier of Texas Execution Drugs Has Multiple Drug Enforcement Agency Violations; Questions Remain Regarding Drug Acquisition in Other States*, Death Penalty Information Center (Jul. 11, 2024), https://deathpenaltyinfo.org/npr-investigation-reveals-supplier-of-texas-execution-drugs-has-multiple-drug-enforcement-agency-violations-questions-remain-regarding-drug-acquisition-in-other-states.

[44] *Human Drug Compounding*, Food & Drug Admin., https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding (last visited Dec. 30, 2024).

[45] *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry*, Food & Drug Admin. (May 2018), https://www.fda.gov/media/97359/download.

manufacturing practice,"[46] and are subject to FDA inspection "according to a risk-based schedule."[47] As of the date of this report, there are 88 compounding pharmacies registered as 503B outsourcing facilities, 31 of which have never been inspected by the FDA. In 55 of the 57 facilities that have been inspected, FDA officials have issued a Form 483, officially noting "significant objectional conditions" at the facility.[48]

Some state lethal injection protocols include the administration of a sedative prior to execution, but those states require a physician to prescribe the sedative.[49] On the federal level, the Bureau of Prisons (BOP) has determined that in order to administer a sedative prior to execution, a prescription would be required, which would in turn require the participation of a medical professional.[50] It is internal BOP policy that the BOP medical staff do not administer drugs in connection with the execution process.[51] Moreover, states that involve medical professionals in the execution process rely on those professionals doing so at their own risk, and likely rely on extensive state secrecy statutes.[52] The American Medical Association's code of ethics prohibits physician participation in a legally authorized execution.[53]

II. Review of the Federal Execution Protocol Addendum

a. BOP's Development of the 2019 Addendum to the Federal Execution Protocol

In 2017, in a memorandum to the Attorney General, the Director of BOP requested approval to issue an Addendum to its Federal Execution Protocol that provided only for "the use of a single drug, phenobarbital sodium (pentobarbital), as the lethal agent."[54] The proposed addendum also specified procedural details such as dosage, identification of appropriate injection sites, and the number of backup syringes.[55] The memorandum detailed the development of the

---

[46] *Guidance Document: Current Good Manufacturing Practice*, Food & Drug Admin. (Jan. 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-guidance-human-drug-compounding-outsourcing-facilities-under.

[47] *See Compounding and the FDA: Questions and Answers*, Food & Drug Admin. https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers (last visited Dec. 30, 2024).

[48] *See Registered Outsourcing Facilities*, Food & Drug Admin., https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities (last visited Dec. 30, 2024) (noting that a Form 483 "does not constitute a final agency determination of whether any condition is in violation of the [Food, Drug, and Cosmetic] Act or any relevant regulations").

[49] *See, e.g.*, *Georgia Diagnostic and Classification Prison Lethal Injection Procedures*, Georgia Dept. of Corrections (Jul. 17, 2012), https://dpic-cdn.org/production/legacy/GeorgiaProtocol07.17.2012.pdf (last visited Dec. 30, 2024).

[50] Dep. of Rick Winter, *In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 19-MC-0145 (D.D.C. Sept. 20, 2020) (on file).

[51] *Id*.

[52] *See* Nadia N. Sawicki, *Clinicians' Involvement in Capital Punishment - Constitutional Implication*, 371 N. Engl. 103 J. Med. vol 2. 103-105 (2014); *see also* Nadia N. Sawicki, *Doctors, Discipline, and the Death Penalty*, 27 Yale L. & Pol'y Rev. 107 (2008).

[53] *Opinion 9.7.3, Capital Punishment*, American Medical Association, https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2022-08/9.7.3.pdf (last visited Dec. 30, 2024).

[54] Memorandum from the Federal Bureau of Prisons, *Approval of Bureau of Prisons' Death Penalty Protocol Addendum* (Nov. 27, 2017) (on file) [hereinafter "2017 BOP Memo"].

[55] *Id.*

addendum, including a review of state protocols, visits to state execution sites, and consultations with other Department components.[56] In the course of its review, BOP considered several alternatives to using pentobarbital in a single dose,[57] but determined that due to "complications inherent in obtaining multiple drugs" a single-drug pentobarbital protocol "was the most suitable method based on its widespread use by the states and its acceptance by many courts."[58]

In anticipation of future litigation, BOP retained a consulting firm, Elite Medical Experts,[59] to identify medical experts to review the addendum and prepare to testify about it in court.[60] The firm identified two medical professionals to review the addendum: Dr. Craig W. Lindsley of the Vanderbilt Center for Neuroscience Drug Discovery, and Dr. Joseph F. Antognini, a clinical professor of anesthesiology and pain medicine at the University of California Davis School of Medicine.

Dr. Lindsley submitted a 550-word report stating that in his expert opinion and "deep knowledge of the pharmacology of pentobarbital," the protocol would "produce a humane death with limited suffering and pain."[61] He wrote that, in his view, a person would lose consciousness within 10 to 30 seconds after being administered 5 grams of pentobarbital and would "be unaware of any pain or suffering due to the rapidity of the effect." Although he stated that he reviewed "the available literature and case studies in the public domain," his report did not include any citations.[62]

According to BOP's memorandum, Dr. Antognini did not submit a separate written evaluation of the protocol, but he "concur[ed] with the Addendum" and was "prepared to submit an expert report in defense of the protocol."[63] Despite later testifying that BOP was aware of experts with conflicting views on pentobarbital, a BOP representative stated that "[a]fter consulting with [Dr. Lindsley and Dr. Antognini], we didn't feel it was necessary to reach out to more."[64]

---

[56] *Id.*

[57] Prior to the identification of a domestic pentobarbital supplier, BOP considered the use of fentanyl as the lethal substance. *See* Memorandum from the Federal Bureau of Prisons, *Use of Fentanyl in Executions* (Mar. 7, 2018) (on file).

[58] 2017 BOP Memo, *supra* note 54, at 4.

[59] Today, Elite Medical Experts describes its mission as "align[ing] the top minds in healthcare – Professors of Medicine & Surgery – as experts in complex litigation." According to its website, "[w]ith nearly 8000 engagements domestically and abroad, Elite solves challenges so that our clients win." *See History & Mission,* Elite Medical, https://elitemedicalexperts.com/history-mission/ (last visited Dec. 30, 2024).

