# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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In the Matter of the Federal Bureau of Prisons' Execution Protocol Cases,

LEAD CASE: Roane, et al. v. Barr

THIS DOCUMENT RELATES TO:

ALL CASES

Case No. 19-mc-145 (TSC)

# **MEMORANDUM OPINION**

Plaintiffs are inmates on federal death row who challenge Defendants' efforts to execute them pursuant to the 2019 Federal Bureau of Prisons' Execution Protocol (the 2019 Protocol or the Protocol). Defendants have filed an omnibus motion for summary judgment on Plaintiffs' Administrative Procedure Act (APA) claims and a motion to dismiss all remaining claims pursuant to Fed. R. Civ. P. 12(b)(6). All Plaintiffs have moved for partial summary judgment, (ECF No. 236), as to the violations of the Food, Drug, and Cosmetic Act (FDCA) in Count XI of the Amended Complaint, (ECF. No. 92).<sup>1</sup> Most of these claims have been addressed in one way or another by this court or the Court of Appeals for the District of Columbia Circuit, and it is the court's intention to enter final judgment on most of the remaining claims.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Plaintiff William Emmett LeCroy has advised the court that he joins this motion. His contraryto-law FDCA claims appear in Count V of his Amended Complaint. (*See* ECF No. 245.)

<sup>&</sup>lt;sup>2</sup> The court has not yet ruled on Plaintiff Norris Holder's applied Eighth Amendment claim (ECF No. 94), and Plaintiffs' motion, (ECF No. 238), to alter the court's August 20, 2020 judgment, (ECF No. 205).

For the reasons set forth below, Defendants' omnibus motion is GRANTED in part. The court DENIES Defendants' motion as to the FDCA claims in Count XI, but the motion is GRANTED in all other respects except as to Norris Holder's as-applied Eighth Amendment challenge. Accordingly, Plaintiffs' motion for partial summary judgment on the FDCA claims in Count XI (and in Count V of Plaintiff LeCroy's Amended Complaint) is GRANTED, but the injunctive relief sought therein is DENIED for all Plaintiffs except Norris Holder.<sup>3</sup>

## I. BACKGROUND

### A. 2004 Execution Protocol

In 2005, James H. Roane, Jr., Richard Tipton, and Cory Johnson, three federal death row inmates, sued, alleging that their executions were to be administered under an unlawful and unconstitutional execution protocol. *Roane v. Gonzales*, 1:05-cv-02337 (D.D.C.), ECF No. 1 ¶ 2. The court preliminarily enjoined their executions. *Roane*, ECF No. 5. Four other death row inmates intervened, and their executions were enjoined as well. *See Roane*, ECF Nos. 23, 27, 36, 38, 67, and 68. During this litigation, Defendants produced a 50-page document (the 2004 Main Protocol) outlining the Bureau of Prisons' (BOP) execution procedures. *Roane*, ECF No. 179-3. Defendants then produced two three-page addenda to the 2004 Main Protocol. *See Roane*, ECF No. 177-3 (Addendum to Protocol, July 1, 2007) (the 2007 Addendum); ECF No. 177-1 (Addendum to Protocol, Aug. 1, 2008) (the 2008 Addendum). In 2011 the Department of Justice (DOJ) announced that the BOP did not have the drugs it needed to implement the 2008 Addendum. *See* Letter from Office of Attorney General to National Association of Attorneys General, (Mar. 4, 2011), https://files.deathpenaltyinfo.org/legacy/documents/2011.03.04.holder. letter.pdf. Defendants informed the court that the BOP "has decided to modify its lethal

<sup>&</sup>lt;sup>3</sup> The court will rule separately on Plaintiff Holder's request for injunctive relief.

injection protocol but the protocol revisions have not yet been finalized." *Roane*, ECF No. 288 at 2. In response, the court stayed the *Roane* litigation. No further action was taken in the cases for over seven years.

#### B. 2019 Execution Protocol

On July 24, 2019, the DOJ announced a new addendum to the execution protocol, (ECF No. 39-1, Admin. R. at 874–78), replacing the three-drug protocol of the 2008 Addendum with a single drug: pentobarbital sodium. (*Id.* at 879–80.) The BOP also adopted a new protocol to replace the 2004 Main Protocol. (*Id.* at 1021–72.) The 2019 Protocol provides for three injections, the first two containing 2.5 grams of pentobarbital in 50 milliliters of diluent each, and the third containing 60 milliliters of a saline flush. (*Id.* at 880.) The 2019 Protocol does not refer to the form or source of the drug, or measures of quality control, and its description of the intravenous administration of the drug simply provides that the BOP Director or designee "shall determine the method of venous access" and that "[i]f peripheral venous access is utilized, two separate lines shall be inserted in separate locations and determined to be patent by qualified personnel." (*Id.*)

Following this announcement, the court held a status conference in *Roane* on August 15, 2019. (*See* Minute Entry, Aug. 15, 2019.) In addition to the *Roane* plaintiffs, the court heard from counsel for three other federal death row inmates, all of whom cited the need for additional discovery on the new protocol. (*See* ECF No. 12, Status Hr'g Tr.) Defendants indicated that they were unwilling to stay the executions, and the court bifurcated discovery and ordered Plaintiffs to complete 30(b)(6) depositions by February 28, 2020, and to file amended complaints by March 31, 2020. (*See* Minute Entry, Aug. 15, 2019.)

## 1. November 20, 2019 Preliminary Injunction

Four inmates with scheduled execution dates filed complaints or motions to intervene in the *Roane* action challenging the 2019 Protocol, and each inmate subsequently moved to preliminarily enjoin his execution.<sup>4</sup> On November 20, 2019, the court granted the four Plaintiffs' motions for preliminary injunction, finding that they had demonstrated a likelihood of success on their claims that the 2019 Protocol exceeds the authority set forth in the Federal Death Penalty Act (FDPA). (See ECF No. 50, Nov. 20, 2019 Mem. Op. at 13, 15; ECF No. 50, Nov. 20, 2019 Order.) The court did not rule on Plaintiffs' other claims, including that the 2019 Protocol is arbitrary and capricious under the Administrative Procedure Act (APA), that it violates the Food, Drug, and Cosmetic Act (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. (Id. at 13.) Following the court's order, three more death row inmates filed complaints which in turn were consolidated with *Roane*.<sup>5</sup> The court denied Defendants' motion to stay the court's preliminary injunction. (See Minute Order, Nov. 22, 2019.) The D.C. Circuit likewise denied Defendants' motion to stay, In re Fed. Bureau of Prisons' Execution Protocol Cases, No. 19-5322 (D.C. Cir. Dec. 2,

<sup>&</sup>lt;sup>4</sup> Daniel Lewis Lee filed his complaint on August 23, 2019 (*see Lee v. Barr*, 1:19-cv-02559 (D.D.C.), ECF No. 1), and his motion for a preliminary injunction on September 27, 2019. (ECF No. 13, Lee Mot. for Prelim. Inj.) On August 29, 2019, Alfred Bourgeois moved to preliminarily enjoin his execution. (ECF No. 2, Bourgeois Mot. for Prelim. Inj.) Dustin Lee Honken filed an unopposed motion to intervene in *Lee v. Barr*, which was granted. (ECF No. 26, Honken Mot. to Intervene.) He then moved for a preliminary injunction on November 5, 2019. (ECF No. 29, Honken Mot. for Prelim. Inj.) Wesley Ira Purkey filed a complaint and a motion for a preliminary injunction under a separate case number, 1:19-cv-03214, which was consolidated with *Roane*. (ECF No. 34, Purkey Mot. for Prelim. Inj.)

<sup>&</sup>lt;sup>5</sup> These plaintiffs are Norris G. Holder, Jr., 1:19-cv-3520; Brandon Bernard, 1:20-cv-474; and Keith Dwayne Nelson, 1:20-cv-557.

2019), as did the United States Supreme Court on December 6, 2019. *Barr v. Roane*, 140 S. Ct. 353 (2019). However, three Justices issued a statement indicating their belief that Defendants were likely to prevail on the merits. *Id*.

On November 21, 2019, Defendants filed an interlocutory appeal of the court's November 20, 2019 Order. (*See* ECF No. 52.) On April 7, 2020, the D.C. Circuit reversed. *Execution Protocol Cases*, 955 F.3d at 108. Neither of the two Judges on the panel who voted to reverse agreed on the FDPA's statutory requirements, but they nonetheless rejected on the merits Plaintiffs' claim that the federal government was required by the FDPA to follow procedures set forth in state execution protocols. *Id.* at 112 (per curiam). The panel expressly declined to rule on Plaintiffs' remaining statutory and constitutional claims, as "the government did not seek immediate resolution of all the plaintiffs' claims" and the claims "were neither addressed by the district court nor fully briefed in this Court." *Id.* at 113. The Court of Appeals denied Plaintiffs' application for a stay of the mandate and petition for a writ of certiorari on June 29, 2020. *Bourgeois*, 2020 WL 3492763.

Meanwhile, Plaintiffs filed their Amended Complaint on June 1, 2020, (ECF No. 92, Am. Compl.), the same day Holder filed a separate supplemental complaint, (ECF No. 94.)

