

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 11-13891

FILED U.S. COURT OF APPEALS ELEVENTH CIRCUIT SEPTEMBER 7, 2011 JOHN LEY CLERK
--

D.C. Docket No. 3:11-cv-00700-MMH-TEM

MANUEL VALLE,

Plaintiff-Appellant,

versus

STEVEN SINGER,
in his official capacity as the Warden of Florida State Prison,

TIMOTHY CANNON,
in his official capacity as the Execution Team Leader,

EDWIN BUSS,
in his official capacity as the Secretary,
Florida Department of Corrections,

UNKNOWN EXECUTIONERS,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(September 7, 2011)

Before CARNES, HULL and WILSON, Circuit Judges.

PER CURIAM:

Manuel Valle is a death row prisoner who is scheduled to be executed by the State of Florida. The State originally scheduled his execution by lethal injection for August 2, 2011. The Florida Supreme Court granted a stay to allow a Florida circuit court to determine whether the State's use of an altered lethal injection protocol—one that substituted pentobarbital for sodium thiopental in its three-drug execution cocktail—violates the Eighth Amendment. Following an evidentiary hearing, the circuit court denied relief. The Florida Supreme Court affirmed, lifting its previously issued stay. Valle's execution was rescheduled for September 6, 2011; this Court's temporary stay expires September 8, 2011 at 7:00 pm.

Valle also brought suit in federal district court. He filed a complaint under 42 U.S.C. § 1983 and a motion for a temporary restraining order ("TRO") and preliminary injunction and to stay his execution. On August 9, the district court denied his motion, concluding, *inter alia*, that Valle failed to demonstrate a

substantial likelihood of success on the merits of his Eighth Amendment claim—a prerequisite for injunctive relief.¹ Valle appeals that decision and also asks this Court to enter a stay of execution so that he can obtain a merits ruling on his complaint. He concedes that this Court’s recent decisions rejected similar challenges. Valle seeks to distinguish those cases—allowing Georgia and Alabama to proceed with executions using pentobarbital instead of sodium thiopental—because he alleges that Florida, unlike Georgia and Alabama, has a history of problems with properly effecting executions.²

“A stay of execution is equitable relief which this Court may grant only if the moving party shows that: (1) he has a substantial likelihood of success on the merits; (2) he will suffer irreparable injury unless the injunction issues; (3) the stay would not substantially harm the other litigant; and (4) if issued, the injunction would not be adverse to the public interest.” *DeYoung v. Owens*, 646 F.3d 1319, 1324 (11th Cir. 2011) (internal quotation marks omitted). “We review the district court’s denial of [defendant’s] motions for a TRO and stay of execution for abuse

¹ Valle also filed a second motion for a temporary restraining order seeking to delay his execution. The district court noted that, except for the procedural history, the motion was virtually identical to the first motion. Therefore, it denied the second motion for the same reasons stated in the previous order.

² Valle notes in his brief that his complaint before the district court raised four separate claims. His filing in this court, however, focuses exclusively on the Eighth Amendment claim. Accordingly, we do the same.

of discretion.” *Id.* at 1324 n.2.

“To state an Eighth Amendment claim, [the defendant] must demonstrate that (1) the State is being deliberately indifferent (2) to a condition that poses a substantial risk of serious harm to him. In the lethal injection context, this standard requires an inmate to show an objectively intolerable risk of harm that prevents prison officials from pleading that they were subjectively blameless for purposes of the Eighth Amendment.” *Id.* at 1325 (internal quotations marks and citations omitted).

We conclude that Valle has not demonstrated that he has a substantial likelihood of success on the merits of his Eighth Amendment claim for the reasons set out in Part C.1 of the district court’s thorough and well-reasoned discussion of the lethal injection issue. We adopt that part of the district court’s opinion as our own. For the convenience of the reader, we reproduce that part of the opinion, as well as some introductory parts of it, as an appendix to this one.³

Because Valle has failed to show a substantial likelihood of success on the merits, we need not address the other three requirements for issuance of a stay of execution. *See DeYoung*, 646 F.3d at 1328 (“DeYoung has not demonstrated a

³ The appendix is part of the district court’s order but with the district court’s Westlaw citations updated to the Federal Reporter and all quotations checked for accuracy.

substantial likelihood of success on the merits of his claims. Therefore, the Court denies DeYoung's motion for a stay of execution in this Court."); *Parker v. State Bd. of Pardons and Paroles*, 275 F.3d 1032, 1035 (11th Cir. 2001) (holding that death row inmate who failed to establish substantial likelihood of success on merits of his clemency claims was not entitled to temporary restraining order, preliminary injunction, or stay of execution).

For the foregoing reasons, we conclude that Valle does not satisfy the first requirement for the issuance of a stay of execution, and thus we deny Valle's motion.⁴

MOTION FOR STAY OF EXECUTION IS DENIED; DISTRICT COURT'S ORDER IS AFFIRMED.

⁴ Based on the same rationale, we conclude that the district court did not abuse its discretion in denying Valle's motion for a stay of execution.

APPENDIX

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

MANUEL VALLE,

Plaintiff,

v.

Case No. 3:11-cv-700-J-34TEM

STEVEN SINGER,
etc.; et al.,

Defendants.