[60] The review was coordinated through, and paid for by, the United States Attorney's Office in D.C. in anticipation of future litigation.

[61] Lindsley Report, *In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 19-MC-145 (D.D.C. Sept. 20, 2020) (on file) [hereinafter "Lindsley Report"].

[62] *See id*.

[63] 2017 BOP Memo, *supra* note 54.

[64] Decl. of Rick Winter, *In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 19-MC-145 (D.D.C. Sept. 20, 2020) (on file).

Regarding the sourcing of pentobarbital, BOP initially intended to import powdered API pentobarbital from a foreign registered facility.[65] In a revised version of the memorandum from July 2019, however, BOP indicated it had identified a domestic source willing to provide the base ingredients and a compounding pharmacy to develop and produce the drug for executions.[66]

In July 2019, Attorney General Barr directed BOP to adopt an addendum to the Federal Execution Protocol that provided for the use of pentobarbital.[67] Four individuals on the federal death row brought suit to prevent BOP's use of the protocol, alleging that the protocol was unlawful and unconstitutional. A district court issued a preliminary injunction to prevent BOP from carrying out executions under the revised protocol, finding that the protocol "exceed[ed] the statutory authority" of the Federal Death Penalty Act insofar as it "create[d] a single implementation procedure" not authorized by the Act.[68] The U.S. Court of Appeals for the D.C. Circuit, however, vacated that injunction.[69] In June 2020, the Department announced Attorney General Barr had directed BOP to schedule the execution of four inmates,[70] the first of whom was executed on July 14, 2020,[71] a few hours after the U.S. Supreme Court vacated a district court order to stay the execution.[72] In total, 13 people were executed using the BOP's single-drug protocol between July 2020 and January 2021.[73]

---

[65] *See* 2017 BOP Memo, *supra* note 54, at 1 (stating "BOP also believes it has a viable plan to obtain pentobarbital. BOP intends to import powdered pentobarbital from a foreign FDA-registered facility" and would use a domestic compound pharmacy to create the injectable solution).

[66] After press reports publicly identified the BOP's source for pentobarbital API, the company announced that it would no longer manufacture pentobarbital. *See* Lauren Gill & Daniel Moritz-Rabson, *Company Linked to Federal Execution Spree Says it Will no Longer Produce Key Drug*, The Intercept (Jun. 22, 2024), https://theintercept.com/2024/06/22/pentobarbital-execution-drug-absolute-standards/.

[67] *See* Memorandum from the Federal Bureau of Prisons, *The Federal Bureau of Prisons' Federal Execution Protocol Addendum* (Jul. 24, 2019) (adopted and signed by the Attorney General) (on file) [hereinafter "FBOP Protocol Memorandum"].

[68] *In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 19-mc-145, 2019 WL 6691814, at *7 (D.D.C. Nov. 20, 2019) ("There is no statute that gives the BOP or DOJ the authority to establish a single implementation procedure for all federal executions.").

[69] *In re Federal Bureau of Prisons' Execution Protocol Cases*, 955 F.3d 106 (D.C. Cir. 2020).

[70] *See Executions Scheduled for Four Federal Inmates Convicted of Murdering Children*, U.S. Dep't of Just. (June 15, 2020), https://www.justice.gov/opa/pr/executions-scheduled-four-federal-inmates-convicted-murdering-children.

[71] Haley Fuchs, *Government Carries Out First Federal Execution in 17 Years*, N.Y. Times (July 14, 2020), https://www.nytimes.com/2020/07/14/us/politics/daniel-lewis-lee-execution-crime.html.

[72] *Barr*, 591 U.S. at 980 (noting that pentobarbital had been "used to carry out over 100 executions, without incident," and had been "repeatedly invoked by prisoners as a less painful and risky alternative to the lethal injection protocols of other jurisdictions").

[73] As previously noted, the Department amended 28 CFR Part 26, "Death Sentence Procedures," in November 2020. A discussion of those changes is below. *See infra*, at 19.

b. OLP's Review

As directed by the Attorney General, OLP undertook a comprehensive review of the federal execution protocol addendum. OLP consulted with experts, including academics, medical professionals, drug safety experts, and advocacy groups. OLP also conducted a literature review, including legal materials and medical and scientific research specifically related to the use of pentobarbital. OLP reviewed all available documentation related to prior executions using pentobarbital, including autopsy reports and witness accounts. OLP reviewed state execution protocols[74] and consulted with state representatives. OLP also consulted relevant Department components, including BOP, the U.S. Marshals Service, the Criminal Division, the Civil Division, the Office of the Solicitor General, the Drug Enforcement Administration, the Civil Rights Division, the Bureau of Justice Statistics, and the National Institute of Justice. And OLP consulted with other federal agencies, including the Department of Health and Human Services. In addition, in September 2022, OLP published a request for information in the Federal Register.[75] The request yielded comments from the Federal Capital Habeas Project, experienced capital counsel, and members of Congress.

The primary areas of concern related to the use of pentobarbital include the risk of flash pulmonary edema; pain associated with the injection of a highly alkaline solution into the bloodstream; and the lack of clarity as to whether pentobarbital causes individuals to become unconscious, and therefore incapable of feeling pain, or simply unresponsive. Based on recent medical research evaluating autopsy data from executions that used pentobarbital, information collected from autopsies conducted on two individuals recently executed by the federal government, recent witness accounts from federal and state executions, and a review of medical expert testimony in litigation, OLP concludes that there remains significant uncertainty about whether pentobarbital can be used in a single-drug execution protocol without causing unnecessary pain and suffering.

c. Risk of Flash Pulmonary Edema

A review of available research and consultation with academics indicates that there is a risk of flash (acute) pulmonary edema with the use of pentobarbital in executions.[76] Pentobarbital is a barbiturate, and flash pulmonary edema is a complication of barbiturate overdose. It occurs through several mechanisms, including direct caustic injury to the lungs, negative pressure pulmonary edema as the individual struggles to breathe against an obstructed airway, and diminished power of contraction by the heart.[77] As pulmonary edema can cause "a

