Doc. 112 West et al v. Brewer et al WO 1 2 3 4 5 IN THE UNITED STATES DISTRICT COURT 6 7 FOR THE DISTRICT OF ARIZONA 8 9 10 Thomas Paul West, et al. No. CV-11-1409-PHX-NVW 11 Plaintiffs, FINDINGS OF FACT AND CONCLUSIONS OF LAW 12 and VS. **ORDER** 13 Janice K. Brewer, et al. 14 Defendants. 15 16 17 18 Plaintiffs have filed a complaint pursuant to 42 U.S.C. § 1983 alleging violations 19 of their rights to be free from cruel and unusual punishment and to due process and equal 20 protection of the law based on Arizona's implementation of its lethal injection protocol. 21 Evidence was received and argument heard on December 5-7, 2011. The Court has also 22 considered the parties' pre-hearing briefs and read the deposition transcripts submitted by 23 the parties. The Court's findings of fact and conclusions of law follow. Almost all of the 24 facts are stipulated or otherwise undisputed. Where these findings differ from the 25 evidence of one side or the other, they are based on the evidence more persuasive to the 26 Court. 27 28

I. Procedural Background

Plaintiffs are death row inmates under the supervision of the Arizona Department of Corrections ("ADC"). Plaintiff Todd Smith was sentenced to death for a crime committed after November 23, 1992, and therefore will be executed by lethal injection under A.R.S. § 13-757. Plaintiffs Gregory Dickens, Charles Hedlund, Robert Wayne Murray, and Theodore Washington were sentenced to death for crimes committed before November 23, 1992, and therefore may choose under A.R.S. § 13-757(b) whether to be executed by lethal injection or lethal gas. They have not yet chosen the method of execution. Plaintiff West was executed by lethal injection on July 19, 2011.

In 2007, Plaintiffs filed a § 1983 complaint challenging numerous aspects of Arizona's lethal injection protocol. That protocol was based on Department Order 710, dated November 1, 2007, and as modified by an exhibit submitted by the parties as part of a joint report to the Court. *See Dickens v. Brewer*, No. CV-07-1770-PHX-NVW, 2009 WL 1904294, at *1 & n.2 (D. Ariz. Jul. 1, 2009) (unpublished order). Department Order 710 stated, and continues to state, "These procedures shall be followed as written unless deviation or adjustment is required, as determined by the Director of the Arizona Department of Corrections."

The version of the protocol at issue in *Dickens* required sequential administration of: (1) sodium thiopental, an ultra fast-acting barbiturate that induces unconsciousness; (2) pancuronium bromide, a paralytic neuromuscular blocking agent that prevents any voluntary muscle contraction; and (3) potassium chloride, which causes skeletal muscle paralysis and cardiac arrest. On July 1, 2009, this Court granted summary judgment in favor of Defendants, concluding that Arizona's protocol was "substantially similar" to that approved by the Supreme Court in *Baze v. Rees*, 553 U.S. 35 (2008), and thus did not subject inmates to a substantial risk of serious harm in violation of the Eighth Amendment. On February 9, 2011, the Court of Appeals for the Ninth Circuit affirmed.

Dickens v. Brewer, 631 F.3d 1139 (9th Cir. 2011). The appellate court's mandate issued on April 18, 2011.

On June 10, 2011, ADC amended Department Order 710 to provide for the administration of sodium pentothal (thiopental) *or* pentobarbital as the first of the three sequentially-administered drugs in its lethal injection protocol.

On July 15, 2011, three days prior to Thomas West's scheduled execution, Plaintiffs brought this action under 42 U.S.C. § 1983, alleging that ADC's unwillingness to follow its written lethal injection protocol and its substitution of pentobarbital for sodium thiopental create a substantial risk they will suffer unnecessary pain during execution, in violation of the Eighth and Fourteenth Amendments to the United States Constitution. Plaintiff West also filed an emergency motion for temporary restraining order and injunctive relief, seeking to enjoin Defendants from carrying out his execution.

On July 17, 2011, the Court declined to stay West's execution, finding no likelihood of success on the merits of Plaintiffs' complaint. *See West v. Brewer*, 2011 WL 2836754 (D. Ariz. Jul. 18, 2011) (unpublished order), *aff'd*, 652 F.3d 1060 (9th Cir.), *cert. denied*, 131 S. Ct. 3092 (2011). Following West's execution, the Court denied Defendants' motion for summary dismissal under Federal Rule of Civil Procedure 12(b)(6) and ordered expedited discovery.