ORDER

A. Introduction

Plaintiff Manuel Valle, a prisoner sentenced to death by the State of Florida, was scheduled to be executed by lethal injection on Tuesday, August 2, 2011, at 6:00 p.m. On July 18, 2011, Valle, represented by counsel, filed a Complaint (Doc. #1) and Memorandum of Law and Argument in Support of the Complaint (Memorandum) (Doc. #2) pursuant to 42 U.S.C. § 1983. In the Complaint and Memorandum, Valle challenges the State of Florida's lethal injection procedures and asserts that the Florida Department of Corrections' recent change from sodium thiopental to pentobarbital, as the first of three drugs used in the lethal injection protocol, constitutes cruel and unusual punishment in violation of the Eighth Amendment and also violates his rights protected by the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution. Additionally, he alleges that the Florida Department of Corrections' current policies and procedures and its history of failing to follow its own written execution procedures, combined

with the recent substitution of pentobarbital, will unnecessarily cause a risk of the infliction of pain and suffering and will create a substantial risk of serious harm to Valle at his upcoming execution. As relief, Valle seeks declaratory and injunctive relief aimed at stopping the State of Florida from executing him using its lethal injection protocol, as well as a stay of execution to allow his § 1983 action to be fully and fairly litigated without an imminent execution date looming.

* * *

B. Background

Following lengthy state trial court proceedings which included two separate trials and three sentencing proceedings, Valle was sentenced to death for the 1978 murder of Officer Louis Pena of the Coral Gables Police Department.³ Valle appealed his sentence to the state supreme court, which denied his direct appeal on May 2, 1991. Valle v. State, 581 So.2d 40 (Fla. 1991). Valle then petitioned the United States Supreme Court for a writ of

³ In the trials, Valle was also convicted of other non-capital crimes, including the attempted murder of another Coral Gables Police Officer, Gary Spell, and possession of a firearm by a convicted felon. See Valle v. State, 474 So.2d 796, 798 (Fla. 1985), cert. granted, judgment vacated by Valle v. Florida, 476 U.S. 1102 (1986).

certiorari, which was denied on December 2, 1991. Valle v. Florida, 502 U.S. 986 (1991). Thus, Valle's conviction and sentence became final on December 2, 1991.

In 2000, the Florida Legislature established lethal injection as the method of execution in the State of Florida. Lightbourne v. McCollum, 969 So.2d 326, 341-42 (Fla. 2007), cert. denied, 553 U.S. 1059 (2008). Although the applicable state statute provides for the method of execution, it does not set forth the specific procedures or drugs to be used. Id. at 342. Instead, the legislature delegated the responsibility for establishing appropriate procedures to the Florida Department of Corrections (FDOC). Id. Until recently, lethal injection in the State of Florida was accomplished by a three-drug protocol utilizing sodium thiopental to render the condemned person unconscious, followed by the administration of pancuronium bromide, a neuromuscular blocking agent, and finally a dose of potassium chloride. Id. at 345. According to the Complaint, the FDOC, on June 9, 2011, released a new lethal injection procedure in which it publically advised, for the first time, that the State intended to replace sodium thiopental with pentobarbital. See Complaint at 22-23, paragraphs 65-67. Additionally, on June 30, 2011, the State announced that Valle's execution was scheduled for August 2, 2011. See Motion to Dismiss at 2.

In this action, pursuant to 42 U.S.C. § 1983, Valle asserts that Florida's intention to execute him using pentobarbital in the three-drug lethal injection sequence, instead of sodium thiopental,

violates his Eighth Amendment right to be free from cruel and unusual punishment. He asserts that, as a result of this substitution, he may be conscious after being injected with pentobarbital, and thus subjected to significant pain during the administration of the final two drugs. In support of his claims, Valle points to a report and an affidavit provided by Dr. David B. Waisel, M.D. See P. Ex. B, Waisel's Expert Report and Affidavit. In his report, Dr. Waisel expresses concern regarding the lack of clinical history related to the use of pentobarbital for anesthesia. See generally Id. Additionally, in his affidavit, Dr. Waisel opines that, based on his reviews of descriptions of the June 23, 2011 execution of Roy Willard Blankenship, pentobarbital may inadequately anesthetize the inmate and subject him to a substantial risk of serious harm and extreme, torturous and needless pain and suffering. Valle also relies on a position paper released by Lundbeck, Inc., the manufacturer of pentobarbital, which he contends reflects the manufacturer's judgment that the drug is "untested and unsafe for use in judicial lethal injections," has not been approved by the Food and Drug Administration (FDA) to induce anesthesia, has no relevant clinical history, and "no relevant clinical reference doses on which to determine what dose would cause a clinically adequate depth of anesthesia, much less an adequate lethal injection dose." Complaint at 6, paragraph 24.

Valle asserts that "[t]he combination of significant unknowns from a lack of clinical history related to using pentobarbital to

induce anesthesia, inadequate implementation of procedural safeguards and a cavalier attitude toward lethal injection puts [him] at risk for serious undue pain and suffering." Id. Thus, Valle relies not only on the recent substitution of pentobarbital, but also upon his concerns regarding the inadequate training and experience of execution team members, inadequate monitoring of the IV lines, inadequate monitoring of consciousness by unqualified individuals, FDOC's failure to conduct meaningful review of its processes, as well as its failure to respond to public information requests. Id. at 15-22.

Defendants have filed a Motion to Dismiss, in which they assert that Valle's claims are barred by the applicable statute of limitations, and further that he has failed to state any claim upon which relief can be granted. Motion to Dismiss at 3-4, 12-17. In Plaintiff's Response, recognizing that many of his arguments have been addressed by the decisions of the United States Supreme Court in Baze v. Rees, 553 U.S. 35, 50 (2008), and the Florida Supreme Court in Lightbourne, Valle contends that his challenges are new and different because:

It is only within the past year that Mr. Valle learned that U.S. prisons across the country have been obtaining the drugs used in executions illegally. It is only recently that Mr. Valle learned that the Defendants have failed to comply with even the administrative requirements that were written into their own procedures. It is only since June 9, 2011[,] that Mr. Valle learned that the Defendants have substituted an untested and non-FDA approved drug for sodium thiopental. It has only been since the warrant for his execution was signed that he

learned that the sole manufacturer of pentobarbital, Lundbeck, Inc., has issued a warning that it cannot guarantee the safety and efficacy of the drug in the execution of human beings. And it is only in the past week that Mr. Valle learned that there have been more botched executions around the country where pentobarbital was used.