[74] *See* Appendix (State Execution Protocols).
[75] Request for Information Regarding the Manner of Execution Regulations, 87 Fed. Reg. 58531 (Sept. 27, 2022) https://www.federalregister.gov/documents/2022/09/27/2022-20889/request-for-information-regarding-the-manner-of-execution-regulations.
[76] Although the research into pentobarbital is limited, the available research conforms with findings made in other drugs. *See* M W Potts & P W Smethurst, *Pleural effusion complicating thiopentone administration. A case report,* 39(1) Br J Anaesth. (1967) (finding pulmonary edema developing after the administration of sodium thiopental).
[77] Jin Ma et al., *Negative Pressure Pulmonary Edema,* 26(2), Exp Ther Med. (Aug. 4, 2023), doi: 10.3892/etm.2023.12154.

feeling of suffocating or drowning that worsens when lying down,"[78] experts have likened it to the experience elicited during waterboarding.[79]

A 2022 study by physicians Joel Zivot, Mark Edgar, and David Lubarsky reviewed autopsy reports from eight states (Alabama, Arkansas, Arizona, Florida, Georgia, Ohio, Oklahoma, and Virginia) using pentobarbital as a single drug or using midazolam[80] in a drug cocktail.[81] The study noted that pentobarbital is a highly alkaline solution (pH between 9.8-11) and that "massive quantities of acidic or basic solution entering the bloodstream during lethal injection may be directly toxic to pulmonary capillary endothelial cells and that the earliest manifestation of this injury is the escape of edema fluid into the lungs."[82] In essence, the drug's pH level is so high that it damages the blood vessels in the lungs and causes them to fill with fluid, leading to the feeling of drowning.

In their review of autopsy findings of 15 individuals executed by a protocol involving pentobarbital, Zivot, Edgar, and Lubarsky found evidence of lung edema in 10 of 15 cases, or 66 percent. This was evidenced by the "presence of froth, frothy fluid or blood-tinged froth located in the in the tracheobronchial tree… or fluid in lung parenchyma or small airways."[83] The authors noted froth in the airways "requires breathing to create froth, so the timing of pulmonary edema must, [by] definition, occur prior to the administration of a paralyzing agency or heart stopping medication."[84]

Finally, the authors wrote that for people who experience sudden death, which is the intended effect of lethal injection, the weight of a person's lungs after death should approximate normal lung weight, or an average of 234 grams.[85] Among the autopsies examined of those executed by lethal injection, however, "lung weights observed in this study were all above 400 grams (average weights for right and left lungs, respectively, in… pentobarbital executions 723 grams and 631 grams), indicating some combination of vascular congestion and parenchymal edema."[86]

---

[78] *Pulmonary edema; Sudden (acute) pulmonary edema signs and symptoms*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/pulmonary-edema/symptoms-causes/syc-20377009 (last visited Jan. 3, 2024).

[79] Noah Caldwell, Ailsa Chang & Jolie Myers, *Gasping for Air: Autopsies Reveal Troubling Effects of Lethal Injection,* NPR (Sept. 21, 2020), https://www.npr.org/2020/09/21/793177589/gasping-for-air-autopsies-reveal-troubling-effects-of-lethal-injection [hereinafter "NPR Report"].

[80] Midazolam is a benzodiazepine, while pentobarbital is a barbiturate. Both drugs act to depress the central nervous system but affect the functioning of the nervous system in different ways. *See* Thejasvi N. Lingamchetty, Seyed Alireza Hosseini & Abdolreza Saadabadi, *Midazolam*, StatPearls, National Library of Medicine (June 5, 2023), https://www.ncbi.nlm.nih.gov/books/NBK537321/ (last visited Jan. 3, 2024).

[81] Joel B. Zivot, Mark A. Edgar & David Lubarsky, *Execution by lethal injection: Autopsy findings of pulmonary edema,* (2022), doi.org/10.1101/2022.08.24.22279183 [hereinafter "Zivot Study"].

[82] *Id.*

[83] *Id*.

[84] *Id*.

[85] *Id*. (citing Hans Joachim, Ursus Nikolaus Riede & Christian Mittermayer, *The Weight of Human Lungs as a Diagnostic Criterium (Distinction of Normal Lungs from Shock Lungs by Histologic, Morphometric and Biochemical Investigations),*162(1) Pathology - Research and Practice, 24-40 (May 1978), doi.org/10.1016/S0344-0338(78)80129-0).

[86] Zivot Study, *supra* note 81.

NPR also recently released a detailed report that reviewed 216 autopsies that involved an internal examination of the lungs, some of which were likely reviewed by Zivot, Edgar, and Lubarsky's study.[87] In state executions that used pentobarbital as a single drug, 47 out of 58 autopsies were found to have signs of edema determined.[88]

Two autopsies were conducted after recent federal executions with pentobarbital, and both showed signs of pulmonary edema. First, the Associated Press (AP) reported on an autopsy of Corey Johnson's body following his execution in January 2021, and while the autopsy has not been made public, the AP reported that Johnson suffered from pulmonary edema and that "so much fluid rushed up his trachea that some exited his mouth."[89] Second, the autopsy of Wesley Purkey's body following his federal execution in July 2020, also found "severe bilateral acute pulmonary edema" and evidence of "[f]rothy pulmonary edema" in Purkey's trachea and mainstem bronchi, suggesting that fluid had built up in his lungs.[90] The physician performing the autopsy weighed Purkey's lungs and found that his right lung weighed 1140 grams and his left lung weighed 1160 grams[91] (as compared to the approximate normal lung weight, an average of 234 grams[92]).

Given the rare and specific circumstances in which such large amounts of pentobarbital are injected into humans, there are not additional scientific studies that address the risk of flash pulmonary edema in the context of lethal injection. Nonetheless, Zivot, Edgar, and Lubarsky's study of autopsy reports, and the review of autopsies reported by NPR and the AP, suggest that pulmonary edema is a significant risk when pentobarbital is used in executions.

The autopsy data also provide support for the expert statements and declarations that have been used by legislators considering amending state execution protocols and by courts in litigation related to executions using lethal injections.