## 2. July 13, 2020 Preliminary Injunction—Eighth Amendment Claims

On June 15, 2020, the DOJ and BOP scheduled new execution dates for three Plaintiffs in the case: Daniel Lewis Lee on July 13, 2020, Wesley Ira Purkey on July 15, 2020, Dustin Lee Honken on July 17, 2020, and Keith Dwayne Nelson on August 28, 2020. (ECF No. 99.)

On July 13, 2020, the court preliminarily enjoined the executions of Lee, Purkey, Honken, and Nelson, finding that they had demonstrated a likelihood of success on the merits of their claim that the 2019 Protocol is cruel and unusual in violation of the Eighth Amendment. Once again, it did not rule on their other statutory and constitutional claims. (*See* ECF No. 135, July 13 Mem. Op. at 18, 22.) The D.C. Circuit declined to stay or vacate the court's injunction, *see 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 (U.S. July 14, 2020) (per curiam). Hours later, Defendants executed Lee.

## 3. July 15, 2020 Preliminary Injunction—Remaining Claims

On July 15, 2020, the court preliminarily enjoined the executions of Purkey, Honken, and Nelson, finding that they had demonstrated a likelihood of success on the merits of their claims that the 2019 Protocol violates the FDCA (ECF No. 145, July 15 Mem. Op. at 28.) The court found, however, that Plaintiffs were unlikely to succeed on their claims that the 2019 Protocol is arbitrary and capricious under the APA, violates the CSA, and deprives Plaintiffs of their right to counsel under the First, Fifth, and Sixth Amendments.

The D.C. Circuit declined to stay or vacate the court's injunction, *see Execution Protocol Cases*, No. 20-5210 (D.C. Cir. July 16, 2020), but the Supreme Court vacated the injunction without addressing the merits on July 16, 2020. *Barr v. Purkey*, No. 20A10, 2020 WL 4006821 (U.S. July 16, 2020) (per curiam). Later that week, Defendants executed Purkey and Honken.

## 4. Motion to Dismiss Regarding Plaintiffs' Eighth Amendment Claims

On July 31, 2020, Defendants filed their combined motion to dismiss and for summary judgment. (ECF Nos. 169, 170, Defs. Mot.)

On August 15, the court granted Defendants' motion as to the Eighth Amendment claims in Count II of the Amended Complaint. (ECF No. 193, Aug. 15 Order.) In the light of the Supreme Court's ruling in *Lee*, the court found that, absent particular medical circumstances, the

use of pentobarbital would withstand Eighth Amendment scrutiny despite evidence of excruciating pain.

## 5. August 27, 2020 Permanent Injunction—FDCA Claims

Given his impending execution, on August 4, 2020, Plaintiff Keith Nelson filed an emergency cross-motion for summary judgment on the pending FDCA claims (ECF No. 180), one of which the court had already determined was likely to succeed on the merits. (*See* July 15 Mem. Op. at 13.)

On August 27, 2020, the court entered judgment in favor of Nelson on Count XI of the Amended Complaint and enjoined Defendants from proceeding with Nelson's execution until the government could "comply with the requirements of the [(FDCA)]," (ECF No. 213, Aug. 27 Mem. Op. at 13.) The court found that the use of pentobarbital for lethal injection was subject to the FDCA, and that the government's intent to use it without satisfying the FDCA's premarketing, labeling, and prescription requirements was unlawful. (*Id.* at 10.) The court rejected Nelson's contention that DOJ's failure to explain its violation of the FDCA and the FDA commissioner's failure to bring an enforcement action were arbitrary and capricious. (*Id.* at 11–12.)

Defendants immediately appealed, and the D.C. Circuit vacated the injunction on the basis that "inter alia, there [were] insufficient findings and conclusions that irreparable injury will result from the statutory violation found by [this] court." *Execution Protocol Cases*, No. 20-5260 (D.C. Cir. Aug. 27, 2020) (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); *Withrow v. Larkin*, 421 U.S. 35, 44–45 (1975)).

On August 28, 2020, Nelson filed an emergency request for the court to clarify and/or amend its August 27<sup>th</sup> judgment. (ECF No. 222.) After a hearing that same day, the court

denied Nelson's request because he failed to demonstrate the requisite irreparable harm to warrant injunctive relief. (ECF No. 226.) Defendants executed Nelson later that afternoon.

## C. <u>The Present Dispute</u>

With regard to the claims in the Amended Complaint, the court has previously: (1) dismissed Count II (Eighth Amendment violation) for failure to state a claim as to all Plaintiffs but Norris Holder (*see* Aug. 15 Order); (2) granted summary judgment in favor of Defendants as to Count X (failure to exercise enforcement authority) and the alleged FDCA violations in Count VIII (failure to explain violations of the FDCA), (ECF No. 214); (3) denied Defendants' motion for summary judgment as to the FDCA component of Count XI (violation of the FDCA), (*id.*); and (4) entered summary judgment in favor of former Plaintiff Keith Nelson (but no other Plaintiff) as to the FDCA component of Count XI, (*id.*).

Defendants argue that they are entitled to judgment as a matter of law under Fed. R. Civ. P. 12(b)(6) on the following remaining claims in the Amended Complaint: the non-APA claims in Counts I (Fifth Amendment Due Process violation), III (deliberate indifference), IV (access to counsel), and VII (unconstitutional delegation of legislative power). Defendants seek summary judgment on the APA claims in Counts V (ultra vires agency action), VI (violation of notice-andcomment rulemaking), VIII (arbitrary and capricious agency action), IX (failure to enforce the CSA), and XI (violation of the CSA).

Defendants' motion has been fully briefed. The remaining Plaintiffs have moved for partial summary judgment only as to the FDCA claims in Count XI (and Count V of Plaintiff LeCroy's Amended Complaint). (ECF No. 236, Pls. Mot. for Partial Summ. J.)

#### II. DISCUSSION

### A. Defendants' Motion to Dismiss for Failure to State a Claim

## 1. Legal Standards

A motion to dismiss under Rule 12(b)(6) for failure to state a claim "tests the legal sufficiency of a complaint." *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible when the factual content allows the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Plaintiff's factual allegations need not be "detailed," but "the Federal Rules demand more than 'an unadorned, the-defendant-unlawfully-harmed-me accusation." *McNair v. District of Columbia*, 213 F. Supp. 3d 81, 86 (D.D.C. 2016) (quoting *Iqbal*, 556 U.S. at 678). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are insufficient. *Iqbal*, 556 U.S. at 678.

While a court generally does not consider matters beyond the pleadings on a motion to dismiss, it may consider "the facts alleged in the complaint, documents attached as exhibits or incorporated by reference in the complaint, or documents upon which the plaintiff's complaint necessarily relies even if the document is produced not by the plaintiff in the complaint but by the defendant in a motion to dismiss[.]" *Ward v. D.C. Dep't of Youth Rehab. Servs.*, 768 F. Supp. 2d 117, 119–20 (D.D.C. 2011) (internal quotation marks and citations omitted); *see also Equal Emp't Opportunity Comm'n v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624 (D.C. Cir. 1997).

### 2. <u>Fifth Amendment Due Process—Count I</u>

In Count I of their Amended Complaint, Plaintiffs allege that Defendants' failure to disclose material information regarding the development of the 2019 Protocol and the procedures that will be used to carry out their executions deprives them of their lives and liberty without adequate due process as guaranteed by the Fifth Amendment. (Am. Compl. ¶¶ 119, 121.) Their claim is based on their argument that the Due Process Clause requires the government to allow them to "determin[e] all aspects of the 2019 Protocol that violate provisions of federal law or constitute cruel and unusual punishment." (*Id.* ¶ 119.)

"The Fifth Amendment Due Process Clause protects individuals from deprivations of 'life, liberty, or property, without due process of law."" *Atherton v. District of Columbia Office of Mayor*, 567 F.3d 672, 689 (D.C. Cir. 2009) (citing U.S. Const. amend. V). A procedural due process violation "occurs when an official deprives an individual of a liberty or property interest without providing appropriate procedural protections. Liberty interests arise out of the Constitution itself or 'may arise from an expectation or interest created by state laws or policies."" *Id.* (quoting *Wilkinson v. Austin*, 545 U.S. 209, 221 (2005)).

There is no question that "[b]eing deprived of life unequivocally implicates a constitutionally protected interest." (Am. Compl. ¶ 118 (internal quotation marks omitted); Defs. Mot. at 22.) But Plaintiffs have already received the due process to which they are entitled for their life interests by virtue of their criminal trials and appeals; the legality of their death sentences is not before the court. Therefore, Plaintiffs' life interests are not implicated in challenging the 2019 Protocol. *See Zink v. Lombardi*, 783 F.3d 1089, 1109 (8th Cir. 2015) ("The prisoners in this case already have received due process for the deprivation of their life interests:

They were convicted and sentenced to death after a trial in Missouri court, and their convictions and sentences were upheld on appeal.").