Plaintiff's Response at 7. In sum, Valle asserts that the replacement of sodium thiopental with pentobarbital when combined with Florida's history and the deficiencies in its procedures subjects him to a substantial risk of serious harm. As such, he seeks a temporary restraining order and an immediate stay of his impending execution.

C. Motion to Stay

Very recently, the Eleventh Circuit Court of Appeals reiterated the requirements for a stay of execution:

A stay of execution is equitable relief which this Court may grant "only if the moving party shows that: (1) he has a substantial likelihood of success on the merits; (2) he will suffer irreparable injury unless the injunction issues; (3) the stay would not substantially harm the other litigant; and (4) if issued, the injunction would not be adverse to the public interest."

DeYoung v. Owens, (DeYoung II⁴), 646 F.3d 1319,1324 (11th Cir. 2011) (quoting Powell v. Thomas, 641 F.3d 1255, 1257 (11th Cir. 2011) (per curiam), cert. denied, 131 S.Ct. 2487 (2011))

⁴ In DeYoung II, the Eleventh Circuit affirmed the decision in DeYoung v. Owens, Case No. 1:11-cv-2324-SCJ (N.D. Ga. 2011), Order (Doc. #27), filed July 20, 2011 (DeYoung I). A copy of DeYoung I is appended to Defendants' Notice of Supplemental Authority (Doc. #12).

cert. denied, No. 11-5361, 2011 WL 2870756 (U.S. July 20, 2011).

1. Substantial Likelihood of Success on the Merits

As the moving party, Valle bears the burden of establishing that he has a substantial likelihood of succeeding on the merits of his § 1983 claims raised in this action. Henyard v. Sec'y, Dep't of Corr., 543 F.3d 644, 647 (11th Cir. 2008) (per curiam). Upon review of the record and each of the claims raised in this action, the Court determines that Valle's Motion to Stay is due to be denied because Valle has failed to meet his burden of establishing that he has a substantial likelihood of success on his claims.

Florida's recent replacement of sodium thiopental with pentobarbital in the three-drug lethal injection sequence underlies the bulk of Valle's claims in this action.⁵ Specifically, Valle asserts that, under Florida's present protocol, at his upcoming execution, he may be conscious after being injected with pentobarbital, and thus, able to feel pain during the administration of the final two chemicals. Valle's claims brought under 42 U.S.C. § 1983 are subject to Florida's four-year personal injury statute of limitations.⁶ See Van Poyck v. McCollum, 646 F.3d

⁵ Florida's June 8, 2011 substitution of pentobarbital for sodium thiopental coincides with the substitution made by other states within the Eleventh Circuit, both Georgia and Alabama. See DeYoung I at 4-5 n.2. Indeed, as noted in DeYoung I: "A number of states have recently adopted the use of pentobarbital as U.S. manufactured sodium thiopental is no longer available following the decision of Hospira, Inc., the sole U.S. manufacturer of the drug, to discontinue its production." Id.

⁶ Section 1983 creates a cause of action against any person who acts in violation of the constitutional rights of another while

865, 866 (11th Cir. 2011) (per curiam) (citing Henyard, 543 F.3d at 647). Florida adopted lethal injection as a method of execution on January 14, 2000. Thereafter, condemned persons, such as Valle, had thirty days under the statute to select a preferred method of execution, or until February 13, 2000. See Henyard, 543 F.3d at 647. Consequently, to the extent Valle wished to challenge Florida's intention to execute him by lethal injection, he was required to bring his § 1983 action within four years of February 13, 2000, i.e., by February 13, 2004, absent a later "significant change" in Florida's execution protocol. As previously noted, Valle did not file this Complaint until July 18, 2011. Thus, it appears that Valle's claims in this action would be barred as the suit was filed well beyond the four- year limitations period.

Despite the significant passage of time since February 2004, Valle contends that his claims are not barred by the statute of limitations, because Florida's substitution of pentobarbital for sodium thiopental in the three-drug lethal injection protocol constitutes a substantial change in the method of execution. In McNair v. Allen, 515 F.3d 1168, 1174 (11th Cir. 2008), cert. denied, 553 U.S. 1098 (2008), the Eleventh Circuit Court of Appeals

acting under color of state law. Here, Valle challenges the constitutionality of the execution procedure he is scheduled to undergo. Such challenges are appropriately brought under § 1983. Hill v. McDonough, 547 U.S. 573, 576 (2006); McNair v. Allen, 515 F.3d 1168, 1176 (11th Cir. 2008) ("[T]he Supreme Court has sanctioned the filing of § 1983 claims challenging the constitutionality of execution methods."), cert. denied, 553 U.S. 1098 (2008).

concluded that "a method of execution claim accrues on the later of the date on which state review is complete, or the date on which the capital litigant becomes subject to a new or substantially changed execution protocol." Thus, the Court must consider whether Valle has alleged facts supporting a conclusion that Florida has changed or substantially altered its execution protocol.