Dr. Mark Edgar, one of the co-authors of the study discussed above, and an Associate Professor of Pathology at Emory University, submitted a comment to the Montana Legislature as it considered legislation to change its execution protocol in 2021.[93] In his comment, Dr. Edgar

---

[87] According to NPR, the reporters gathered 305 autopsy reports of inmates executed between 1990 and 2019 through public records requests or through evidence submitted in federal court cases, 216 of which contained an examination of the lungs. The states included Alabama, Arkansas, Arizona, Florida, Georgia, Ohio, Oklahoma, Tennessee and Virginia. Zivot, Edgar, and Lubarsky's study included 43 autopsy reports from Alabama, Arkansas, Arizona, Florida, Georgia, Ohio, Oklahoma, and Virgina. Therefore, while the NPR story includes a broader set of autopsies, it is likely there is overlap with those reviewed by Zivot, Edgar, and Lubarksy. *See* Zivot Study, *supra* note 81.

[88] *See* NPR Report, *supra* note 79.

[89] Michael Tarm, *Fuller Picture emerges of the 13 federal executions at the end of Trump's presidency*, AP News (Oct. 3, 2023), https://apnews.com/article/trump-executions-biden-death-penalty-brandon-bernard-c1b26807c5c40b337d14485c3d6df2de.

[90] *See* DeJong Autopsy report, *In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 19-MC-145 (D.D.C. Sept. 20, 2020) (on file).

[91] *Id.*

[92] Zivot study, *supra* note 81.

[93] *See* Public Comment by Mark Edgar, Montana Senate Judiciary Committee (March 22, 2021), https://archive.legmt.gov/bills/2021/Minutes/Senate/Exhibits/jus62a02.pdf; *see also* Alex Sakariassen, *Revising lethal injection – and reviving a death penalty in legal limbo*, Montana Free Press (Feb. 3, 2021), https://montanafreepress.org/2021/02/03/revising-lethal-injection-and-reviving-a-death-penalty-in-legal-limbo.

stated that he had "found evidence of prisoners developing acute and severe pulmonary edema...in both pentobarbital and midazolam executions," which, he argued, "produces sensations similar to drowning or asphyxiation as fluid occupies a greater volume of the air spaces."[94] He also wrote that in his review of autopsies conducted after an execution using pentobarbital, "at least two-thirds...showed findings consistent with development of acute pulmonary edema" during the execution, which he characterized as a "terrifying, horrific and painful condition that causes great suffering as the person struggles to breathe without being able to exchange air because of the compromised lungs."[95]

Dr. Gail Van Norman, a practicing internist and anesthesiologist and Adjunct Professor of Bioethics at the University of Washington, submitted an expert declaration on the risk of flash pulmonary edema in lethal injection executions involving pentobarbital.[96] She stated that the single-drug pentobarbital protocol would "subject executed prisoners to severe pain and suffering, when they remain conscious and aware prior to their deaths."[97] Dr. Van Norman described flash pulmonary edema as occurring extremely rapidly, stating that the "administration of a large dose of barbiturate causes lung injury, which in turn causes flash pulmonary edema."[98] She stated that as pulmonary edema sets in, the person has to "work harder and harder to breathe, and suffers sensations of shortness of breath and excruciating air hunger, similar to the sensations experienced in drowning and near-drowning victims."[99] She also noted that the drowning sensation is "one of the most powerful, excruciating feelings known to man," and is "deliberately elicited in 'the enhanced interrogation technique' called waterboarding."[100]

d. Risk of pain associated with the injection of a highly alkaline solution

In addition to concerns related to flash pulmonary edema, experts have warned that the use of high amounts of pentobarbital in a single-drug execution protocol could cause extreme pain upon the initial injection. As Zivot, Edgar, and Lubarsky describe in their study of autopsies pentobarbital is highly alkaline with a pH level between 9.8 and 11, and is like other barbiturates that "have long been known to cause vascular injury if improperly administered."[101]

Here again, given the rare circumstances in which such large amounts of pentobarbital are injected into humans, there are not specific scientific studies that evaluate the risk of pain in the context of lethal injection. Nonetheless, studies have noted that barbiturates can damage the veins in the body, causing the drug to leak into the surrounding tissue.[102] In Dr. Van Norman's opinion, "[p]entobarbital can cause excruciating pain if injected rapidly into veins, particularly if

---

[94] *Id.*
[95] *Id.*
[96] *See* Declaration of Dr. Van Norman submitted Nov. 1, 2019, at 31, *In re Federal Bureau of Prisons' Execution Protocol Cases*, 471 F. Supp. 3d 209 (D.D.C. 2020) (*vacated sub nom. Barr*, 591 U.S. 979) (on file) [hereinafter "2019 Van Norman Decl."].
[97] Declaration of Dr. Van Norman submitted Sept. 29, 2020, *In re Federal Bureau of Prisons' Execution Protocol Cases*, 471 F. Supp.3d 209 (D.D.C. 2020)) (on file).
[98] *Id.*
[99] 2019 Van Norman Decl. at 31, *supra* note 96.
[100] *Id.* at 34.
[101] Zivot Study, *supra* note 81, at 7.
[102] *See* Shibata Y. et al., *Injury due to extravasation of thipoental and propofol: risks/effects of local cooling/warming in rats,*8 Biochem Biophys Rep., 207-11 (2016), https://pubmed.ncbi.nlm.nih.gov/28955958/.