Plaintiffs' liberty interest in disclosure fares no better. "A due process right to disclosure requires an inmate to show a cognizable liberty interest in obtaining information about execution protocols." Trottie v. Livingston, 766 F.3d 450, 452 (5th Cir. 2014). Plaintiffs have not identified a cognizable liberty interest in information about the 2019 Protocol that could lead to potential claims. See Lewis v. Casey, 518 U.S. 343, 354 (1996) (explaining that the state need not "enable [a] prisoner to *discover* grievances, and to *litigate effectively* once in court"). Courts have routinely found no due process rights implicated when a death row inmate claims he has not received enough information about an execution protocol. See, e.g., Phillips v. DeWine, 841 F.3d 405, 420 (6th Cir. 2016) (finding plaintiff had no due process right to the identity of individuals and entities that participate in the lethal injection process); Jones v. Comm'r, Ga. Dep't of Corr., 811 F.3d 1288, 1292–93 (11th Cir. 2016) (quoting Wellons v. Comm'r, Ga. Dep't of Corr., 754 F.3d 1260, 1267 (11th Cir. 2014)) ("Neither the Fifth, Fourteenth, or First Amendments afford [a prisoner] the broad right to know where, how, and by whom the lethal injection drugs will be manufactured, as well as the qualifications of the person or persons who will manufacture the drugs, and who will place the catheters."); Zink, 783 F.3d at 1108 (8th Cir. 2015) ("The prisoners' claim that they are unable to discover information regarding the execution protocol is thus insufficient as a matter of law to state a due process claim."); Trottie, 766 F.3d at 452 (finding that uncertainty regarding the effect of an execution drug was not a "cognizable liberty interest" and, thus, did not trigger "a due process right to disclosure"); Sells v. Livingston, 750 F.3d 478, 481 (5th Cir. 2014) (discussing id.) ("No appellate decision ha[s] yet held that obtaining information about execution protocols was a liberty interest, which meant that

failing to disclose could not be a due-process violation."); *Sepulvado v. Jindal*, 729 F.3d 413, 420 (5th Cir. 2013) ("There is no violation of the Due Process Clause from the uncertainty that Louisiana has imposed [] by withholding the details of its execution protocol."); *Williams v. Hobbs*, 658 F.3d 842, 852 (8th Cir. 2011) (finding that plaintiffs' inability to gain more information about an execution protocol did not amount to a due process violation).

Despite the case law, Plaintiffs argue that this Circuit held otherwise in *Roane v. Leonhart*, 741 F.3d 147 (D.C. Cir. 2014). The court is unpersuaded. In *Roane*, the D.C. Circuit ordered that Jeffrey Paul (a plaintiff in this case) be allowed to intervene in the challenge to the 2004 Protocol, which included a due process challenge to Defendants' refusal to disclose execution procedures. *Id.* at 149, 152. In response to Defendants' argument that the claims had become moot since a three-drug protocol would no longer be used, the Court found that Paul's "due process challenge, which attack[ed] a refusal to disclosure procedures that will be used [in the execution], is an independent claim that remains live." *Id.* at 150. The court does not read this as endorsing the claim's merits; the D.C. Circuit was addressing only whether the due process challenge was moot, as Plaintiffs concede in their opposition brief.<sup>6</sup> (*See* ECF No. 184, Pls. Opp'n at 16.) Thus, Plaintiffs have not identified a case in any Circuit finding that a deathrow inmate has a due process right to disclosure of information about an execution protocol.

Plaintiffs also argue that because the BOP Director has the discretion to amend the execution procedures, a plaintiff may not receive sufficient notice and opportunity to challenge the manner of his execution, which is what occurred with the Lee and Purkey executions. (Am.

<sup>&</sup>lt;sup>6</sup> Plaintiffs also argue that this court's subsequent grant of an unopposed preliminary injunction in *Roane* indicates the court's view that the due process claim was likely to succeed on the merits. (*See* Pls. Opp'n at 16.) The court took no position on the merits of the due process claim in its two-sentence order, however. (*See Roane*, ECF No. 336.)

Compl. ¶ 120.) But, although 28 C.F.R. § 26.4 requires the warden of the designated facility to "notify the prisoner under sentence of death of the date designated for execution at least 20 days in advance," Plaintiffs can point to no case establishing a *constitutionally* protected interest to sufficient notice of an execution. (Although the court has previously expressed its concern with the government's haste to execute Plaintiffs before their claims have been fully litigated, ultimately, Plaintiffs have not identified a due process violation that would warrant relief on Count I.

### 3. Deliberate Indifference—Count III

In Count III, Plaintiffs allege that the means of execution established in the 2019 Protocol constitutes deliberate indifference to a substantial risk of serious harm, thereby violating the Fifth and Eighth Amendments. (Am. Compl. ¶¶ 132–34.) They argue that Defendants have chosen to disregard substantial risks that the 2019 Protocol will cause "severe pain and suffering, including a sensation of drowning or asphyxiation" that creates an experience of "panic," "terror," and "agony." (Pls. Opp'n at 13 (citing ECF No. 24, Normal Decl. at 34) (internal quotation marks omitted).) Defendants urge the court to dismiss these claims for the same reasons the court dismissed Plaintiffs' other Eighth Amendment claims, namely that the use of pentobarbital does not rise to the level of cruel and unusual punishment. (Defs. Mot. at 10; ECF No. 193, Aug. 15 Order (dismissing Plaintiffs' Eighth Amendment claims in Count II).) Having already determined that "the use of pentobarbital will withstand Eighth Amendment scrutiny, no matter the evidence of excruciating pain," the court concludes that Plaintiffs' deliberate indifference claims similarly fail. (Aug. 15 Order at 5.)

"A prison official's 'deliberate indifference' to a substantial risk of serious harm to an inmate violates the Eighth Amendment." *Farmer v. Brennan*, 511 U.S. 825, 828 (1994). To

state a viable deliberate indifference claim, a plaintiff must show that a prison official "knows of and disregards an excessive risk to inmate health or safety." *Id.* at 837 (noting also that prison officials "must both be aware of facts from which the inference could be drawn that a substantial risk of serious harms exists, and he must also draw the inference.").

The Supreme Court has made clear that the government's use of pentobarbital under the 2019 Protocol does not present a substantial or excessive risk of serious harm. *See Lee*, 2020 WL 3964985, at \*1 (explaining that pentobarbital "has become a mainstay of state executions" and "[h]as been used to carry out over 100 executions, without incident"); *Zagorski v. Parker*, 139 S. Ct. 11, 11–12 (2018) (Sotomayor, J., dissenting) (noting that pentobarbital does not carry the risks of "drowning, suffocating, and being burned also from the inside out" and "is widely conceded to be able to render a person fully insensate"). As the court already posited in dismissing Count II of the Amended Complaint, "[s]o long as pentobarbital is widely used . . . no amount of new evidence will suffice to prove that the pain pentobarbital causes reaches unconstitutional levels." (Aug. 15 Order at 4.) Absent deliberate indifference, there is no Fifth<sup>7</sup> or Eighth Amendment violation as presented in Count III.

To the extent Plaintiffs argue that a deliberate indifference claim is distinct from and invokes a lower standard than "cruel and unusual punishment," they have not shown so convincingly. (*See* Pls. Opp'n at 13 ("[D]eliberate indifference need not involve torturous pain and suffering in order to be actionable as a wrongful deprivation of appropriate medical care.").) Nor have they identified a case in which a court denied a method-of-execution challenge but

<sup>&</sup>lt;sup>7</sup> Plaintiffs argue that when an individual is harmed by a government agent's deliberate indifference, the individual has a viable Substantive Due Process claim under the Fifth Amendment. (*See* Am. Compl. ¶ 129 (quoting *West v. Atkins*, 487 U.S. 42, 58 (1988) (Scalia, J., concurring).)

nonetheless upheld a deliberate indifference claim based on the same facts. Accordingly, Count III fails to state a claim for relief.

# 4. Access to Counsel—Count IV

In Count IV, Plaintiffs claim that the 2019 Protocol violates their right to counsel and access to the courts guaranteed by the First, Fifth, and Sixth Amendments. Plaintiffs argue that because they have a constitutional right to counsel in order to assert violations of their fundamental rights, they also have the right to have their counsel monitor the execution for possible Eighth Amendment violations. (*See* Pls. Opp'n at 18–19.)

The 2019 Protocol permits up to two defense attorneys to be present as witnesses during their client's execution (Admin. R. at 1024), and while it does not allow witnesses to bring their cell phones with them, an attorney "may request" the use of their phone if "legitimate need arises," and "will have immediate access to [a phone] outside of the witness room." (ECF No. 111-3, Decl. of Tom Watson, at 3.)

Plaintiffs contend that the 2019 Protocol impermissibly prohibits counsel from viewing the setting of the IVs, from communicating with their clients during the execution, and from having a quick and easy means of communicating with the court. (Pls. Opp'n at 19.) While these are all serious concerns, Plaintiffs fail to show that this access is constitutionally mandated. As Defendants note, the cases on which Plaintiffs rely are both out-of-Circuit and factually distinct. *See, e.g., Cooey v. Strickland*, No. 04-cv-1156, 2011 WL 320166, at \*6 (S.D. Ohio Jan. 28, 2011) (declining to decide whether the Constitution mandated that counsel be present at the execution where Ohio law already permitted counsel to be present). Plaintiffs suggest that the court adopt Justice Thomas' concurrence in *Lewis*, 518 U.S. at 380–82 (Thomas, J., concurring), in which he wrote that the Due Process Clause requires a right to access the courts to assert

violations of fundamental rights. That single concurrence, while compelling, cannot be the basis for this court to find that Plaintiffs have stated a claim for relief.

