UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

In the Matter of the Federal Bureau of Prisons' Execution Protocol Cases,	)	
LEAD CASE: *Roane, et al. v. Barr*	)	Case No. 19-mc-145 (TSC)
THIS DOCUMENT RELATES TO:	)	
ALL CASES	)	

MEMORANDUM OPINION

Plaintiff Keith Nelson was sentenced to death on March 11, 2002. The government plans to carry out his execution on August 28, 2020 in accordance with the procedures set forth in the 2019 Bureau of Prisons Execution Protocol (hereinafter "the Protocol"). (ECF No. 99.) The focal point of the Protocol—and of this case—is the use of the drug pentobarbital sodium. (*See* ECF No. 39-1, Admin R. (AR) at 875.)

Before the court are Nelson's and the government's cross-motions for summary judgment as to the alleged violations of the Food, Drug, and Cosmetic Act (FDCA) in Counts VIII, X, and XI of the Amended Complaint. (*See generally* ECF No. 92, Am. Compl.; ECF No. 170, Defs. Mot.; ECF No. 180, Nelson Cross-Mot.). All three counts are brought pursuant to the Administrative Procedure Act (APA). Nelson alleges that: (i) the Bureau of Prisons (BOP) and U.S. Department of Justice (DOJ) acted arbitrarily and capriciously by failing to provide adequate justification for their failure to comply with the FDCA (Count VIII), (Am. Compl. ¶ 163); (ii) the Food and Drug Administration (FDA) commissioner acted arbitrarily and capriciously by refusing to exercise his enforcement authority under the FDCA (Count X), (*id.* ¶ 182); and (iii) the government's use of pentobarbital under the Protocol is contrary to law

because it violates the FDCA (Count XI), (*id.* ¶ 188). Nelson also asks the court to enjoin the government from executing him using pentobarbital that has been acquired without a prescription or otherwise in violation of the FDCA.

In its July 15, 2020 Memorandum Opinion granting Plaintiffs' motion for a preliminary injunction, the court—and the U.S. Court of Appeals for the District of Columbia Circuit on review—determined that Plaintiffs had demonstrated a likelihood of success on the merits of at least some of their FDCA claims. (ECF No. 145, July 15 Mem. Op. at 7.); *In re Fed. Bureau of Prisons' Execution Protocol Cases*, No. 20-5206, slip op. at 3 (D.C. Cir. July 15, 2020). The Supreme Court summarily vacated the court's injunction but did not address the merits of the FDCA claims. *Barr v. Purkey*, No. 20A10, 2020 WL 4006821 (July 16, 2020).

For the reasons that follow, the court finds that Nelson is entitled to summary judgment as to Count XI. This finding is compelled by Circuit precedent which has not been reversed—or addressed—by the Supreme Court. The court grants the government's motion for summary judgment as to Count X in its entirety and Count VIII to the extent it concerns violations of the FDCA. Accordingly, both motions are GRANTED IN PART and DENIED IN PART.

I. BACKGROUND

The court has set forth the facts of this case in detail in prior opinions. Nelson, along with the other plaintiffs in the case, filed the operative Complaint on June 1, 2020, alleging that the Protocol is arbitrary and capricious under the APA, that it violates the FDCA and the Controlled Substances Act (CSA), that it violates Plaintiffs' right to counsel in violation of the First, Fifth, and Sixth Amendments, and that it is cruel and unusual in violation of the Eighth Amendment.

On July 13, 2020, the court preliminarily enjoined the executions of Plaintiffs Lee, Purkey, Honken, and Nelson. (ECF No. 135 at 22.) It found that these four Plaintiffs had demonstrated a likelihood of success on the merits of their claims that the Protocol is cruel and unusual in violation of the Eighth Amendment, but it did not rule on their other statutory and constitutional claims. (*Id.* at 18.) The D.C. Circuit declined to stay or vacate the court's injunction, *see In re Fed. Bureau of Prisons' Execution Protocol Cases*, No. 20-5199 (D.C. Cir. July 13, 2020), but the Supreme Court vacated the injunction early in the morning of July 14, 2020, *Barr v. Lee*, No. 20A8, 2020 WL 3964985 (July 14, 2020) (per curiam). The majority explained that Plaintiffs' Eighth Amendment claim "face[d] an exceedingly high bar" given that the Court had "yet to hold that a State's method of execution qualifies as cruel and unusual." *Id.* at *1 (quoting *Bucklew v. Precythe*, 139 S. Ct. 1112, 1124 (2019)). It also emphasized that "[l]ast-minute stays . . . should be the extreme exception, not the norm." *Id.* at *2. Four justices dissented. *Id.* at *2–3.