extravasation [where IV fluid leaks from the veins] or infiltration of the peripheral IV catheter occurs, or if inadvertent intra-arterial injection occurs."[103] In these cases, she argues, it would cause "significant, excruciating pain for prisoners undergoing judicial lethal injection with IV barbiturates."[104]

e. Witness accounts

In light of the limited research and unanswered questions about the risks of pulmonary edema and pain associated with lethal injection by pentobarbital, witness accounts take on greater significance and provide important anecdotal evidence. Witness accounts from the 13 federal executions using pentobarbital are particularly relevant.[105] In February 2021, AP News reported that "executioners who put [those] 13 inmates to death in the last months of the Trump administration likened the process of dying by lethal injection to falling asleep…but those tranquil accounts are at odds with reports by The Associated Press and other media witnesses of how prisoners' stomachs rolled, shook and shuddered as the pentobarbital took effect inside the U.S. penitentiary death chamber in Terre Haute, Indiana."[106] During the execution of Alfred Bourgeois in 2020, witnesses reported that he "grimaced and furrowed his eyebrows. He began to exhale rhythmically, and his stomach started to quiver uncontrollably."[107] It was observed during Lezmond Hall's execution in 2020 that his "chest heaved" and his "stomach area began to throb."[108] Similarly, in 2020, witnesses reported that William LeCroy's "midsection quickly began to heave uncontrollably" after the pentobarbital was administered.[109] In addition, in 2020, eyewitnesses observed that as the drug was administered to Orlando Hall, he "appeared to wince briefly and twitched his feet...open[ing] his mouth wide, as if he was yawning…[e]ach time that was followed by short, seemingly labored breaths."[110]

f. Consciousness versus responsiveness

It is not clear whether a person who receives 5 grams of pentobarbital can feel and experience the impact the drug has on the body. Throughout litigation related to the use of pentobarbital in lethal injection, experts have debated whether 5 grams of pentobarbital leaves a person in a state of disconnected consciousness, and therefore unable to experience impacts

[103] 2019 Van Norman Decl. at 8, *supra* note 96.
[104] *Id.*
[105] Witness accounts of non-federal executions have also indicated a risk of pain and suffering. See Declaration of Dr. Edgar submitted October 24, 2019, *In re Federal Bureau of Prisons' Execution Protocol Cases*, 471 F. Supp.3d 209 (D.D.C. 2020).
[106] *See* Michael Tarm, *Executioners sanitized accounts of deaths in federal cases*, AP News (Feb. 17, 2021), https://apnews.com/article/executioners-sanitized-accounts-of-death-25d133f59039150c2e308ba1a2a5caef.
[107] Michale Tarm, *US Executes Louisiana truck driver who killed daughter, 2*, AP News (Dec. 11, 2020), https://apnews.com/general-news-32f7e296aba11d7d749bb996cffe623b.
[108] Michael Tarm & Felicia Fonseca, *Only Native American on federal death row executed,* AP News (Aug. 25, 2020), https://apnews.com/general-news-d10a18eff9cdf43afda8810bf859949d.
[109] Jennifer Henderson & Steve Almasy, *Federal government executes inmate who blamed murder victim for using witchcraft on him*, CNN (Sept. 22, 2020), https://www.cnn.com/2020/09/22/us/federal-execution-william-lecroy/index.html.
[110] Jill Salter, *US government executes man convicted of killing Texas teen,* AP News (Nov. 18, 2020), https://apnews.com/article/kidnapping-coronavirus-pandemic-executions-terre-haute-william-barr-d25b85a78580efbacf899d6919ce1a15.

including flash pulmonary edema,[111] or whether the drug leaves a person in a state of connected consciousness, in which they may or may not be physically responsive to pain of pulmonary edema but are experiencing that pain.[112]

This question is unanswered by scientific study in the context of capital punishment, and it remains debated even within clinical settings involving anesthesia.[113] Recent studies have sought to distinguish "connected consciousness" from "responsiveness." While responsiveness can indicate connected consciousness, a lack of responsiveness "does not equate to the absence of internal or external awareness."[114] Indeed, studies argue that while "a state of disconnected consciousness is the optimal level of anesthesia, as it likely avoids both awareness and the possible dangers of oversedation...there are no reliably tested indices that can discriminate between connected consciousness, disconnected consciousness, and complete unconsciousness."[115]

III. Conclusion

After an extensive review of available scientific, medical, and legal research; recent autopsies of individuals who have received lethal injections of pentobarbital; consultation with experts within and outside the Department; and solicitation and consideration of public comments, there remains significant uncertainty about whether the use of pentobarbital as a single-drug lethal injection causes unnecessary pain and suffering. In the face of such uncertainty, the Department should err on the side of

---

[111] Dr. Lindsley's report stated that he believed a person would lose consciousness within 10-30 seconds of administering 5g of pentobarbital, and respiratory depression or heart failure would ensue within minutes. He opined that even if edema occurred within one minute of administration, the brain would be so profoundly depressed that the person would not experience it. *See* Lindsley Report, *supra* note 61. BOP's other retained expert, Dr. Joseph F. Antognini, stated : "It is my opinion, to a reasonable degree of medical and scientific certainty, that 1) the inmate would become unconscious within 20-30 sec after the initiation of the infusion of the pentobarbital, followed by respiratory arrest, cardiovascular collapse and death; 2) injection of massive doses (5 grams) of pentobarbital would not inflict mild, moderate or severe pain; 3) pulmonary edema, if it occurs ante-mortem, would not be perceived by the inmate because of the profound brain suppression caused by pentobarbital." Declaration of Dr. Antognini submitted June 25, 2020, *In re Federal Bureau of Prisons' Execution Protocol Cases*, 471 F. Supp.3d 209 (D.D.C. 2020) (on file).

[112] *See* 2019 Van Norman Decl., *supra* note 96. Dr. Van Norman argued that "it is extremely likely that prisoners given even high doses of barbiturates retain consciousness long enough to experience pain and suffering during the execution process using single-drug pentobarbital." She also argued that that Dr. Antognini, "despite decades of evidence to the contrary, appears to believe that unresponsiveness accurately predicts unconsciousness. This is a grave error."

[113] *See* Javier Montupil et al., *The Nature of Consciousness in Anesthesia*, 8 British Journal of Anesthesia Open 100224 (2023), https://pubmed.ncbi.nlm.nih.gov/37780201/.

[114] *Id.* (citing Robert D. Sanders et. al., *Unresponsiveness ≠ unconsciousness*, 116 Anesthesiology 946 (2012), https://pubmed.ncbi.nlm.nih.gov/22314293/); Charlotte Martial et al., *Near-Death Experience as a Probe to Explore (Disconnected) Consciousness*, 24(3) National Library of Medicine 173 (2020), https://pubmed.ncbi.nlm.nih.gov/31982302/; Melanie Boly et al., *Consciousness and responsiveness: lessons from anesthesia and the vegetative state,* 26(4) Current Opinion in Anesthesiology 444 (2013), https://pubmed.ncbi.nlm.nih.gov/23743554/.