Not surprisingly, the recent substitution of pentobarbital as the first of the three-drug lethal injection protocol used by various states has resulted in a flurry of activity in courts across the country and within the Eleventh Circuit.⁷ Of particular import to Valle's claims before this Court are a series of recent decisions from within the Eleventh Circuit. On May 16, 2011, a district court in Alabama denied an inmate's motion to stay his execution, which relied on the substitution of pentobarbital for sodium thiopental, based on the court's conclusion that the inmate failed to meet his burden of demonstrating a substantial likelihood

⁷ DeYoung I; DeYoung II; Powell (Williams) v. Thomas (Powell (Williams) I), Case No. 2:11-CV-376-WKW, 2011 WL 1843616 (M.D. Ala. May 16, 2011), aff'd, Powell (Williams) v. Thomas (Powell (Williams) II), 641 F.3d 1255 (11th Cir. 2011) (per curiam), cert. denied, Williams v. Thomas, 131 S.Ct. 2487 (2011); Powell v. Thomas (Powell I), No. 2:11-CV-376-WKW [WO], 2011 WL 2292108 (M.D. Ala. June 9, 2011), aff'd, Powell v. Thomas (Powell II), 643 F.3d 1300 (11th Cir. 2011) (per curiam), petition for cert. filed, No. 10-11055, 10A1235, (U.S. June 15, 2011), and other courts across the country. See Pavatt v. Jones, 627 F.3d 1336 (10th Cir. 2010), cert. denied, 131 S.Ct. 974 (2011); West v. Brewer, No. CV-11-1409-PHX-NVW, 2011 WL 2836754 (D. Ariz. July 18, 2011); Jackson v. Danberg, Case No. 06-300-SLR (D. Del. July 12, 2011), (Doc. #148) (granting a stay of execution), vacated, Jackson v. Danberg, Case No. 11-9000 (3d Cir. July 21, 2011); Cooey v. Kasich, Nos. 2:04-cv-1156, 2:09-cv-242, 2:09-cv-823, 2:10-cv-27, 2011 WL 2681193 (S.D. Ohio July 8, 2011).

of success given his "heavy burden" to prove an Eighth Amendment claim. Powell (Williams) I. The Eleventh Circuit Court of Appeals upheld the denial concluding "[t]he replacement of sodium thiopental with pentobarbital does not constitute a significant alteration in the [Alabama Department of Corrections'] lethal injection protocol, and . . . such an amendment does not violate the Eighth Amendment under the cases cited by [plaintiff]." Powell (Williams) II, 641 F.3d at 1258.

Thereafter, in reliance on Powell (Williams) II, the district court dismissed inmate Powell's § 1983 action challenging Alabama's lethal injection protocol based upon a finding that it was barred by the statute of limitations. See Powell I. Specifically, the district court concluded that the alteration of Alabama's three-drug lethal injection protocol (by the substitution of pentobarbital for sodium thiopental) was not a significant or substantial change in the execution protocol so as to reset the applicable statute of limitations. Id. at *4. Additionally, the court rejected Powell's Fourteenth Amendment due process challenge based upon the state's secrecy of its processes noting that Powell could have challenged the secrecy surrounding the method of execution beginning in 2002. Id. As a result, the state's change to pentobarbital did not "awaken this long stale claim." Id. On review, the Eleventh Circuit Court of Appeals agreed. Powell II. On June 15, 2011, in Powell II, the Eleventh Circuit rejected Powell's attempt to relitigate the issue of whether Alabama's change in the first drug of the lethal injection protocol was a

significant change for purposes of restarting the statute of limitations. 643 F.3d at 1304-05.⁸ As such, the court found that the Eighth Amendment challenge was barred by the statute of limitations, and further that the Eighth and Fourteenth Amendment challenges to the change in execution protocol based upon the secrecy in which it was accomplished were similarly barred by the statute of limitations. Id. at 1305.

In an effort to distinguish the instant case from the recent Powell decisions, Plaintiff asserts that his "case presents claims and a factual basis unlike any presented before to seek a stay." Motion to Stay at 6. He not only complains about Florida's replacement, on June 8, 2011, of sodium thiopental with pentobarbital, as the first drug in the three-drug lethal injection sequence, but also that Florida has a "broken lethal injection process." Id. In support of his assertions, Valle points to the following: (1) the June 23, 2011 execution by lethal injection, using pentobarbital, of inmate Roy Willard Blankenship in Georgia, as detailed in the Affidavit and Expert Report of Dr. David B. Waisel, M.D. (P. Ex. B, Waisel's Expert Report and Affidavit); (2) the July 1, 2011 pentobarbital manufacturer's position paper condemning the use of pentobarbital for executions by lethal injection and noting that the drug is not approved for such use; and (3) "Florida's unique history of botched executions," (exemplified by the 2006 execution of Angel Diaz), the Defendants'

⁸ [Footnote regarding Westlaw citations omitted.]

unchecked discretion in deviating from and not following the written execution procedures, and "Florida's already broken lethal injection process," including the inadequate training, experience, and qualifications of the execution team members. Valle's protestations notwithstanding, the purported distinctions upon which he relies are neither new nor, based on Eleventh Circuit precedent, are they sufficient alone or in combination with one another to carry his burden.

Following the filing of the Complaint and the Motion to Stay, the Eleventh Circuit Court of Appeals had another opportunity to consider the substitution of pentobarbital for sodium thiopental, this time in an action by a Georgia inmate who raised claims strikingly similar to those of Valle. See generally DeYoung II. Inmate DeYoung sought a stay of his execution scheduled for July 20, 2011, arguing that Georgia's lethal injection protocol violated his Eighth Amendment right to be free from cruel and unusual punishment. DeYoung II, 646 F.3d at 1323. He contended that the use of pentobarbital subjected him to a substantial risk of serious harm because pentobarbital was insufficiently tested for use as an anesthetic and that in prior executions using pentobarbital, specifically the execution of Roy Blankenship, the drug failed to "painlessly anesthetize the prisoners." Id.