On July 14, 2020, Plaintiffs Purkey, Honken, and Nelson filed an emergency motion, (ECF No. 144), asking the court to rule on the remaining grounds asserted in their motion for a preliminary injunction, (ECF No. 102). The court did so on July 15, 2020 and again enjoined Purkey, Honken, and Nelson's executions. (ECF No. 146.) It found that of Plaintiffs' remaining claims, only those alleging violations of the FDCA were likely to succeed on the merits. (July 15 Mem. Op. at 7.) A three-judge panel of the D.C. Circuit agreed and denied the government's request to stay this court's injunction pending appeal. *In re Fed. Bureau of Prisons' Execution Protocol Cases*, No. 20-5206 (D.C. Cir. July 15, 2020).

The Supreme Court again vacated this court's injunction but did not address the FDCA claims. *Barr v. Purkey*, No. 20A10, 2020 WL 4006821 (July 16, 2020).

The government filed an omnibus motion to dismiss all Plaintiffs' non-APA claims and a motion for summary as to Plaintiffs' APA claims on July 31, 2020. (*See generally* Def.'s Mot.) As noted, Nelson filed a cross-motion for summary judgment on his FDCA claims.

II. LEGAL STANDARDS

A. Standards for Summary Judgment

Summary judgment is appropriate if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett,* 477 U.S. 317 (1986); *Waterhouse v. Dist. of Columbia*, 298 F.3d 989, 991 (D.C. Cir. 2002). A court may enter summary judgment on a "claim or defense . . . or [a] part of each claim or defense." Fed. R. Civ. P. 56(a). A dispute of fact is "genuine" only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby*, 477 U.S. 242, 248 (1986). A dispute is "material" only when it involves facts "that might affect the outcome of the suit under the governing law." *Id.* at 248. "[F]actual disputes that are 'irrelevant or unnecessary' do not affect the summary judgment determination." *Holcomb v. Powell*, 433 F.3d 889, 895 (D.C. Cir. 2006) (*quoting Liberty Lobby*, 477 U.S. at 248). The party seeking summary judgment "bears the heavy burden of establishing that the merits of his case are so clear that expedited action is justified." *Taxpayers Watchdog, Inc., v. Stanley*, 819 F.2d 294, 297 (D.C. Cir. 1987).

In considering a motion for summary judgment, the court must view all facts in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The moving party "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the 'pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits . . .'

which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp.*, 477 U.S. at 323.

As a preliminary matter, both parties agree—as does the court—that the questions presented on these cross-motions are questions of law which are appropriate for resolution on motions for summary judgment. (*See* Nelson Cross-Mot. at 3–4; ECF No. 187, Defs. Opp'n to Nelson Cross-Mot. at 1.)

B. The APA

Although Nelson alleges that the government has failed to comply with the FDCA, it would be more accurate to describe his claims as challenges under the APA for agency actions that are "arbitrary and capricious" and "not in accordance with law"—violations for which the APA provides a private right of action. 5 U.S.C. §§ 702, 706(2)(A). *See also Chrysler Corp. v. Brown*, 441 U.S. 281, 316–18 (1979) (finding government violations of Trade Secrets Act reviewable even where Act contained no private right of action).

On a motion for summary judgment in a suit seeking APA review, the court must set aside any agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). The court's review is "highly deferential" and begins with a presumption that the agency's actions are valid. *Envtl. Def. Fund, Inc. v. Costle*, 657 F.2d 275, 283 (D.C. Cir. 1981). The court is "not empowered to substitute its judgment for that of the agency," *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), but instead must consider only "whether the agency acted within the scope of its legal authority, whether the agency has explained its decision, whether the facts on which the agency purports to have relied have some basis in the record, and whether the agency considered the relevant factors," *Fulbright v. McHugh*, 67 F. Supp. 3d 81, 89 (D.D.C. 2014) (quoting *Fund for Animals v. Babbitt*,

903 F. Supp. 96, 105 (D.D.C. 1995)). The plaintiff bears the burden of establishing the invalidity of the agency's action. *Id.*

III. DISCUSSION

A. The Contrary to Law Claim (Count XI)

With respect to Count XI, Nelson argues that the government must acquire a prescription for pentobarbital for use in the execution and that its failure to do so was "not in accordance with law." (Nelson Cross-Mot. at 2.) Nelson also contends that the compounded pentobarbital the government intends to use in his execution has not been approved by the FDA and does not otherwise qualify for an exemption from FDA approval. (*Id.* at 6–7.) The government maintains that pentobarbital is not subject to the FDCA when used for lethal injections. (Defs. Opp'n to Nelson Cross-Mot. at 4.) The court addresses the prescription requirement first.