[115] *See* Jiang Yandong & Jamie Sleigh, *Consciousness and General Anesthesia: Challenges for Measuring the Depth of Anesthesia*, 140(2) Anesthesiology 313 (2024), https://pubmed.ncbi.nlm.nih.gov/38193734/; *see also* Vincent Bonhomme et. al., *General Anesthesia: A Probe to Explore Consciousness*, 13 Frontiers in Systems Neuroscience 36 (2019), https://pubmed.ncbi.nlm.nih.gov/31474839/.

humane treatment and avoidance of unnecessary pain and suffering and cease the use of pentobarbital unless and until that uncertainty is resolved.

Part 2 – Manner of Execution Regulations

I. Background

The manner of execution by state and federal authorities has changed over the course of the nation's history. The Supreme Court canvassed that history in *Baze v. Rees*, and noted that "hanging was the 'nearly universal form of execution'" by the middle of the 19th century,[116] but that widespread concerns about the inhumanity of hanging led to adoption of electrocution on the "well-grounded belief that electrocution is less painful and more humane than hanging."[117] Although hanging, lethal gas, and firing squads were used for executions as well, until the late 20th century, electrocution was the predominant manner of execution. At that time, another round of public pressure to reconsider the optimal way to ensure a humane death by execution led states to turn to lethal injection as a preferred manner, and by the turn into the 21st century, the federal government and all of the state governments that implemented the death penalty adopted lethal injection.[118]

The federal, and most of the state, lethal injection protocols involved a three-drug "cocktail": first a barbiturate to sedate the prisoner, second a paralytic to halt respiration, and third a lethal agent to induce cardiac arrest. The Department issued a regulation in 1993 providing for lethal injection to be the sole manner of execution, but that regulation did not specify which substance or substances would be used. By the time of the next three federal executions, which occurred in 2001-2003, an execution protocol had been developed that instructed the use of a "cocktail" of sodium thiopental, pancuronium bromide, and potassium chloride.[119] That protocol was refined and revised several times over subsequent years, but the three drugs remained the same.[120]

In 2011, the Department of Justice could no longer procure sodium thiopental. States were similarly unable to purchase that barbiturate for use in executions. Public pressure brought to bear on pharmaceutical companies to refuse to supply lethal execution drugs meant that alternative sources, or alternative drugs, needed to be acquired for executions by lethal injection to continue.[121] The Department addressed that challenge by amending the federal execution

---

[116] *Baze*, 553 U.S. at 41 (citation omitted).
[117] *Id.* at 42 (quoting Malloy v. South Carolina, 237 U.S. 180, 185 (1915)).
[118] *See* Appendix. While lethal injection is the primary method used, some states have used alternative methods in recent years. As an example, Alabama (in 2002), South Carolina (in 2004 and 2008), and Virginia (in 2009, 2019, and 2013) have used electrocution in capital punishment.
[119] *See supra* Part 1, I(b) at 5-6.
[120] *See In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 12-CV-0782, 2019 WL 6691814, at *2 (D.D.C. Nov. 20, 2019).
[121] *See supra* note 31; *see also* Rebecca Katz, *Lethal Injection Challenges Continue Across the Country,* Am. Bar Assoc. (Mar. 1, 2012), https://www.americanbar.org/groups/committees/death_penalty_representation/project_press/2012/spring/li_challenges_continue/; Chris McGreal, *Lethal Injection Drug Production Ends in the US*, The Guardian (Jan. 23, 2011), https://www.theguardian.com/world/2011/jan/23/lethal-injection-sodium-thiopental-hospira.

protocol to require pentobarbital as the sole drug for lethal injection, and some states also began using pentobarbital, either as a substitute for sodium pentothal in a multi-drug "cocktail" or as a single drug lethal injection. But because the manufacturer of the injectable form of pentobarbital had also announced that it would not be supplying its product for use in executions, the Department needed to acquire the raw ingredient and have the injectable product made by a compounding pharmacy, as did several states.[122]

While some states still had statutorily authorized methods of execution in addition to lethal injection, they had mostly been using only lethal injections for some years. In addition to seeking alternative suppliers of execution drugs in the face of manufacturers' refusal to supply them, states began to turn to – or turn back to – other methods of execution. Of the 27 states that currently employ the death penalty, all have lethal injection as a sole or possible manner of execution: 13 have it as the sole manner;[123] 4 have it as the default manner, if the prisoner does not select another method;[124] 6 have it as the default, but if lethal injection is unavailable or deemed unconstitutional, other methods become the default;[125] and 4 have it as one of several options available to the correctional authority or for the prisoner to choose among.[126]

Thus, when the Department resumed federal executions in 2020, it was in an atmosphere of increasing uncertainty about the consistent availability of drugs for executions, and also of awareness that states were in the same position, and thus could be expected to turn to other methods authorized by their own statutes. These realizations helped spur the amendments to the Manner of Federal Executions regulation, conducted through notice-and-comment rulemaking and finalized on November 27, 2020.[127]

II. Review of the Manner of Execution Regulations

The Federal Death Penalty Act (FDPA) provides that a capital sentence in a federal case is to be implemented "in the manner prescribed by the law of the State in which the sentence is imposed."[128] The FDPA further provides that federal authorities "may use appropriate State or local facilities for the purpose [of execution], may use the services of an appropriate State or local official or of a person such an official employs for the purpose, and shall pay the costs thereof."[129] In other words, a federal execution must be carried out in the manner that the State would, and the federal authorities may make use of State personnel and facilities for that execution.