Plaintiffs' remaining arguments in support of their claims in Count IV are similarly unpersuasive. First, they contend that the absence of controlling precedent and the novelty of their claimed constitutional rights precludes the government from meeting its burden under Rule 12(b)(6). (Pls. Opp'n at 19. ("[I]n the absence of *controlling* precedent... such novelty precludes Defendants from demonstrating, as a matter of law, that Plaintiffs do not state a claim for relief that is plausible on its face" (internal citations and quotation marks omitted)).) The court declines Plaintiffs' invitation to find the lack of supporting precedent to be grounds upon which to stake a claim.

Finally, Plaintiffs also argue that Defendants' decision to utilize the 2019 Protocol during the COVID-19 pandemic infringes their right to counsel by forcing counsel to risk their own health and safety to attend Plaintiffs' executions. As the court has already explained however, these problems are not the result of the 2019 Protocol, or indeed any of Defendants' actions, but of the pandemic itself. (July 15 Mem. Op. at 14.) Furthermore, these claims closely resemble the pandemic-related claims brought by spiritual advisors and family members in separate litigation, and which were rejected by the courts. *See Hartkemeyer v. Barr*, No. 20-cv-336 (S.D. Ind. July 14, 2020), ECF No. 84 (denying preliminary injunction based on APA and Religious Freedom Restoration Act claims), *appeal filed*, No. 20-2262 (7th Cir. July 14, 2020); *Peterson v. Barr*, No. 20-2252, 2020 WL 3955951 (7th Cir. July 12, 2020) (vacating preliminary injunction based on APA claims).

Accordingly, Count IV of the Amended Complaint will be dismissed.

## 5. <u>Unconstitutional Delegation of Power-Count VII</u>

In Count VII, Plaintiffs argue that if the court finds that § 3596 of the FDPA authorizes the Attorney General to establish a federal execution protocol, "then the statute has failed to provide an intelligible principle" which constitutes "a forbidden delegation of legislative power." (Am. Compl. ¶ 158 (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928) (internal quotation marks omitted).) In support of this argument, Plaintiffs detail Congress's repeated refusal to pass laws expressly granting the Attorney General authority to develop a federal execution protocol. (*See* Pls. Opp'n at 22–25.)

Plaintiffs fail to state a claim for unconstitutional delegation power. First, "failed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a [] statute." *Execution Protocol Cases*, 955 F.3d at 122 (Katsas, J., concurring) (quoting *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994)).

More fundamentally, the statute itself cannot fairly be read as lacking an intelligible principle. As Plaintiffs note, a "nondelegation inquiry always begins (and often almost ends) with statutory interpretation." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019). And in the last hundred years, the Supreme Court has "found the requisite 'intelligible principle' lacking in only two statutes, one of which provided literally no guidance for the exercise of discretion, and the other of which conferred authority to regulate the entire economy on the basis of no more precise a standard than stimulating the economy by assuring 'fair competition.'" *Whitman v. Am. Trucking Ass 'ns*, 531 U.S. 457, 474 (2001) (citing *Panama Refin. Co. v. Ryan*, 293 U.S. 388 (1935); *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935)); *see also* Keith E. Whittington & Jason Iuliano, *The Myth of the Nondelegation Doctrine*, 165 U. Penn. L. Rev. 379, 380 (2017) (describing a "predictable pattern" in nondelegation doctrine cases whereby a

court invokes the doctrine and the Supreme Court "inevitably grants certiorari and overturns the appellate decision").

Here, the FDPA delivers sufficient guidance. It provides that the U.S. Marshal "shall supervise implementation of the sentence in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). In this sentence alone, Congress vested the U.S. Marshal with authority to oversee an execution *and* constrains the exercise of that authority to the limits of relevant state law. This is far different from the two cases where Congress failed to supply an intelligible principle.

### B. Defendants' Motion for Summary Judgment

### 1. Legal Standards

"When reviewing motions for summary judgment in a suit seeking review of an agency's actions, the standard under Fed. R. Civ. P. 56(a) does not apply." *Beyond Nuclear v. U.S. Dep't of Energy*, 233 F. Supp. 3d 40, 47 (D.D.C. 2017) (citing *Coe v. McHugh*, 968 F. Supp. 2d 237, 239 (D.D.C. 2013)). Rather, 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. *Envt'l. 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)).

### 2. Arbitrary and Capricious-Count VIII

In Count VIII, Plaintiffs allege that the DOJ and BOP have not provided sufficient explanations for: the adoption of the 2019 Protocol and the procedures contained therein; the use of pentobarbital as an execution drug; the failure to comply with applicable laws, including the CSA and FDCA<sup>8</sup>; and the absence of safeguards to prevent the significant risk of pain and suffering from acute pulmonary edema and the use of sub-potent or improperly compounded drugs. (Am. Compl. ¶ 163.) Thus, they contend, the 2019 Protocol was not the product of reasoned decision-making and constitutes arbitrary and capricious agency action in violation of the APA. (*Id.* ¶ 164.) But the record before the court does not support these arguments.

The record shows that the BOP explained how it arrived at the details and procedures set forth in the 2019 Protocol. (*See* Admin. R. at 929–34.) It explained that it needed a new protocol because the availability of sodium pentothal, a drug used in its previous protocol, had declined. (Admin. R. at 930.) It then "benchmarked with state practices, reviewed case law, consulted with medical professionals, and reviewed available professional literature." (*Id.*) It concluded that pentobarbital was frequently used for lethal injections, was "litigation tested," and achieved "a deeper level of unconsciousness" than other contenders. (*Id.* at 931, 932.) Furthermore, it settled on a one-drug, rather than three-drug, protocol for three reasons: i) "there are complications inherent in obtaining multiple drugs (availability obstacles) and navigating the respective expiration dates", ii) "acquiring and storing one drug is administratively more

<sup>&</sup>lt;sup>8</sup> The court has already found that DOJ and BOP's failure to explain non-compliance with the FDCA requirements did not violate the APA.

efficient", and iii) "administering one drug reduced the risk of errors during administration." (*Id.* at 931.) The record also indicates that the BOP consulted with medical professionals and reviewed expert testimony to assess the safety of pentobarbital. (*See id.* at 401–524, 527–761.) Finally, the BOP explained that it "secured a compounding pharmacy to store the API [(active pharmaceutical ingredient)] and to convert the API into injectable form as needed . . . [and] conferred with DEA to ensure the compounding pharmacy is properly registered." (*Id.* at 933.)

Although an agency can always provide more explanation for its actions, the record here is sufficient to fend off a challenge that the adoption of the 2019 Protocol was not the product of rational decision-making. And, at the very least, the record dispenses with the contention that the DOJ and BOP failed to provide "*any* explanation for their planned used of pentobarbital as an execution drug." (Am. Compl. ¶ 163 (emphasis supplied).)

Plaintiffs' opposition brief makes clear that the crux of Count VIII is the BOP's alleged failure to consider the risk of flash pulmonary edema, the risk of faulty IV placement, and the dangers of using a compounded drug, but these arguments have already been litigated and rejected. While the Protocol "does not discuss the risk of flash pulmonary edema specifically, the BOP need not consider every possible risk associated with its chosen method of execution." *Execution Protocol Cases*, No. 20-5206, slip op. at 2 (D.C. Cir. July 17, 2020). And the BOP's analysis was enough to pass muster under the arbitrary and capricious standard. *Id.* As for the risk of faulty IV placement, both this court and the D.C. Circuit concluded that the BOP had in fact studied "the difficulties of IV-line placement" and that its decision "to allow medically trained personnel to determine how best to place the IV line was [not] unreasonable." *Id.* (citing Admin. R. at 931–32); (July 15 Mem. Op at 9.) Finally, the court has already found that, under Supreme Court precedent, the BOP's decision to use a compounded form of pentobarbital where

domestic supplies are unavailable was not arbitrary or capricious. (July 15 Mem. Op. at 9 (citing *Bucklew v. Precythe*, 139 S. Ct. 1112, 1125 (2019).)

Plaintiffs efforts to revive these arguments are unavailing. They argue that while this court denied a request for a preliminary injunction on their arbitrary and capricious claim, it did not resolve their claim "that the 2019 Protocol and the accompanying Administrative Record lack adequate explanations for the challenged policy decision." (Pls. Opp'n at 27.) The court fails to see how its conclusion that none of these allegations rose "to the level of arbitrariness or capriciousness for an APA violation" leaves anything left to be decided on this issue. (July 15 Mem. Op. at 8.)

In their sole remaining claim in Count VIII, Plaintiffs allege that the government acted arbitrarily and capriciously in failing to discuss its non-compliance with the CSA. (Am. Compl. ¶ 172.) Defendants are entitled to summary judgment here because, as discussed below, there is no CSA violation.