The Eleventh Circuit, in rejecting DeYoung's claims, unequivocally reiterated its finding that the substitution of pentobarbital for sodium thiopental does not result in a substantially changed execution protocol. Id. at 1325. Moreover,

addressing DeYoung's attempt to revisit the statute of limitations issue in reliance on evidence regarding the Blankenship execution, the court noted, "the mere act of proffering additional reasons not expressly considered previously will not open the door to reconsideration of the question by a second panel." Id. (quoting Smith v. GTE Corp., 236 F.3d 1292, 1302 (11th Cir. 2001) (quotation marks and ellipsis omitted)). Nevertheless, the Eleventh Circuit considered and rejected DeYoung's Eighth Amendment claim on the merits, finding the additional proffered evidence did not undermine Powell's conclusion. Specifically referencing the events surrounding the Blankenship execution, the court determined that DeYoung failed to "establish a substantial risk of serious harm from the pentobarbital, or even that Blankenship necessarily suffered any harm, much less serious harm." DeYoung II, at 1326.

The Eleventh Circuit explained:

First, as the district court pointed out, "Dr. Waisel entirely failed to provide a medical explanation for why pentobarbital might have caused Blankenship pain. To the contrary, Dr. Waisel testified that a patient will not feel pain at the moment when a drug is introduced intravenously unless it is a drug, such as potassium chloride, which causes a burning sensation."

Second, the district court noted that Dr. Waisel admitted that "any 'suffering' was short lived as it clearly ended within a few minutes-three minutes at the most-after the pentobarbital was injected." The Eighth Amendment does not protect against all harm, only serious harm; and it does not prohibit all risks, only substantial risks. "Simply because an execution method may result in pain, either by accident or an inescapable consequence of death, does not establish the sort of 'objectively intolerable risk of harm'

that qualifies as cruel and unusual." Baze, 553 U.S. at 50, 128 S.Ct. at 1531 (plurality opinion). In any event, Dr. Waisel was not present at the Blankenship execution; rather, he opines from the witnesses' varied descriptions of Blankenship's movements that those movements were a sign of "discomfort," which Dr. Waisel termed "suffering." Dr. Waisel acknowledged that no one reported any movement by Blankenship after the nurse's consciousness check. Further, Blankenship's autopsy revealed no evidence of trauma. The catheters were inside Blankenship's veins and the veins were not burst or broken. There was no infiltration of fluid in the soft tissue of the right arm near the catheter site.

Notably too, DeYoung presented no evidence to show that unconsciousness is not achieved after the complete administration of a 5000-mg dose of pentobarbital.

All parties agree that the purpose of the anesthetic in Georgia's three-drug lethal injection protocol is to render the inmate unconscious before administration of the second and third drugs. As the record demonstrates, and the district court found, a consciousness check was performed on Blankenship after he was administered the pentobarbital and prior to injection of the second drug pancuronium bromide, as Georgia's lethal injection protocol requires. It is clear that Blankenship's execution did not proceed to the second drug until after he was fully unconscious. And as the district court found, DeYoung's execution, or any other under the Georgia protocol, cannot proceed until he is unconscious. To the contrary, Georgia's protocol specifically provides that GDOC officials will not administer the pancuronium bromide but will instead administer more anesthetic-and conduct more consciousness checks-until the inmate has been shown to be unconscious.

DeYoung has wholly failed to show that pentobarbital, once fully administered and allowed to act, is ineffective as an anesthetic. As the district court succinctly found, Georgia's "use of pentobarbital does

not create a substantial risk of serious harm to inmates."

DeYoung II, 646 F.3d at 1326-27 (footnote omitted).

Plaintiff's attempt to distinguish his claim from the binding Powell precedent, based upon the Blankenship execution and the affidavit of Dr. Waisel, is significantly undermined if not entirely foreclosed by DeYoung II. Indeed, the affidavit of Dr. Waisel relied upon by Valle, see P. Ex. B at 14-18, is identical, in substance, to that considered and found to be insufficient by the district court and the Eleventh Circuit Court of Appeals in DeYoung I and DeYoung II.⁹ See DeYoung v. Owens, Case No. 1:11-cv-2324-SCJ (N.D. Ga. 2011), Affidavit of Dr. David B. Waisel, M.D. (Doc. #3-15), filed July 15, 2011, at 1-5.¹⁰ Moreover, Florida's protocol, like that of Georgia in DeYoung II,¹¹ calls for 5 grams

⁹ In Plaintiff's Response to the Motion to Dismiss, Valle also argues for the first time, without reference to any affidavit or other evidence, that "Powell himself had the unfortunate distinction of becoming Alabama's first botched execution by lethal injection." Plaintiff's Response at 5. Valle described the start of the execution: "[w]itnesses reported that after the start of the execution, Mr. Powell violently jerked his head up off the gurney, turned his head from side to side, clenched his jaw, . . . appeared to be in pain[,] and [h]is eyes remained open for quite a while." Id. at 5 n.1. However, when recently faced with such evidence in the DeYoung II case, the Eleventh Circuit stated: "DeYoung's evidence about the Powell execution does not change our conclusion. . . . Powell's counsel [(who had witnessed the execution)] did not know at what time the various chemical[s] were administered." DeYoung II, 646 F.3d at 1327 n.5.