The most significant revisions made to the manner of execution regulation in 2020, reflecting the Department's awareness that it might confront a situation in which it was "required

[122] *See supra* Part 1, I(b) at 5-6.
[123] *See* Appendix (states include: Georgia, Indiana, Kansas, Kentucky, Montana, Nebraska, Nevada, North Carolina, Ohio, Oregon, Pennsylvania, South Dakota, and Texas).
[124] *Id.* (states include Alabama, Arizona, California, and Florida).
[125] *Id.* (states include Arkansas, Idaho, Oklahoma, Tennessee, Utah and Wyoming).
[126] *Id.* (states include Louisiana, Missouri, Mississippi, and South Carolina).
[127] Manner of Federal Executions, Final Rule, 85 Fed. Reg. 75846 (Nov. 27, 2020), https://www.federalregister.gov/documents/2020/11/27/2020-25867/manner-of-federal-executions.
[128] 18 U.S.C. § 3596(a).
[129] 18 U.S.C. § 3597(a).

to execute a Federal inmate according to the law of a State that uses a method other than lethal injection,"[130] were to repeat those two statutory provisions in the text of the regulation itself. The expressed motivation for aligning the regulation with the statute was to eliminate possible legal arguments against using a manner other than lethal injection (should the law of the sentencing State require another manner), and the final rule's explanatory text also made clear that the Department anticipated that, in such a case, "the most expedient means of carrying out the execution may be to arrange for State assistance."[131]

Whatever the motivation for making these changes, however, the fact of the matter is that they simply reiterate what the FDPA already states; were these changes not made, or were they rescinded, the law would remain the same.

Much the same can be said for the 2020 amendments that reiterated the Attorney General's broad delegation authority: The new regulatory language declares that "[a]ny task or duty assigned to any officer of the Department of Justice by this part may be delegated by the Attorney General to any other officer or employee of the Department of Justice."[132] That adds no authority that the Attorney General does not already possess, by virtue of long-standing federal statute, namely that "[a]ll functions of other officers of the Department of Justice and all functions of agencies and employees of the Department of Justice are vested in the Attorney General," and "[t]he Attorney General may from time to time make such provisions as he considers appropriate authorizing the performance by any other officer, employee, or agency of the Department of Justice of any function of the Attorney General."[133]

Finally, that the 2020 amendments gave the Attorney General authority to make exceptions to the regulations, while not simply a repetition of existing statutory authority, ultimately is not a cause for undue concern. The new language introduced through the rulemaking declared that "[w]here applicable law conflicts with any provision of this part, the Attorney General may vary from that provision to the extent necessary to comply with the applicable law."[134] It does not allow the Attorney General unfettered license to ignore or depart from the regulations' requirements. Rather, it acknowledges that there could be otherwise controlling law that might conflict with the regulatory requirements, and that the Attorney General then would have to comply with the law – but only when, and to the extent, it was necessary to meet that law's requirements.

Although there is nothing necessarily to modify or rescind in the manner of execution regulation, the pentobarbital evaluation described above compels the conclusion that the Attorney General should require such an evaluation of any other manner of execution before it is utilized by the federal government. The 2020 amendments to that regulation were undertaken in light of the changed operational facts about executions: It was increasingly likely that states would adopt alternative methods to lethal injection, it was a simple fact that the federal

---

[130] Manner of Federal Executions, Proposed Rule, 85 Fed. Reg. 47324 (proposed Aug. 5, 2020), https://www.federalregister.gov/documents/2020/08/05/2020-15039/manner-of-federal-executions.
[131] *Id.*
[132] *See* 28 C.F.R. § 26.1(c).
[133] *See* 28 U.S.C. §§ 509–510 (2002).
[134] *See* 28 C.F.R. § 26.1(b).

government was only equipped with the apparatus and experience of lethal injection, and so a future execution might well involve the Department's availing itself of a state facility and personnel to conduct a federal execution.

Were that circumstance to come to pass – and the Notice of Proposed Rulemaking for the 2020 amendments[135] makes clear that the possibility of just such a circumstance motivated the rulemaking – the Department should adhere to its responsibility to treat individuals humanely and avoid unnecessary pain and suffering. If a federal execution is to take place by a manner of execution other than the lethal injection of pentobarbital, the same kind of evaluation of that manner should be done as was done here on pentobarbital, with the same consideration of the risks posed by that method. And if the Attorney General in that case is not confident that the manner of execution does not risk inhumane treatment or unnecessary pain and suffering, then the Bureau of Prisons should be ordered not to proceed.

If the Attorney General determines that the manner of execution itself does not risk inhumane treatment or unnecessary pain and suffering, but that the Federal Bureau of Prisons does not have the capability, experience, and expertise to implement an execution in that manner, the Attorney General should determine before proceeding that the implementation of the execution in those facilities and by those personnel will not create a risk of inhumane treatment or unnecessary pain and suffering.

III. Conclusion

Because the amendments made in 2020 largely reflect statutory law, there is no present reason to modify or rescind them. However, if the federal government were required to conduct an execution by a manner other than lethal injection of pentobarbital, the Department should undertake an analysis of that manner like the one engaged in here with regard to pentobarbital before that other manner may be implemented.

[135] *See* Manner of Federal Executions, Proposed Rule, 85 Fed. Reg. 47324 (proposed Aug. 5, 2020), https://www.federalregister.gov/documents/2020/08/05/2020-15039/manner-of-federal-executions..

Appendix: State by State Execution Protocol (as of January 8, 2025)

State	Current Protocol/Statute	Determination	Most Recently Used
Alabama	Lethal injection, nitrogen hypoxia, electrocution. (Protocol issued August 25, 2023) (Ala. Code § 15-18-82.1.c)	Person must affirmatively choose nitrogen hypoxia or electrocution.	Nitrogen Hypoxia (November 22, 2024)
Arizona	Lethal injection or lethal gas; lethal injection is the default. (Protocol issued April 20, 2022) (Ariz. Rev. Stat. § 13-757)	If person was sentenced before November 23, 1992, they may select lethal gas.	1-drug pentobarbital (November 16, 2022)
Arkansas	Lethal injection; if needed, electrocution. *Protocol not publicly available.* (Ark. Code Ann. § 5-4-617)	If lethal injection is deemed "invalidated by a final and unappealable court order" then electrocution.	3-drug lethal injection, beginning with midazolam (April 27, 2017)
California	Lethal injection or lethal gas; lethal injection is the default. *No current protocol in place.* (Cal. Penal Code § 3604)	Person may request lethal gas.	Lethal injection (January 17, 2006) *Gubernatorial moratorium*
Florida	Lethal injection or electrocution. (Protocol issued March 10, 2023) (Fla. Stat. Ann. § 922.105)	Person must affirmatively choose electrocution.	3-drug lethal injection, beginning with etomidate (August 29, 2024)
Georgia	Lethal injection of pentobarbital. (Protocol issued July 17, 2012) (Ga. Code Ann. § 17 – 10-38)		1-drug lethal injection, pentobarbital (March 20, 2024)
Idaho	Lethal injection or firing squad. (Protocol issued October 11, 2024) (Idaho Code Ann. § 19 – 2716)	The Director of the IDOC must determine if lethal injection is available.	1-drug lethal injection, pentobarbital (attempted February 28, 2024)
Indiana	Lethal injection. *Protocol not publicly available.* (Ind. Code Ann. § 35-38-6-1)		Lethal Injection (December 18, 2024)
Kansas	Lethal injection. *No current protocol in place.* (Kan. Stat. Ann. § 22-4001)		Hanging (June 22, 1965)