## 3. <u>Ultra Vires Agency Action—Count V</u>

In Count V of their Amended Complaint, Plaintiffs allege that the 2019 Protocol constitutes ultra vires agency action in violation of § 3596(a) of the FDPA.<sup>9</sup> That provision requires that in carrying out a death sentence, "the Attorney General shall release the person sentenced to death to the custody of a United States marshal, who shall supervise implementation

<sup>&</sup>lt;sup>9</sup> In Count V, Plaintiffs also allege that Defendants' development of the Protocol without requisite authority violates the Take Care Clause of the U.S. Constitution. But Plaintiffs did not respond to Defendants' summary judgment argument on this claim, and therefore appear to have abandoned it. In any event, it is not clear that the Take Care Clause claim presents a justiciable controversy. *See Citizens for Responsibility & Ethics in Wash. v. Trump*, 302 F. Supp. 3d 127, 138–40 (D.D.C. 2018). And even assuming such a claim is justiciable, the one presented in the Amended Complaint is another iteration of Plaintiffs' improper delegation claim, which the court finds unavailing.

of the sentence in the manner prescribed by the law of the State in which the sentence is imposed." 18 U.S.C. § 3596(a). Plaintiffs argue that the Protocol conflicts with this directive because it "implement[s] a protocol that differs in material respects from the applicable states." (Am. Compl. ¶ 146.) Furthermore, in their view, the Protocol does not require a U.S. Marshal to supervise the implementation of a death sentence—that responsibility, they contend, has been impermissibly delegated to the BOP. (*Id.* ¶ 147.)

Defendants argue that the claims in Count V have already been rejected by the D.C. Circuit, which directed that judgment be entered in Defendants' favor on these issues. (Defs. Mot. at 31.) This contention is unsupported by the record. In its November 2019 order granting a preliminary injunction, the court found that Plaintiffs were likely to succeed on the merits of their claim that the 2019 Protocol exceeds statutory authority. In so concluding, it found that "the FDPA gives decision-making authority regarding 'implementation'" of federal death sentences to states, and therefore, to the extent the Protocol creates a single procedure, "it is not authorized by the FDPA." (ECF No. 50, Nov. 20 Mem. Op. at 7, 12.) It also posited that the requirement that executions be carried out "in the manner prescribed" by state law referred to both the selection of the execution method and the procedures utilized during the execution.

Two Judges on the D.C. Circuit rejected this interpretation and directed the entry of judgment on the "primary FDPA claim," i.e. that the Protocol contravenes the FDPA requirement that executions be implemented in accordance with the execution procedures of the state where the inmate was sentenced. *Execution Protocol Cases*, 955 F.3d at 112. However, those Judges took different paths to that conclusion. Judge Katsas concluded that the FDPA "regulates only the top-line choice among execution methods, such as the choice to use lethal injection instead of hanging or electrocution." *Id.* But Judge Rao found that the FDPA requires

the government "to follow execution procedures set forth in state statutes and regulations, but not execution procedures set forth in less formal state execution protocols." *Id.* She also concluded that because the 2019 Protocol allows the government to depart from its procedures to comply with state statutes and regulations, it did not run afoul of the FDPA. *Id.* 

Judge Tatel, in dissent, agreed with this court's assessment and found that "section 3596(a), best understood, requires federal executions to be carried out using the same procedures that states use to execute their own prisoners—procedures set forth not just in statutes and regulations, but also in protocols issued by state prison officials pursuant to state law." *Id.* at 146. Judge Tatel addressed Defendants' complaint that this result would require it to follow every nuance of the state protocols, writing that "section 3596(a) requires the federal government to follow only 'implementation' procedures, which plaintiffs define as those procedures that 'effectuat[e] the death,' including choice of lethal substance, dosages, vein-access procedures, and medical personnel requirements." *Id.* at 151 (internal citations omitted).

In light of this plurality decision, the court cannot grant summary judgment as to all the claims in Count V. Plaintiffs correctly point out that the panel did not issue a precedential opinion on two additional arguments: i) whether the 2019 Protocol illegally delegates authority to the BOP that rightfully belongs to the U.S. Marshal; and ii) whether the 2019 Protocol conflicts with the manner of execution prescribed by the "law" of each relevant state involved here, which the controlling opinion (Judge Rao's) defines as the relevant state's statutes and formal regulations. (*See* Pls. Opp'n at 32.) Thus, the court must once again enter the thicket.

## *i.* The U.S. Marshal's Authority to "Supervise"

Plaintiffs' claim that the 2019 Protocol improperly assigns the U.S. Marshal's authority to the BOP fails as a matter of law.<sup>10</sup> In Plaintiffs' view, the BOP has usurped from the Marshal the "primary authority to determine the manner of federal executions," which includes the authority to "formulate" an execution protocol, to "select" which drugs are used, and to "order execution personnel to depart from the established procedures." (Pls. Opp'n at 33.) This argument finds no support in the text of the FDPA.

Section 3596 requires that the U.S. Marshal "supervise implementation" of the death sentence. The critical word here is "supervise,"<sup>11</sup> which is undefined in the statute. The court must therefore rely on its plain meaning. "To 'supervise' is to 'superintend' or 'oversee," but not to "formulate," "determine," or "select" the manner of federal execution. *Execution Protocol Cases*, 955 F.3d at 134 (Rao, J., concurring) (citing Supervise, Merriam Webster's Collegiate Dictionary (11th ed. 2014)); (*see also* Pls. Opp'n at 33.)

Statutory history supports the conclusion that "supervise" does not mean the U.S. Marshal has the exclusive authority to carry out federal executions or to institute procedures for doing so. In prior death penalty statutes, Congress used more expansive language in describing the U.S. Marshal's duties during an execution. For instance, in the 1937 version, Congress provided that the U.S. Marshal was "charged with the execution of the sentence." *See* 50 Stat. at

<sup>&</sup>lt;sup>10</sup> Judge Katsas previously found this claim unconvincing on the merits. Judge Rao found that, because Plaintiffs did not raise the issue before this court in the preliminary injunction briefing, it was waived on appeal. But, as Defendants acknowledge, Judge Rao's opinion did "not substantively address the question." (ECF No. 191, Defs. Reply at 17.)

<sup>&</sup>lt;sup>11</sup> As Judge Rao explained in her concurrence, "[t]he ordinary meaning of 'implementation of the sentence' includes more than 'inflicting the punishment of death.'" *Execution Protocol Cases*, 955 F.3d at 133 (Rao, J., concurring); (*see infra* at 29.) Neither party has advanced an alternative meaning of the term "implementation." (*See* Pls. Opp'n at 33.)

304. This language is more akin to the dominant role Plaintiffs ascribe, or at least, leaves room for Plaintiffs' interpretation.

The 2019 Protocol does not divest the U.S. Marshal of this supervisory authority. In fact, it mandates that the U.S. Marshal is to "oversee the execution and to direct which other personnel may be present at it." *In Re Fed. Bureau of Execution Protocol Cases*, 955 F.3d at 124 (Katsas, J.) (referencing Admin. R. at 885). The execution cannot begin without the Marshal's approval, and it is the Marshal who certifies that the execution has been carried out. *Id.* (referencing Admin. R. at 895, 899). The court therefore concludes that the U.S. Marshal supervises—i.e., oversees and superintends over—the execution.

Furthermore, the fact that the U.S. Marshal must supervise an execution does not preclude other DOJ components from participating. Indeed "all functions of agencies and employees of the Department of Justice"—of which both the Marshals Service and the BOP are parts—"are vested in the Attorney General." Thus, any authority inherent in the Attorney General's power to enforce a death sentence that has not been specifically assigned to a DOJ component may be delegated. *See* 28 U.S.C. §§ 509, 510; *United States v. Giordano*, 416 U.S. 505, 514 (1974) (finding unexceptional the proposition that the Attorney General may freely delegated his power where Congress does not say otherwise).<sup>12</sup>

The 2019 Protocol, as written, still provides the U.S. Marshal the power to supervise the implementation of a death sentence. Therefore, the court finds that the 2019 Protocol does not

<sup>&</sup>lt;sup>12</sup> Defendants takes this argument a step further and argue that even if the supervisory authority granted to U.S. Marshal includes the authority to develop execution procedures, the Attorney General may freely reassign that power to another DOJ component. *See Execution Protocol Cases*, 955 F.3d at 125. The court need not resolve this argument, having already concluded that the Protocol does not divest the Marshal of supervisory duties.

improperly delegate authority to the BOP. The government is entitled to summary judgment as to this aspect of Count V.