The "core" legislative purpose of the FDCA is to ensure that a "drug" is "safe and effective for its intended use." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). To do so, it expressly conditions the dispensing of controlled substances, including pentobarbital, upon either (i) "a written prescription of a practitioner licensed by law to administer such drug," or (ii) "an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist." 21 U.S.C. § 353(b)(1)(B).

It is undisputed that a prescription is required to dispense pentobarbital in the ordinary course. It is also undisputed that the government has not obtained a prescription—nor does it intend to—for the use of pentobarbital in Nelson's execution. This presents a pure legal question: is pentobarbital subject to the FDCA when used for lethal injection? Under D.C. Circuit precedent, the answer appears to be yes. Thus, the government's failure to acquire a

prescription for the use of pentobarbital in Nelson's execution is contrary to law and thereby violates the APA.

In reaching this conclusion, this court is mindful of the fact that the Supreme Court has vacated two of its injunctions in this case. However, this court is now tasked with deciding whether to enter a final judgment and is guided by what the D.C. Circuit has held—and what the Supreme Court has not.

The D.C. Circuit has previously held that drugs used in executions are subject to the FDCA. *See Cook v. FDA*, 733 F.3d 1, at 10–11 (D.C. Cir. 2013) (finding that "the FDA's policy of admitting foreign manufactured thiopental designed for state correctional facilities, as well as the several individual admissions of such shipments . . . violate[d] substantive prohibitions of the FDCA"). And a unanimous three-judge panel affirmed this court's conclusion on that issue in this very case. *In re Fed. Bureau of Prisons' Execution Protocol Cases*, No. 20-5206, slip op. at 3 (D.C. Cir. July 15, 2020) (discussing *Cook*, 733 F.3d 1) (explaining that the government's argument that drugs used for lethal injunctions are not subject to the FDCA "conflicts with the necessary premise of a published precedential decision of our court").

This precedent forecloses the government's argument that because lethal injection drugs are intended to kill, they could not possibly be regulated by laws intended to ensure that a drug is "safe and effective" for its intended use. (Defs. Opp'n to Nelson Cross-Mot. at 4 (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).); *see also In re Fed. Bureau of Prisons' Execution Protocol cases*, No. 20-5206 (D.C. Cir. July 15, 2020). Violations of the FDCA carry "the risk that the drug[s] will not function as intended," therefore the statute must apply in the lethal-injection context, because a lethal injection drug that does not function as intended may "result in conscious suffocation, pain, and cardiac arrest." *Beaty v. FDA*, 853 F.

Supp. 2d 30, 37 (D.D.C. 2012), *aff'd in relevant part sub nom. Cook*, 733 F.3d 1. This is especially so where, as here, Defendants have justified the Protocol on the grounds that pentobarbital will render inmates insensate during the execution process. Where 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.

Therefore, the court finds that the pentobarbital the government intends to use to execute Nelson requires "a written prescription of a practitioner licensed by law to administer such drug," or "an oral prescription of such practitioner which is reduced promptly to writing and filed by [a] pharmacist." 21 U.S.C. § 353(b)(1)(B). The government's failure to acquire such a prescription is "not in accordance" with the FDCA and thereby violates the APA. *See* 5 U.S.C. § 706(2)(A). Nelson is therefore entitled to judgment in his favor as to Count XI.