On August 3, 2011, Plaintiffs filed an amended complaint. Plaintiffs allege that ADC's unwillingness to follow its written lethal injection protocol and its use of pentobarbital in place of sodium thiopental create a substantial risk they will suffer unnecessary pain during execution, in violation of the Eighth Amendment. Plaintiffs further allege that ADC's unwillingness to follow its written lethal injection protocol violates their right to equal protection under the Fourteenth Amendment and that ADC's

¹During a pretrial conference, Plaintiffs withdrew their allegation concerning the substitution of pentobarbital for sodium thiopental. (Doc. 76 at 42.)

failure to provide notice of changes to its lethal injection protocol violates their right to due process under the Fourteenth Amendment. Plaintiffs seek equitable, declaratory, and injunctive relief to prevent Defendants from carrying out their executions until such time as Defendants can demonstrate that properly trained staff and medical personnel can properly implement Arizona's lethal injection procedures in a manner that complies with the Eighth Amendment.

On November 10, 2011, the parties each filed proposed findings of fact and conclusions of law. Following a pretrial conference, the Court entered the parties' joint amended pretrial order identifying the contested and uncontested facts and issues of law. A three-day bench trial was held December 5-7, 2011.

II. Undisputed Legal Standards

To prevail on a § 1983 claim, a plaintiff must show that, while acting under color of state law, the defendants deprived or will deprive him of a right secured by the Federal Constitution or laws of the United States. *See Gibson v. United States*, 781 F.2d 1334, 1338 (9th Cir. 1986).

The Eighth Amendment to the United States Constitution, applicable to the States through the Due Process Clause of the Fourteenth Amendment, provides, "Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." *Baze v. Rees*, 553 U.S. at 47. Subjecting individuals to a risk of future harm—not simply actually inflicting pain—can qualify as cruel and unusual punishment under the Eighth Amendment. *Id.* at 49-50. The Eighth Amendment will be violated where there is a "substantial risk of serious harm" that is sure or very likely to cause pain and needless suffering. *Dickens v. Brewer*, 631 F.3d at 1144-46 (adopting plurality in *Baze*, 553 U.S. 35); *see also Brewer v. Landrigan*, 131 S. Ct. 445 (2010) (Mem.). The risk must be 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 (citing *Farmer v. Brennan*, 511 U.S. 825, 842 (1994)).

In the context of carrying out an execution by lethal injection, if the State refuses to adopt a proffered feasible, readily implemented alternative that significantly reduces a substantial risk of severe pain, without a legitimate penological justification, such refusal can be viewed as "cruel and unusual" under the Eighth Amendment. *Baze*, 553 U.S. at 52. A court reviewing the constitutionality of a state's written lethal injection protocol must look beyond the facial constitutionality of the protocol when presented with evidence of improper administration. *Dickens*, 631 F.3d at 1146. "[F]ailing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride." *Baze*, 553 U.S. at 53.

The Equal Protection Clause of the Fourteenth Amendment commands that no State shall "deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. State action burdening a fundamental right is subjected to strict scrutiny and will be sustained only if it is narrowly tailored to serve a compelling state interest. *Zablocki v. Redhail*, 434 U.S. 374, 388 (1978).

The Due Process Clause of the Fourteenth Amendment provides that no State shall "deprive any person of life, liberty, or property without due process of law." U.S. Const. amend. XIV, § 1. "The touchstone of due process is protection of the individual against arbitrary action of government." *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974). The procedural due process guarantee protects against the denial of fundamental procedural fairness. *Cnty. of Sacramento v. Lewis*, 523 U.S. 833, 846 (1998). The substantive due process guarantee "protects against government power arbitrarily and oppressively exercised." *Id.* at 846 (citing *Daniels v. Williams*, 474 U.S. 327, 331 (1986)).

IV. Undisputed Facts

A. Dickens Litigation

Arizona's current lethal injection protocol has its genesis in *Dickens v. Brewer*. During the *Dickens* litigation, the parties engaged in good-faith discussions to resolve some of the issues raised by Plaintiffs. A subsequently filed joint report indicated that Defendants had agreed to modify Arizona's lethal injection protocol in the following ways: (1) lethal chemicals will be administered by default through an intravenous ("IV") peripheral line, not a central line in the femoral vein; (2) IV lines will be placed only by medically licensed individuals with at least one year current and regular practice placing such lines;² (3) ADC will conduct license and background checks of Medical Team members annually and upon issuance of an execution warrant; (4) ADC will maintain any documentation establishing the qualifications and training of the Medical Team members; (5) ADC will use a clinical concentration of thiopental of 2.5%; (6) ADC will eliminate use of a "false" line; and (7) ADC will not permit Dr. Alan Doerhoff and Medical Team Member #3 to participate in future executions. *See* Pl.'s Ex. 173 at 3 & Attach. A.³