¹⁰ This exhibit is not available on Westlaw; therefore the Court cites to the document that appears on the Pacer Case Locator. See <https://pcl.uscourts.gov/search>.

¹¹ See DeYoung II, 646 F.3d at 1323 (noting that 5000 milligrams of pentobarbital is used, as the first drug, in the three-drug protocol and stating that the "[l]ack of sodium thiopental availability led Georgia on May 13, 2011[,]

of pentobarbital to be administered as the first drug of the three-drug protocol. P. Ex. A, Execution by Lethal Injection Procedures. Florida's protocol also specifically requires a consciousness check after the administration of the 5 grams of pentobarbital, and prior to the administration of the second drug of the three-drug protocol. Id. If, after the consciousness check the individual is not unconscious, the procedure is started anew, with a new set of chemicals. Id. Thus, as in DeYoung II, under Florida's protocol, the execution cannot proceed until the individual is rendered unconscious. Id.

Based on Eleventh Circuit precedent, the undersigned concludes that Florida has not made a significant alteration in its lethal injection protocol. Plaintiff has failed to support his assertion that his case is distinguishable from the Eleventh Circuit's decisions in the Powell cases and DeYoung II, and mere speculation cannot substitute for evidence that the use of pentobarbital will or very likely will cause serious illness and needless suffering. Indeed, as the United States Supreme Court has instructed, the fact that "an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of 'objectively intolerable risk of harm' that qualifies as cruel and unusual." Baze, 553 U.S. at 50.

Nevertheless, Valle also attempts to distinguish his case from the Powell decisions by asserting that Lundbeck, Inc., the sole

to switch to the use of pentobarbital as the anesthetic in its lethal injection protocol").

manufacturer of pentobarbital, issued a position paper on July 1, 2011, condemning the misuse of that drug for executions by lethal injection. Motion to Stay at 11. The pertinent portion of this position paper, upon which Valle relies, states:

The use of pentobarbital to carry out the death penalty in [United States] prisons falls outside its approved indications. Lundbeck cannot assure the associated safety and efficacy profiles in such instances. Lundbeck does not promote pentobarbital for use as part of lethal injections and is doing everything in its power to put an end to this misuse.

Id. (quoting Lundbeck's Position Regarding the Misuse of Pentobarbital in Execution of Prisoners, available at <http://www.lundbeck.com/Media/pentobarbital.asp>).

Lundbeck's July 1, 2011 position paper does not support a finding that the substitution of pentobarbital for sodium thiopental constitutes a significant change in Florida's execution protocol. Notably, as acknowledged by Valle, Hospira, Inc., the only manufacturer approved by the FDA to manufacture sodium thiopental, also condemned the use of that drug for lethal injections. See Motion to Stay at 8. However, this objection did not warrant its withdrawal from the various states' lethal injection protocols. Indeed, whether or not a manufacturer objects to the use of its drug for executions appears to have little, if any, evidentiary weight. See Powell (Williams) I, at *8 n.7 ("Williams emphasizes that the manufacturer of pentobarbital has pronounced that it is opposed to its drug being used for executions, but fails to demonstrate how that fact is in any way relevant to the issues and his burden.").

Moreover, Lundbeck's statements that the use of pentobarbital in lethal injections falls outside its approved indications and that it cannot assure pentobarbital's safety and efficacy when used in such a fashion, see Complaint at 8-9, paragraph 31, fall short of meeting Valle's burden. As the Supreme Court has explained,

the conditions presenting the risk must be sure or very likely to cause serious illness and needless suffering, and give rise to sufficiently imminent dangers. We have explained that to prevail on such a claim[,] there must be a substantial risk of serious harm, an objectively intolerable risk of harm that prevents prison officials from pleading that they were subjectively blameless for purposes of the Eighth Amendment.

Baze, 553 U.S. at 50 (internal citation and quotation marks omitted). As such, "[a] stay of execution may not be granted . . . unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain. He must show that the risk is substantial when compared to the known and available alternatives." Id. at 61. The statements by Lundbeck do not satisfy this burden.

Preliminarily, the Court recognizes that other courts have rejected claims that the absence of FDA approval of a drug for use in lethal injections means that the drug is unsafe or suggests that it is sure or very likely to cause serious illness or needless suffering. See Brewer v. Landrigan, 131 S.Ct. 445 (2010) (vacating a stay of execution which was based upon a finding that the plaintiff had a substantial likelihood of success on the merits of his claim that the use of sodium thiopental manufactured by a foreign source and not approved by the FDA creates a substantial

and unnecessary risk of serious harm in violation of the Eighth Amendment); Cook v. Brewer, 637 F.3d 1002, 1006-07 (9th Cir. 2011) ("Cook relies on his allegations that Arizona's sodium thiopental is imported and not approved by the FDA. But Landrigan . . . advises that these facts are not sufficient to state a plausible Eighth Amendment claim"); Powell (Williams) I, at *7-8 (finding that the plaintiff did not have a substantial likelihood of success on the merits of his challenge to the lethal injection protocol based on the substitution of pentobarbital for sodium thiopental, which was supported in part by Dr. Waisel's assertion that the use of pentobarbital as an agent to induce anesthesia is not FDA approved). Moreover, Lundbeck's asserted lack of information as to the efficacy and safety of pentobarbital for use in lethal injections does nothing to establish a demonstrated risk of severe pain or needless suffering. Indeed, the United States District Court of Arizona arrived at this same conclusion when faced with Lundbeck's opposition to the use of pentobarbital in the lethal injection process in Arizona:

Finally, the Court does not find the manufacturer's "warning" against pentobarbital use in executions to be persuasive. Although the company relayed to the Georgia Department of Corrections it could not "assure the associated safety and efficacy" of using pentobarbital for off-label use, it also made clear that it was "adamantly opposed" to the use of pentobarbital "or any product for that matter, for the purpose of capital punishment" because such use "contradicts everything we are in business to do—provide therapies that improve people's lives." (Doc. 1, Ex. N.) This is insufficient evidence to establish a substantial risk of harm.