The court does not read the Supreme Court's vacatur of this court's July 15 injunction to mean that Nelson's FDCA claim fails as a matter of law. (*See* Defs. Opp'n to Nelson Cross-Mot. at 1–2.) The Supreme Court did not opine on the merits of the FDCA claims. And contrary to the government's position, it would be improper for the court to interpret the Supreme Court's vacatur as an indication of how this court should resolve the dispute on the merits. Doing so would "improperly equate[] 'likelihood of success' with 'success,' . . . [and] ignores the significant procedural differences between preliminary and permanent injunctions." *University of Texas v. Camenisch*, 451 U.S. 390, 394 (1981) (noting also that "it is generally inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the merits"). This court must read the Supreme Court's vacatur in light of the "limited purpose" of the injunctive relief Nelson sought at the time. *Id.* at 395 (explaining that preliminary injunctions

"merely [] preserve the relative positions of the parties until a trial on the merits can be held"); *see also Cobell v. Norton*, 391 F.3d 251, 261 (D.C. Cir. 2004) ("Summary judgment substitutes for trial . . . [whereas a] preliminary injunction is just that—preliminary. It does not substitute for a trial, and its usual office is to hold the parties in place until a trial can take place.").

Furthermore, the Supreme Court has expressly declined to consider the "thorny" jurisdictional issue of whether of the FDCA applies to drugs used for executions. *See Heckler v. Chaney*, 470 U.S. 821, 828 (1985); *In re Federal Bureau of Prisons' Execution Protocol Cases*, No. 20-5206, slip op. at 3 (D.C. Cir. July 15, 2020).

Having concluded that pentobarbital is still subject to the FDCA when used in lethal executions, the court also finds that the pentobarbital the government intends to use in Nelson's execution is not exempt from the FDCA's premarketing, label, and prescription requirements. (*See* Nelson Cross-Mot. at 6.) It is undisputed that the government has failed to adhere to these requirements.

Sections 352(f)(1), 355, and 360eee-1 of Title 21 set forth restrictions on drugs subject to the FDCA. 21 U.S.C. § 352(f)(1) (labeling requirements); *id.* § 355 (approval requirements); *id.* § 360eee-1 (manufacturing and distribution requirements). Exempt from these restrictions are drugs that "have been compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility" so long as certain conditions are met. *Id.* § 353b(a). As relevant here, the exemptions do not apply if the outsourcing facility produces a drug that is "essentially a copy of one or more approved drugs," *id.* § 353b(a)(5). "[E]ssentially a copy" means the drug is "identical or nearly identical to an approved drug" or contains a "bulk drug substance that is a component of an approved drug." *Id.* § 353b(d)(2)(A)–(B).

Nelson submits that laboratory tests obtained by the government show that it intends to use an outsourcing facility to produce a compounded product that is "essentially a copy" of FDA-approved pentobarbital. (Nelson Cross-Mot. at 6 (citing AR 4–5, 932–33, 970–1015).) The government does not refute this argument. Instead, it hangs its hat on its claim that pentobarbital is not subject to the FDCA when used for lethal injection—a claim that the court has already rejected. Furthermore, the court's prior finding that the government's decision to use pentobarbital was not arbitrary and capricious does not preclude a finding that its failure to comply with FDCA is contrary to law. (*See* ECF No. 145, Mem. Op. at 9.)

Accordingly, the compounded pentobarbital the government intends to use to execute Nelson is not exempt from the FDCA's premarketing, labeling, and prescription requirements, and Nelson is therefore entitled to summary judgment on Count XI of the amended complaint.

B. <u>The Failure to Enforce Claim (Count X)</u>

In Count X, Nelson asserts that the FDA Commissioner's failure to enforce the FDCA's requirements was arbitrary and capricious. Unlike his contrary-to-law claim in Count XI, this claim is foreclosed by Supreme Court precedent.

It is well established that "an agency's decision not to take enforcement action should be presumed immune from judicial review under § 701(a)(2)." *Cook*, 733 F.3d at 6 (quoting *Chaney*, 470 U.S. at 832). That presumption may be rebutted if "the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id.*

In *Chaney*, a case similar to this one, several death row inmates challenged the FDA Commissioner's refusal to investigate and enforce perceived violations of the FDCA relating to the drugs that would be used in their executions. Applying the standard set forth above, the Supreme Court held that the FDA's general enforcement provisions were "not subject to judicial

review under the APA." *Chaney*, 470 U.S. at 837–38; *see* 21 U.S.C. § 372. It found that the relevant statutes expressly authorized, but did not require, the agency to initiate investigations of alleged FDCA violations. The Court further explained that "Congress may limit the agency's exercise of enforcement power if it wishes, either by setting substantive priorities, or by otherwise circumscribing an agency's power to discriminate among issues or cases it will pursue." *Id.* at 833. Absent such instruction, the decision of whether to take enforcement action would remain "committed to agency discretion." *Id.* at 832.