### *ii.* Relevant State Statutes and Regulations

Defendants argue that there are no surviving claims in Count V. The court disagrees. The D.C. Circuit's opinion leaves two remaining scenarios which preclude the court from granting summary judgment as to Count V without further discussion. The first arises when the Protocol conflicts with a state's top-line method of execution such as lethal injection, electrocution, etc. All three Circuit Judges agreed that this would violate the FDPA. *See Execution Protocol Cases*, 955 F.3d at 112 ("Judge Katsas concludes that the FDPA regulates only the top-line choice among execution methods . . . [while] Judge Rao concludes that the FDPA also requires the federal government to follow execution procedures set forth in state statutes and regulations."); *id.* at 146 (Tatel, J., dissenting) ("I agree with Judge Rao that the term 'manner' refers to more than just general execution method . . . section 3596(a), best understood, requires federal executions to be carried out using . . . procedures set forth not just in [state] statutes and regulations, but also in protocols issued by state prison officials."). The second is when the Protocol conflicts with a state statute or regulation, which Judges Rao and Tatel agreed would violate the FDPA.

Plaintiffs point to three state statutes which they allege conflict with the Protocol's "topline method" of execution. Whereas the Protocol specifies that Plaintiffs are to be executed by lethal injection, South Carolina (where Plaintiff Fulks was sentenced) and Virginia (where Plaintiffs Tipton, Johnson, and Roane were sentenced) allow inmates to choose between execution by lethal injection or electrocution. S.C. Code. § 24-3-530(A); VA Code Ann. § 53.1-

234. Missouri law (where Plaintiff Holder was sentenced) allows for execution by either lethal injection or lethal gas. Mo. Rev. Stat. § 546.720.1.

The court asked Defendants to file a notice indicating whether they were prepared to deviate from the procedures of the 2019 Execution Protocol to accommodate these statutes. (Minute Order, Sept. 14, 2020.) In that notice, Defendants stated that "the government will not execute any plaintiff whose sentence was issued in federal court in Virginia or South Carolina and is subject to the FDPA without complying with those provisions of S.C. Code § 24-3-530(A) or Va. Code Ann. § 53.1-234." (ECF No. 247, Defs. Notice at 5.) And while Missouri has a law on the books that allows an inmate to be executed by lethal gas, the choice of which method to use does not appear to rest with the inmate as it does in South Carolina and Virginia. See Mo. Rev. Stat. § 546.720.1. Thus, the court is satisfied that there is no live controversy as to the alleged discrepancies between the 2019 Protocol and the relevant South Carolina, Virginia, and Missouri laws. See Nat'l Black Police Ass'n v. District of Columbia, 108 F.3d 346, 349 (D.C. Cir. 1997) (en banc) ("Even where litigation poses a live controversy when filed... a federal court [must] refrain from deciding it if events have so transpired that the decision will neither presently affect the parties' rights nor have a more-than-speculative chance of affecting them in the future" (internal citations and quotation marks omitted)).

Beyond the state laws discussed above, Plaintiffs have identified the following state statutes and regulations that conflict with the 2019 Protocol:

- A Georgia statute (applicable to Plaintiffs Battle and LeCroy) requiring the presence of "two physicians to determine when death supervenes." Ga. Code § 17-10-41.
- An Arkansas statute (applicable to Plaintiff Paul) requiring "[c]atheters, sterile intravenous solution, and other equipment" used in executions "be sterilized and prepared in a manner that is safe and commonly performed in connection with the intravenous administration of drugs of that type." Ark. Code § 5-4-617(f).

- An Arkansas statute (applicable to Plaintiff Paul) requiring execution drugs to be (1) FDA-approved, (2) obtained from an FDA-registered facility, or (3) obtained from a nationally accredited compounding pharmacy. Ark. Code § 5-4-617(d).
- A Texas statute (applicable to Plaintiffs Bernard, Bourgeois, Hall, Robinson, and Webster) mandating that executions shall take place "at any time after the hour of 6 p.m. on the day set for the execution." Tex. Code of Crim. Proc. Art. 43.14(a).

The D.C. Circuit's prior decision in this litigation requires Defendants to adhere to these statutes. As Judge Rao wrote, while "formal state law often specifies little more than the method of execution, the federal government is nonetheless bound by the FDPA to follow the level of detail prescribed by state law." *Execution Protocol Cases*, 955 F.3d at 133. Judge Tatel found that the FDPA "best understood, requires federal executions to be carried out using . . . procedures set forth not just in [state] statutes and regulations, but also in protocols issued by state prison officials." *Id.* at 146.

In responding to Plaintiff LeCroy's motion for a preliminary injunction and in its September 15 notice to the court, Defendants advance a narrower reading of Judge Rao's opinion and a more expansive one of Judge Tatel's. (*See* Defs. Opp'n to LeCroy Mot. at 16–17; *see also* Defs. Notice at 2.) Pointing to a Seventh Circuit opinion, Defendants contend that Judge Rao's interpretation of the FDPA is limited to state laws and regulations governing procedures for effectuating death. (*Id.* at 17). In the Seventh Circuit's view, the debate among the D.C. Circuit Judges "was limited to state laws, regulations, and protocols governing *procedures for effectuating death.*" *Peterson v. Barr*, 965 F.3d 549, 554 (7th Cir. 2020) (discussing *Execution Protocol Cases*, 955 F.3d at 122); *see also United States v. Mitchell*, No. 20-9909, 2020 WL 4815961 (9th Cir. Aug. 19, 2020) (adopting the Seventh Circuit's reading of *Execution Protocol Cases*, 955 F.3d at 122). The court is not bound by other Circuits' interpretation of D.C. Circuit precedent and cannot square their limited reading with the language in either Judge Rao or Judge Tatel's opinions.

For instance, in discussing her understanding of the word "implementation," Judge Rao explained that "the ordinary meaning of 'implementation of the death sentence' includes more than 'inflicting the punishment of death' . . . [it includes] additional procedures involved in carrying out the sentence of death." *Execution Protocol Cases*, 955 F.3d at 133 ("the term 'implementation' is commonly used to refer to a range of procedures and safeguards surrounding executions"). She also explained that such "implementation" would include details such as the time, date, place, and method of execution, all of which can fairly be read to include the state statutes Plaintiffs have identified. *Id.* at 134 (quoting Implementation of Death Sentences in Federal Cases, 58 Fed. Reg. 4,898, 4,901–02 (Jan. 19, 1993)).

Similarly, Defendants read Judge Tatel's opinion as acknowledging that the FDPA incorporates "only those state procedures 'that effectuate death,' such as 'choice of lethal substances, dosages, vein-access procedures, and medical-personnel requirements,'" which apply to protocols as well as statutes and regulations. (Defs. Opp'n to LeCroy Mot. at at 6–7 (citing *Execution Protocol Cases*, 955 F.3d at 151).) The court does not share this expansive interpretation; in its view, Judge Tatel was responding to Defendants' contention that his reading would require it to follow "every nuance of state *protocols." Execution Protocol Cases*, 955 F.3d at 151 (emphasis supplied) (internal quotation marks omitted). Judge Tatel's dissent did not address whether this type of de minimis exception applied to state statutes and regulations. *See id.* 

Even if the court agreed with Defendants' broad reading of Judge Tatel's dissent, all the state statutes Plaintiffs have cited in their opposition involve procedures that effectuate death.

The Georgia statute requiring two physicians to certify when death supervenes was no doubt enacted to ensure that death has been effectuated. Furthermore, that statute, as well as the Arkansas laws, are the types of procedures Judge Tatel found effectuate death. *See id.* (citing "choice of lethal substances, dosages, vein access-procedures, and medical-personnel requirements" as examples). Finally, the Texas statute governs when death is to be effectuated and prevents the state from rescheduling an execution after normal court hours despite the pendency of any remaining legal challenges and without providing notice to the prisoners' attorneys—as was the case with the Lee execution.

Despite these findings, the court nonetheless concludes that Defendants are entitled to summary judgment as to the alleged discrepancies between the 2019 Protocol and state law. Defendants state that they intend to comply with Georgia's requirement that two physicians be present at the execution to determine when death supersedes. (Defs. Notice at 2); Ga. Code § 17-10-41. They also state that they intend to comply with the sterilization requirements set forth in § 5-4-617(f) of the Arkansas Code. (Defs. Notice at 4.) Furthermore, as Defendants point out, there is no violation of Arkansas Code § 5-4-617(d), as the government will be using a pentobarbital solution obtained from an FDA-registered facility. (*See* Admin. R. at 1084; ECF No. 36-1, Decl. of Raul Campos ¶ 3.)

With regard to the scheduling requirements in Texas criminal procedure code Article 43.14, Defendants proffer that "BOP will consider, and *may* choose to accommodate, the request of any Plaintiff sentenced by a federal court in Texas who wishes to have an execution scheduled for after 6p.m." as an "administrative grace." (Defs. Notice at 3–4 (emphasis supplied).) Putting aside the question of whether agreeing to execute an inmate after 6 p.m. can be characterized as an act of "grace," Defendants must comply with the Texas provision because it is incorporated

into the FDPA by virtue of D.C. Circuit precedent. *See Execution Protocol Cases*, 955 F.3d at 133 (Rao, J., concurring) ("[T]he federal government is [] bound by the FDPA to follow the level of detail prescribed by state law.").