West v. Brewer, No. CV-11-1409-PHX-NVW, 2011 WL 2836754, at *8 (D. Ariz. July 18, 2011).

Lundbeck's position on the use or misuse of pentobarbital simply does not establish that the use of pentobarbital will subject Valle to a risk of pain and needless suffering. Valle submits no evidence that the administration of 5 grams of pentobarbital during the execution process will cause him needless suffering in and of itself. See DeYoung II, 646 F.3d at 1326-27. Additionally, the evidence before the Court fails to support a conclusion that Valle is likely to establish an objectively intolerable risk that this dosage of pentobarbital will not render Valle unconscious. Id. At 1327.

Dr. Mark Derschwitz, M.D., an anesthesiologist with a Ph.D. in pharmacology, states that pentobarbital is and has been commonly used to induce a barbiturate coma since the mid-1970s. Def. Ex. D, Expert Report of Mark Derschwitz, M.D., Ph.D., at paragraphs 8-10. He further explains:

A dose of 5,000 mg of pentobarbital will cause virtually all persons to stop breathing. In addition, a dose of 5,000 mg of pentobarbital will cause the blood pressure to decrease to such a degree that perfusion of blood to organs will cease or decline such that it is inadequate to sustain life. Thus, although the subsequent administration of vecuronium bromide, a paralytic agent, would have the effect of paralyzing the person and preventing him or her from being able to breathe, virtually every person given 5,000 mg of pentobarbital will have stopped breathing prior to the administration of vecuronium bromide. Thus, even in the absence of the administration of vecuronium bromide and potassium chloride, the administration of

5,000 mg of pentobarbital by itself would cause death in almost everyone.

Id. at paragraph 12. Dr. Waisel, on the other hand, candidly admits that he does not know how the State's dosage of pentobarbital will affect inmates subjected to execution by lethal injection. He explains:

There is no way to know, in any given case, how a massive dose of pentobarbital will affect a human patient, because it has not been tested to any remotely sufficient degree to be able to say. The way Blankenship reacted to the injection of pentobarbital may be indicative of how many human beings will react.

P. Ex. B, Expert Report at 4, paragraph 9 (emphasis added). This asserted lack of knowledge simply cannot satisfy Valle's burden of affirmatively showing that a substantial risk of serious harm exists. Baze, 553 U.S. at 61 (stating that, in order to obtain a stay of execution, a condemned inmate must show that "the State's lethal injection protocol creates a demonstrated risk of severe pain[]" and that "the risk is substantial when compared to the known and available alternatives").

Therefore, neither Lundbeck's July 1, 2011 condemnation of the use of pentobarbital for executions by lethal injection, nor its position that pentobarbital is not approved for use in executions, supports a finding that the substitution of pentobarbital for sodium thiopental subjects him to a substantial risk of serious harm or constitutes a significant change in Florida's execution protocol. Thus, by this assertion, Valle has failed to distinguish

his case from the Powell decisions or the more recent decision in DeYoung II.

Valle presents one further contention in his effort to distinguish his claims from other previous cases seeking a stay of execution. He argues that his assertions are not premised merely on the substitution of pentobarbital for sodium thiopental, but also on "the deadly combination of adding an untested drug to Florida's already broken lethal injection process." Motion to Stay at 6; Plaintiff's Response at 5-6. Referring to what he describes as "Florida's unique history of botched executions" and specifically citing to the 2006 execution of Angel Diaz as an example, Valle asserts that Defendants' history and pattern of deviating from and not following execution procedures violates the Eighth and Fourteenth Amendments. Motion to Stay at 4-5, 16-17, 33. He alleges that the administration of the three drugs, the assessment of IV lines and consciousness, and the continued monitoring of the inmate for consciousness throughout the procedure are inadequate in that the Defendants do not require that the execution team members have adequate training, experience, qualifications, and certification to properly perform the multiple tasks associated with the execution. Id. at 12-16, 23-26. These latter allegations not only support Valle's Eighth Amendment claim but also form the basis of his substantive and procedural due process claims.¹²

¹² The Court notes that Valle's Complaint also includes various allegations regarding illegally obtained drugs and potential black market drugs. Any allegations regarding the illegal obtention of

Since the facts supporting Valle's claim of an "already broken" lethal injection process and "botched" executions "should have been apparent to any person with a reasonably prudent regard for his rights," McNair, 515 F.3d at 1177, in 2006, Florida's "switch to pentobarbital does not awaken this long stale claim." Powell I at *4. Accordingly, Valle has not shown that he has a substantial likelihood of success on the merits of his claims in that "the statute-of-limitations clock did not restart in 2007 when Florida adopted additional safeguards in its lethal injection protocols." Henyard, 543 F.3d at 647-48. Moreover, the substitution of pentobarbital did not reset the statute of limitations. Powell II; Powell (Williams) II. Thus, Valle has not established a substantial likelihood of success on the merits of his claims because the instant § 1983 action was filed beyond the applicable statute of limitations.¹³ Valle became subject to

sodium thiopental are irrelevant given the substitution of pentobarbital for sodium thiopental in the three-drug protocol. The Complaint contains no allegations of fact whatsoever regarding the manner in which FDOC obtains pentobarbital. Valle's allegation that "[o]n information and belief, the FDOC has illegally imported sodium thiopental and/or pentobarbital[,]" see Complaint at 12, paragraph 39, is entirely speculative and lacking in factual support. Moreover, Valle submitted no evidence regarding this allegation in support of the Motion to Stay.