State	Current Protocol/Statute	Determination	Most Recently Used
Kentucky	Lethal injection of pentobarbital. (Protocol issued July 6, 2018)		3-drug lethal injection, beginning with sodium thiopental (November 21, 2008)
Louisiana	Lethal injection, nitrogen hypoxia, or electrocution. (Protocol Issued March 12, 2014) (La. Stat. Ann. § 15:569)	The method used is at the discretion of the secretary of the Department of Public Safety and Corrections.	3-drug lethal injection, beginning with sodium thiopental (January 7, 2010)
Mississippi	Lethal injection is the default option. Authorizes use of nitrogen hypoxia if either lethal injection is held unconstitutional or "otherwise unavailable"; then authorizes electrocution if nitrogen hypoxia and lethal injection are held unconstitutional or "otherwise unavailable"; finally authorizes firing squad if nitrogen hypoxia, lethal injection, and electrocution are held unconstitutional or "otherwise unavailable." *Protocol not publicly available.* (Miss. Code Ann. § 99-19-51)	The Commissioner of Corrections has the authority and discretion to select and obtain the substances and the means necessary to carry out an execution.	3-drug lethal injection starting with midazolam (December 14, 2022)
Missouri	Lethal injection or lethal gas. (Protocol issued October 22, 2013) (Mo. Ann. Stat. § 546.720)	Unclear if person or the Director of the Missouri Department of Corrections selects method.	1-drug lethal injection, pentobarbital (December 3, 2024)
Montana	Lethal injection. (Protocol issued January 16, 2013)		3-drug lethal injection, beginning with sodium thiopental (August 11, 2006)
Nebraska	Lethal injection: by 4-drug protocol, including fentanyl citrate. (Protocol issued November 9, 2017)		4-drug lethal injection: diazepam, fentanyl citrate, cisatracurium besylate, potassium chloride (August 14, 2018)
Nevada	Lethal injection by 3-drug protocol, beginning with an opioid (fentanyl or alfentanil). (Protocol issued June 9, 2021)		Lethal Injection (April 26, 2006)

State	Current Protocol/Statute	Determination	Most Recently Used
North Carolina	Lethal injection by 3-drug protocol of pentobarbital. (Protocol issued October 24, 2013)		3-drug lethal injection, beginning with sodium thiopental (August 18, 2006)
Ohio	Lethal injection. *Protocol not publicly available.* (Ohio Rev. Code. Ann. § 2949.22)		3-drug lethal injection, beginning with midazolam (July 18, 2018) *Gubernatorial moratorium*
Oklahoma	Lethal injection is the default; authorizes use of nitrogen hypoxia if either lethal injection is held unconstitutional or "otherwise unavailable"; then authorizes electrocution if nitrogen hypoxia and lethal injection are held unconstitutional or "otherwise unavailable"; finally authorizes firing squad if nitrogen hypoxia, lethal injection, and electrocution are held unconstitutional or "otherwise unavailable." (Protocol issued February 2020) (Okla. Stat. Ann. tit. 22 § 1014)	"An appellate court of competent jurisdiction" decides method.	3-drug lethal injection, beginning with midazolam (December 19, 2024)
Oregon	3-drug lethal injection protocol *Protocol not publicly available.* (Or. Rev. Stat. Ann. § 137.473)		3-drug lethal injection, beginning with sodium thiopental (May 16, 1997) *Gubernatorial moratorium*
Pennsylvania	Lethal injection. *Protocol not publicly available.* (61 Pa. Stat. and Cons. Stat. Ann. § 4304)		3-drug lethal injection, beginning with sodium thiopental (July 6, 1999) *Gubernatorial moratorium*
South Carolina	Electrocution, firing squad or lethal injection. *Protocol not publicly available.* (S.C. Code Ann. § 24-3-530)	Person must select firing squad or lethal injection "under the direction of the Director of the Department of Corrections." If person fails to select a method, then the	1-drug lethal injection, pentobarbital (November 1, 2024)

State	Current Protocol/Statute	Determination	Most Recently Used
		penalty must be administered by electrocution.	
South Dakota	1-drug lethal injection: pentobarbital. (Protocol issued July 23, 2020) (S.D. Codified Laws § 23A-27A-32.1)		1-drug lethal injection, pentobarbital (November 4, 2019)
Tennessee	Lethal injection of pentobarbital or electrocution. (Tenn. Code Ann. § 40-23-114) *Protocol not publicly available.*	If crime committed before December 31, 1998, person may select electrocution. If lethal injection is deemed unconstitutional or unavailable, then electrocution will be used.	Electrocution (February 20, 2020)
Texas	Lethal injection. (Protocol issued April 2021)		1-drug lethal injection of pentobarbital (October 1, 2024)
Utah	Lethal injection or firing squad. *Protocol not publicly available.* (Utah Code Ann. § 77-18-5.5)	Authorizes firing squad if lethal injection is unavailable or held to be unconstitutional. Also, if person committed crime before May 3, 2004, they may select firing squad.	3-drug lethal injection including pentobarbital (August 8, 2024)
Wyoming	Lethal injection or lethal gas *Protocol not publicly available.* (Wyo. Stat. Ann. § 7-13-904)	Authorizes lethal gas if lethal injection is held to be unconstitutional.	3-drug lethal injection, beginning with sodium thiopental (January 22, 1992)