Nevertheless, the court does not see a controversy here. Christopher Vialva is the only plaintiff sentenced to death in Texas with a scheduled execution date. The court is unaware that he has requested to be executed after 6 p.m. And even if that request has been made and the BOP denied it, it is unlikely this would constitute irreparable harm. To warrant injunctive relief, a plaintiff must demonstrate, inter alia, that he will "suffer[] an irreparable injury, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), which must be "both certain and great" and "of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm," *Wis. Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985; (*see infra* Sec. C.) The court understands the concern that "[t]he ability to schedule an execution at any time of day or night" would allow "Defendants to reschedule and carry out . . . executions almost immediately after the expiration or vacatur of a stay, despite the pendency of additional legal challenges, and with or without notice to the prisoners' attorneys." (Pls. Opp'n at 37.) This is injury is far from "certain," however.

Though the court disagrees with Defendants' interpretation of the D.C. Circuit's decision in *Execution Protocol Cases*, it nonetheless finds that, based on the record before it, Defendants are entitled to summary judgment as to all the claims in Count V.

## 4. Notice-and-Comment Rulemaking—Count VI

Two Judges of this Circuit have already found that the 2019 Protocol is a procedural rule and thus not subject to the notice-and-comment procedures of the APA. *Execution Protocol* 

*Cases*, 955 F.3d at 112, 144–45; (see also ECF No. 209, Order on Mot. to Strike at 2.) Accordingly, Defendants are entitled to summary judgment on Count VI.

## 5. <u>CSA Claims—Counts VIII, IX, and XI</u>

Plaintiffs contend that the 2019 Protocol violates the Controlled Substances Act because it does not require Defendants to obtain a valid written prescription for the pentobarbital it will use to execute them. *See* 21 U.S.C. § 829(a) (requiring valid prescription, issued for a legitimate medical purpose, in dispensing any controlled substance to an "ultimate user"); 21 C.F.R. § 1308.12 (listing pentobarbital as a Schedule II controlled substance).

Plaintiffs' CSA claims fail under the Supreme Court's decision in *Gonzales v. Oregon*, 546 U.S. 243, 272–74 (2006), in which the Court held that the CSA is primarily "a statute combating recreational drug use," and must be read in light of that statutory purpose. *Id.* at 272. In ruling on a challenge to the use of Schedule II controlled drugs for physician assisted suicide, the Court found that "the prescription requirement is better understood as a provision that ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. . . . To read prescriptions for assisted suicide as constituting 'drug abuse' under the CSA is discordant with the phrase's consistent use throughout the statute." *Id.* at 274. This holding appears to exclude from the CSA dispensing lethal injection drugs during an execution. Accordingly, Defendants are entitled to summary judgment on Counts VIII, IX, and the CSA claims in Count XI.

## C. <u>Plaintiffs' Partial Motion for Summary Judgment—Count XI</u>

For the reasons set forth in its August 27, 2020 Memorandum Opinion, the court finds that the remaining Plaintiffs are entitled to summary judgment as to the FDCA claims in

Count XI. (*See generally* Aug. 27 Mem. Op.)<sup>13</sup> To recapitulate, the court found that the pentobarbital the government intends to use in executions is subject to the FDCA and fails to meet the premarketing, labeling, and prescription requirements therein. Thus, the government's use, under the 2019 Protocol, of pentobarbital that has not been prescribed and does not meet other statutory requirements of the FDCA constitutes agency action that is contrary to law in violation of the APA.

### 1. <u>Standard for Irreparable Harm</u>

Given these statutory violations, Plaintiffs ask the court to enjoin their executions. (Pls. Mot. for Partial Summ. J. at 1.) "A finding of a statutory violation does not automatically require the court to issue an injunction." *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, (D.D.C. 2000) (citing *Weinberger v. Romero–Barcelo*, 456 U.S. 305, 313 (1982) ("The grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to [enjoin the conduct] under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law.")). To merit injunctive relief, Plaintiffs must show that: (i) they have "suffered an irreparable injury"; (ii) remedies available at law, such as monetary damages, are inadequate to compensate them for their injury; (iii) "considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted"; and (iv) "the public interest would not be disserved by a permanent injunction." *See eBay Inc*, 547 U.S. at 391.

Having already found that Plaintiffs are entitled to summary judgment as to the FDCA claims in Count XI, the cornerstone here is irreparable injury. It well established that the burden

<sup>&</sup>lt;sup>13</sup> Accordingly, Plaintiff LeCroy is entitled to summary judgment as to the FDCA claims in Count V of his Amended Complaint.

of demonstrating irreparable injury lies with the movant. *See id.* This presents a "very high bar." *Beck v. Test Masters Educ. Servs. Inc.*, 994 F. Supp. 2d 98, 101 (D.D.C. 2014) (quoting *Coal. for Common Sense In Gov't Procurement v. United States*, 576 F. Supp. 2d 162, 168 (D.D.C. 2008)).<sup>14</sup> The injury must be "both certain and great" and "of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm." *Wis. Gas Co.*, 758 F.2d at 674.

In their most recent pleadings, Plaintiffs appear to push back against the standard articulated for irreparable harm by the D.C. Circuit in *Wisconsin Gas* and similar cases. *See, e.g., League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016) (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006)) ("The party seeking a preliminary injunction must make two showings to demonstrate irreparable harm ... the harm must be 'certain and great,' 'actual and not theoretical,' and so 'imminen[t] that there is a clear and present need for equitable relief.'"). For instance, Plaintiff Norris Holder identifies language from the Supreme Court's *Monsanto* decision which suggests that the threat of a future irreparable injury need only be likely, not certain, to warrant injunctive relief. (ECF No. 249, Holder Reply at 2 (citing *Monsanto Co. v. Geerston Seed Farms*, 561 U.S. 139, 162

<sup>&</sup>lt;sup>14</sup> The court is not confined to the administrative record in assessing irreparable harm. *See Eco Tour Adventures, Inc. v. Zinke*, 249 F. Supp. 3d 360, 369 n.7 (D.D.C. 2017) (citing *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989)) ("[E]xtra-record evidence may be used 'in cases where relief is at issue.""). This is because "[t]he issue of injunctive relief is generally not raised in administrative proceedings below and, consequently, there will usually be no administrative record developed on these issues." *Id.* (citing Steven Sark & Sarah Wald, *Setting No Records: The Failed Attempts to Limit the Record in Review of Administrative Actions*, 36 Admin. L. Rev. 333, 345 (1984)) (internal quotations marks omitted). In fact, "it will often be necessary for a court to take new evidence to fully evaluate claims of irreparable harm." *Id.* (internal quotations marks omitted).

(2010) (noting that a permanent injunction "guard[s] against a[] present or imminent risk of likely irreparable harm")).)

The court does not find that *Monsanto* clearly resolves that question because elsewhere in the same decision, the Supreme Court explained that the "respondents cannot show that they *will suffer* irreparable injury if [the challenged agency agency] was allowed to proceed." *Monsanto*, 561 U.S. at 162 (emphasis supplied); *see also Ctr. for Bio. Diversity v. Ross*, 2020 WL 4816458, at \*10 (D.D.C. Aug. 19, 2020) (noting the inconsistency in the Supreme Court's articulation of the irreparable standard in *Monsanto*). To be sure, the Supreme Court has used similar language in other cases. *See, e.g., Winter v. NRDC*, 555 U.S. 7, 20 (2008) ("A plaintiff seeking a preliminary injunction must establish that . . . he is likely to suffer irreparable harm in the absence of preliminary relief."). But even assuming *Monsanto* means a "likelihood" standard of irreparable harm is distinct from a "certainty" standard, it does not matter which standard the court applies in this case. Even under the likelihood of future irreparable harm standard, Plaintiffs do not meet their burden to warrant the extraordinary relief of an injunction.

# 2. <u>Alleged Injury</u>

While it is certainly true that death is irreparable, it is not the government's violation of the FDCA that would cause this injury. Plaintiffs' death sentences were imposed after trials and their convictions and sentences have been affirmed on appeal.

Rather, Plaintiffs allege that they will face health risks from the use of a drug that has not been certified to ensure a humane death. (*See* ECF No. 248, Pls. Reply in Supp. of Pls Mot. for Partial Summ. J. at 3 (characterizing their injury as "the lack of FDCA-required clinical oversight that would require pentobarbital to be administered in a manner... that minimizes the well-documented risk of suffering from the conscious experience of flash pulmonary edema").)

As an initial matter, it is not apparent how securing a prescription would eliminate this alleged harm. Assuming the BOP finds a doctor to write a prescription, Plaintiffs will still be executed using pentobarbital. Thus, the prescription requirement does not in and of itself ensure that Plaintiffs will not be protected from flash pulmonary edema during their executions.

More fundamentally, while the court continues to be concerned at the possibility that inmates will suffer excruciating pain during their executions, Plaintiffs have not established that flash pulmonary edema is "certain" or even "likely" to occur before an inmate is rendered insensate.