¹³ The Court recognizes that Valle also complains that Defendants have consistently refused to reveal information about the training of the execution team and the source or vendor history of the lethal injection drugs, denying him due process of law. Motion to Stay at 24, 27. Defendants respond that this claim is barred by the statute of limitations, because at the time Florida adopted lethal injection, it also adopted the statutes which made the information concerning the process confidential. Defendants' Response at 10-11. This same contention was made in Powell II, 643 F.3d at 1305, and was rejected, with the Eleventh Circuit finding that the issue of the secrecy surrounding a lethal injection protocol is not revived by switching one of the drugs.

execution by lethal injection on February 14, 2000, and consequently had four years to file a federal civil rights claim under 42 U.S.C. § 1983. The Complaint was filed on July 18, 2011, long after the four-year statute of limitations expired; therefore, Valle's claims appear to be untimely. Crowe v. Donald, 528 F.3d 1290, 1292 (11th Cir.), cert. dismissed, 553 U.S. 1077 (2008); McNair, 515 F.3d at 1177-78.

Even if Valle's claims were timely filed, for the reasons previously discussed, they fail as a matter of law because Valle has not met his burden of affirmatively showing that a substantial risk of serious harm exists or that the risk is substantial when compared to the known and available alternatives. See Baze, 553 U.S. at 61. Indeed, Valle's allegations stop well short of complying with the Eighth Amendment standard set forth in Baze in that he has failed to show a "substantial risk of serious harm." Baze, 553 U.S. at 50. Moreover, while Valle asserts in paragraph 56 of the Complaint that "available alternatives exist[,]" he has failed to proffer any alternative procedure or drug, and failed to show that any such alternative procedure or drug is "feasible, readily implemented, and in fact significantly reduce[s] a

Additionally, the Eleventh Circuit has declined to find that there is "a categorical rule entitling defendants to a lethal injection protocol that is legislatively enacted and subjected to extensive litigation." Powell (Williams) II, 641 F.3d at 1258. Thus, to the extent Valle is claiming that secrecy prevented him from litigating his issues up to now, this claim was rejected in Powell (Williams) II and the failure to disclose is not unconstitutional. See Powell (Williams) II, 641 F.3d at 1257-58.

substantial risk of severe pain."¹⁴ Baze, 553 U.S. at 52; Powell (Williams) I, at *9 (citation omitted).

Notably, Valle's various objections to the lethal injection protocol itself have been rejected on the merits in previous cases. See Baze, 553 U.S. at 53-61 (rejecting claims concerning the maladministration of the lethal injection protocol, the failure to adopt untried and untested alternatives, the risk that the procedures will not be properly followed, the absence of additional monitoring by trained personnel, inadequate facilities and training, the placement and monitoring of IV lines, the lack of professional medical experience, and the need for a significant consciousness test); Lightbourne, 969 So.2d at 350 n.22 (rejecting Lightbourne's claims relating to the sufficiency of the August 2007 protocol, including that the revised procedures do not meaningfully increase the qualifications of executioners; there is no requirement that the team warden or executioners have experience in conducting executions; the procedures do not specifically indicate the qualifications needed by each designated team member; phlebotomists are not trained to place catheters in veins; the procedures leave inmates to guess if the execution team members are adequately experienced and medically qualified; the procedures do not provide any method for monitoring the inmate's consciousness after administration of the first drug (sodium pentothal); and the

¹⁴ It is noteworthy that, in Baze, the inmate petitioners proposed a one-drug barbituate-only protocol, using either pentobarbital or sodium thiopental as the suggested alternative drug. Baze, 553 U.S. at 56-58.

contention that pancuronium bromide is used for purely cosmetic reasons); Schwab v. State, 969 So.2d 318 (Fla. 2007) (per curiam) (rejecting similar assertions made by Schwab, focusing primarily on whether the protocols adequately ensure the assessment of consciousness and whether the use of a paralytic drug during the execution is warranted).

Valle also complains that the lethal injection protocol was not recertified between April 2008 and the signing of the June 8, 2011 procedure, denying him due process of law. Motion to Stay at 28. This assertion does little to advance his claim. No certificate of readiness was issued because sodium thiopental was unavailable, and the Governor did not sign any death warrants for death row inmates during the period of unavailability of sodium thiopental. Defendants' Response at 12. It was not until June 8, 2011, that the Secretary of the FDOC represented that the procedure had been reviewed, and certified that the Department was prepared to accomplish an execution by lethal injection. P. Ex. C, June 8, 2011, Letter from Edwin G. Buss, Secretary, to the Honorable Rick Scott. At that time, pentobarbital was substituted for the sodium thiopental in the three-drug protocol permitting the State to certify that it was prepared to carry out the lethal injection protocol. P. Ex. A, Execution by Lethal Injection Procedures, dated June 8, 2011. Thus, the lack of recertification of the process during this period of unavailability of sodium thiopental is not probative of any fact relevant to Valle's claims.

* * *

In consideration of the foregoing, the Court concludes that Valle has failed to carry his burden of establishing that he has a substantial likelihood of succeeding on the claims raised in this action. For this reason alone, the Motion to Stay would be due to be denied.

* * *

DONE AND ORDERED at Jacksonville, Florida, this 9th day of August, 2011, at 11:20 a.m.


MARCIA MORALES HOWARD
United States District Judge