Applying this framework, in *Cook* the D.C. Circuit found that plaintiffs rebutted this presumption. In that case, a group of inmates on death row brought an APA action against the FDA for failing to prohibit the importation of foreign-manufactured sodium thiopental, the drug that would be used to carry out their executions. 733 F.3d at 3. The D.C. Circuit reasoned that the import provisions of the FDCA at 21 U.S.C. § 381(a) "set[] forth precisely when the agency must determine whether a drug offered for import appears to violate the FDCA, and what the agency must do with such a drug." *Id.* at 7. Having determined that the sodium thiopental at issue qualified for an importation ban, the Court found that the agency's refusal to enforce it was contrary to law.

Here, Nelson alleges that the FDCA Commissioner failed to enforce sections 353(b), 353a, and 353b of Title 21. (Am. Compl. ¶ 181.) The court's analysis begins—and ends—with the presumption that such claims are immune from judicial review. Nelson has failed to demonstrate that these provisions contain enforcement "guidelines" that were ignored. In fact, these are not enforcement provisions at all. Section 355 provides the basis for enforcement for § 353(b) (the prescription requirement) and § 353b (setting forth conditions under which drugs may be compounded for human use in an "outsourcing facility" without having to comply with

certain FDCA requirements); however, the Supreme Court has already found that § 355 provides no basis to disturb the presumption of non-justiciability. *See Chaney*, 470 U.S. at 835–36 (describing § 355 as "simply irrelevant to the agency's discretion to refuse to initiate proceedings"); *see also Jerome Stevens Pharm. Inc. v. FDA*, 402 F.3d 1249, 1258 (D.C. Cir. 2005) (explaining that 21 U.S.C. § 355 does not "provide guidelines for the exercise of" the agency's enforcement discretion). And Nelson has not demonstrated how § 353a, which requires a valid prescription reflecting a medical practitioner's order that a "compounded product is necessary for the identified patient," cabins the FDA commissioner's enforcement discretion.

Thus, the government is entitled to summary judgment as to Count X.

C. Failure to Explain Violations of FDCA (Count VIII)

Finally, Nelson is not entitled to summary judgment on Count VIII to the extent the allegations therein implicate the FDCA. In Count VIII, Nelson alleges that neither the DOJ nor the BOP adequately justified their failure to comply with the FDCA. (Am. Compl. ¶ 163.) This position is untenable given the existence of an Office of Legal Counsel opinion advising "that the FDCA does not allow FDA to regulate an article intended for use in capital punishment in the United States." *See* OLC Op., 2019 WL 2235666 at *7. While an agency's failure to follow a statute renders its action contrary to law, its reliance on a well-reasoned advisory opinion which presents a plausible interpretation of that statute cannot be said to arbitrary and capricious. (*See* ECF No. 191 at 24 (confirming the "FDA's adherence to the OLC Opinion regarding the Protocol").)

Accordingly, the court will enter summary judgment in favor of the government on Count VIII as to the alleged FDCA violations therein.

* * * * * *

In granting summary judgment for Plaintiffs on Count XI today, the court does not enter a preliminary stay. It enters final judgment granting Nelson the injunctive relief he seeks until the government can comply with the requirements of the FDCA. As the Supreme Court instructed, this court must do its part to ensure "method of execution questions . . . are resolved fairly and expeditiously." *Lee*, 2020 WL 3964985, at *2. Allowing an execution to proceed under the challenged protocol in light of the government's failure to abide by its own statutory obligations would not comport with any basic notion of fairness. And this court cannot, in good conscience, deny a claim it concludes entitles a litigant to relief absent express guidance to the contrary from the Supreme Court or the D.C. Circuit.

IV. CONCLUSION

For the foregoing reasons, Nelson's emergency cross-motion for summary judgment is GRANTED IN PART. His motion is GRANTED as to Count XI but DENIED as to Count X and Count VIII to the extent it alleges a violation of the FDCA. The government's motion for summary judgment is GRANTED as to Count X and Count VIII (as to the FDCA allegations therein) for all Plaintiffs.

The court hereby enjoins Defendants from executing Keith Nelson until they have met the requirements of the FDCA.

Date: August 27, 2020

Tanya S. Chutkan
TANYA S. CHUTKAN
United States District Judge