The record contains conflicting evidence as to whether pentobarbital can cause flash pulmonary edema before an inmate is rendered unconscious. For instance, Plaintiffs point to declarations submitted by Dr. Gail Van Norman describing the "virtual medical certainty that most, if not all, prisoners will experience excruciating suffering, including sensations of drowning and suffocation" caused by flash pulmonary edema. (Pls. Mot. for Partial Summ. J. at 12 (citing Van Norman Decl. at 7).) Dr. Van Norman states that these risks have been confirmed by the Purkey autopsy results, which revealed that Purkey's lungs "were filled with fluid to the extent of nearly doubling their normal weight, and frothy pulmonary edema fluid filled his main airways all the way up in the trachea." (ECF No. 183-2, Van Norman 2d Supp. Decl. ¶ 5.) Such fluid would have accumulated before death. (Id. ¶ 9.) Dr. Van Norman also suggests that the current understanding in the field of anesthesiology is that barbiturates such as pentobarbital diminish only the subjects' responsiveness to stimuli and not their awareness of such stimuli—including the conscious experience of excruciating pain. (*See* Van Norman Decl. at 13, 22–23, 28–29.)

But Defendants offer conflicting evidence suggesting that an inmate would not experience the effects of flash pulmonary edema before becoming insensate. One of their experts, Dr. Kendall Von Crowns, reasons this is because "[d]ue to the large amount of the drug administered, there would not be enough time for pentobarbital to clear from the respiratory and cardiac receptions of the brainstem." (*See* ECF No. 246-1, Crowns Decl. ¶ 12.) Dr. Joseph Antognini supports this position. In his view, "[e]ven if pulmonary edema did occur ante mortem, the inmates would have been profoundly anesthetized (with cessation of brain activity) and would not have experienced any sensations of pulmonary edema." (ECF No. 246-2, Antognini 2d Supp. Decl. ¶ 3h.)

Furthermore, both Drs. Crowns and Antognini refute Dr. Van Norman's evaluation of the Purkey autopsy. Dr. Antognini disputes the study upon which Dr. Van Norman relies to conclude that there is no correlation between lung weight and the interval between death and autopsy. (*Id.* ¶ 29 ("Most likely, the autopsies [in the study cited by Dr. Van Norman] were performed at intervals of several hours (and perhaps days) after death, and the correlation would have been missed.").) And Dr. Crowns posits that "[t]here is no way to determine based on autopsy findings how quickly the pulmonary edema occurred, but even if the edema was from a 'flash' situation it would take minutes to occur," and inmates injected with five grams of pentobarbital can become insensate within seconds. (Crowns Decl. ¶¶ 3, 10.) Dr. Van Norman, in turn, disputes these conclusions. (*See generally* ECF No. 249-1, Van Norman Additional Suppl. Report.)

After considering the conflicting declarations, the court found that the question of whether an inmate will suffer flash pulmonary edema before becoming insensate was one upon which reasonable minds could differ. Thus, in an attempt to make credibility assessments—and

at the urging of both parties, which claimed an evidentiary hearing was needed to rule in their opponent's favor—the court held an evidentiary hearing on September 18 and 19, 2020. Given the narrow issue and the need to rule before an execution scheduled for September 22, 2020, the court allowed the parties the opportunity to cross examine the other side's experts and conduct limited re-direct examination. *See Cobell v. Norton*, 391 F.3d 251, 261 (D.C. Cir. 2004) (noting that a court should hold a hearing to when it must "make credibility determinations to resolve key factual disputes in favor of the moving party" seeking injunctive relief, but that "[t]he circumstances and interests at stake will affect whether an abbreviated or more extensive evidentiary hearing is necessary"). On the first day of the hearing, Defendants chose not to cross-examine Dr. Van Norman and the Plaintiffs elected to rely on the statements made in her declarations and did not call her as a witness. Plaintiffs cross-examined Drs. Crowns and Antognini.

Plaintiffs unsuccessfully attempted to undermine the evidence upon which Dr. Crowns based his conclusion that "[t]here is no way to determine based on autopsy findings how quickly the pulmonary edema occurred." (*See* Crowns Decl. ¶ 10.) Dr. Crowns admitted that his conclusion that most inmates subjected to a lethal dose of pentobarbital do not experience labored breathing indicative of flash pulmonary edema was based on media and eyewitness reports from executions he did not witness. (*See id.* ¶¶ 5, 11.) He also admitted that he was unaware of more recent news reports from the executions of Lee, Honken, Purkey, and Mitchell describing the inmates as showing labored breathing, gasping for breath, or heaving. While the court noted that Dr. Crowns did not review the more recent news reports that contradicted the ones he had reviewed, it does not find this to completely undermine Dr. Crowns' conclusions. Dr. Crowns explained that an inmate's gasping for breath alone does little to answer the question

of whether the inmate was gasping for breath while conscious. As he noted, gasping or labored breathing alone could be indicative of agonal breathing that occurs right before death but after the inmate is rendered unconscious.

While the court did not find Dr. Antognini unqualified—as Plaintiffs attempted to show during his cross-examination—his reports and testimony did not carry much weight. For one, Dr. Antognini's research has been primarily on animals and he no longer routinely practices in a clinical setting. Furthermore, most of the studies he cites on pentobarbital are rather old, though the court takes his point that many of the most salient studies on pentobarbital were performed in the 1940s, 50s, and 60s. The court has also taken judicial notice of the fact that Dr. Antognini was found to be not qualified to opine on similar issues in another district court litigation. See In re Ohio Execution Protocol Litig., No. 11-1016-EAS-MRM, slip op. at 4 (S.D. Ohio Jan. 27, 2020) ("There is no indication that this Court or any other has been 'distracted' by Dr. Antognini's opinions, as it has consistently given little or no weight to his reports or testimony in this consolidated litigation."). But while this finding is concerning, the court also notes that the Supreme Court has relied on Dr. Antognini's testimony on the effects of pentobarbital. See Bucklew v. Precythe, 139 S. Ct. 1112, 1132 (2019). But even were the court to completely discredit Dr. Antognini's testimony, the evidence in the record does not support Plaintiffs' contention that they are likely to suffer flash pulmonary edema while still conscious.

The court cannot weigh the evidence before it in a vacuum. The Supreme Court has already addressed most of the evidence Plaintiffs have presented in this case and found that it was not enough to warrant injunctive relief. *See Lee*, 2020 WL 3964985 at \*2. The Court also emphasized that pentobarbital "[h]as been used to carry out over 100 executions, without incident." *See Lee*, 2020 WL 3964985, at \*2. And while the Supreme Court reached these

conclusions while this litigation was in a different procedural posture, the irreparable harm inquiry is similar in both the preliminary and permanent injunction context. *Doe v. Mattis*, 928 F.3d 1, 7 (D.C. Cir. 2019) (explaining that the same requirement of irreparable harm applies to preliminary and permanent injunctions). Given the Supreme Court's decision and the competing evidence in this case, Plaintiffs cannot meet their burden of showing that the harm of flash pulmonary edema is likely, let alone "certain" or "imminen[t]." *Wis. Gas Co.*, 758 F.2d at 674; *see also Al-Joudi v. Bush*, 406 F. Supp. 2d 13, 20 (D.D.C. 2005) ("Courts often find a showing of irreparable harm where the movant's health is in imminent danger".).

The same is true for the alleged harm from the government's reliance on bulk compounding to secure a reliable source of pentobarbital. While Plaintiffs argue that the government will subject them "to the risks of compounded drugs [] without any corresponding medical benefit to justify those risks," it is not clear to the court what non-speculative irreparable harm arises from using the government's compounded pentobarbital. (See Pls. Reply at 8 (noting that compounded drugs are "unreliable and dangerous"); *see also* Pls. Mot. for Partial Summ. J. at 13–14.)

During the evidentiary hearing, the court heard competing testimony from Dr. Michaela Almgren and Dr. Peter Swaan regarding their conclusions about the potency and stability of the pentobarbital Defendants intend to use in the executions. This testimony was not particularly helpful because Plaintiffs have not shown that the BOP will be using expired pentobarbital or that the pentobarbital the BOP intends to use was stored in a such a way that would likely cause them to suffer. At most, Plaintiffs showed that such harm was possible, but this is not enough to warrant the extraordinary relief afforded by a permanent injunction.

Having found that Plaintiffs have failed to establish the requisite irreparable harm, the court need not address the remaining factors. *See Wis. Gas Co.*, 758 F.2d at 674 (quoting *Sampson v. Murray*, 415 U.S. 61, 88 (1974) ("The basis for injunctive relief in the federal courts has always been irreparable harm and inadequacy of legal remedies.")

## **III. CONCLUSION**

For the foregoing reasons, the Defendants' motion to dismiss (ECF No. 169) is GRANTED as to Counts I, III, IV, and VII of the Amended Complaint (ECF No. 92) for failure to state a claim. Defendants' motion for summary judgment (ECF No. 170) is likewise GRANTED as to Counts V, VI, VIII, IX, and X, but DENIED as to the FDCA claims in Count XI.

Plaintiffs' motion for partial summary judgment (ECF No. 236) as to Count XI (and Count V of Plaintiff LeCroy's Amended Complaint) is GRANTED, but the court finds that, the statutory violations notwithstanding, Plaintiffs have failed to demonstrate irreparable harm and are therefore not entitled to the injunctive relief sought as to those claims. This ruling will not apply to Plaintiff Norris Holder, whose request for injunctive relief will remain pending. Date: September 20, 2020

<u>Tanya S. Chutkan</u>

TANYA S. CHUTKAN United States District Judge