This Court ultimately granted summary judgment in favor of Defendants, finding that the revised protocol did not subject inmates to a substantial risk of serious harm. In doing so, the Court considered the protocol "as written," including the agreed-upon amendments set forth in the parties' joint report. On appeal, Plaintiffs argued there was a substantial risk ADC will implement the protocol in an unconstitutional manner. The

²Although the joint report's summary of the protocol amendments stated that the lines would be "placed only by medically licensed individuals," the exhibit setting forth the amended protocol required only medical training, not a medical license. The joint report also stated that the summary "in no way affects or changes the complete text of Defendants' agreed-upon changes." Pl.'s Ex. 173 at 2-3 & n.2.

³See also Joint Report at 3 & Attach. A, *Dickens v. Brewer*, No. CV-07-1770-PHX-NVW (D. Ariz. Apr. 9, 2009), Doc. 131.

Ninth Circuit disagreed, finding "no evidence that Arizona will fail to follow it in future executions." *Dickens*, 631 F.3d at 1149.

B. Post-Dickens Litigation

At the time of the *Dickens* litigation, Arizona had yet to carry out any executions using the protocol found to be constitutionally adequate in that case. During the past 14 months, ADC has executed five prisoners by lethal injection and preparations were made for a sixth, who obtained a stay. In addition to the instant complaint, three other prisoners initiated federal litigation challenging the legality of ADC's lethal injection procedures.

On the eve of his execution in October 2010, Jeffrey Landrigan filed a § 1983 complaint describing a nationwide shortage of sodium thiopental and alleging that ADC had illegally imported the drug from a non-FDA-approved foreign manufacturer. The district court granted a temporary restraining order to permit further discovery regarding efficacy of the drug. *Landrigan v. Brewer*, No. CV-10-2246-PHX-ROS, 2010 WL 4269559 (D. Ariz. Oct. 25, 2010) (unpublished order). The Supreme Court reversed, noting there was "no evidence in the record to suggest that the drug obtained from a foreign source is unsafe" and "no showing that the drug was unlawfully obtained." *Brewer v. Landrigan*, 131 S. Ct. at 445. During the *Landrigan* litigation, Defendants claimed they legally obtained the drugs to be used in Landrigan's execution.

Subsequently, Arizona prisoner Daniel Cook filed a complaint similar to that of Landrigan, alleging an unconstitutional risk of serious pain from use of non-FDA approved sodium thiopental. The district court dismissed the complaint, finding it failed to sufficiently state a claim for relief. *Cook v. Brewer*, No. CV-10-2454-PHX-RCB, 2011 WL 251470 (D. Ariz. Jan. 26, 2011) (unpublished order). The Ninth Circuit affirmed and noted that the protocol's safeguards would prevent administration of the second and third drugs if the prisoner were not sufficiently anesthetized. *Cook v. Brewer*, 637 F.3d 1002, 1007-08 (9th Cir. 2011). Based on newly discovered evidence surrounding ADC's acquisition of the foreign-manufactured sodium thiopental, Cook refiled a complaint on

the eve of his scheduled execution. The district court summarily dismissed the complaint, and the Ninth Circuit affirmed. *Cook v. Brewer*, No. CV-11-557-PHX-RCB, 2011 WL 1119641 (D. Ariz. Mar. 28, 2011) (unpublished order), *aff'd*, 649 F.3d 915 (9th Cir.), *cert. denied*, 131 S. Ct. 2465 (2011). During the *Cook* litigation, ADC asserted that it had approval from the Drug Enforcement Administration ("DEA") to import the drugs.

On May 24, 2011, the night before the scheduled execution of Arizona prisoner Donald Beaty, ADC notified Beaty and the Arizona Supreme Court that it intended to substitute pentobarbital for sodium thiopental in carrying out Beaty's execution but that the remaining aspects of the lethal injection protocol would be followed. ADC also indicated that the change was necessitated by information it had received that day from the Department of Justice, which indicated ADC's supply of sodium thiopental was imported without compliance with the Controlled Substance Act and could not be used.

Beaty filed a § 1983 complaint, asserting a due process violation from insufficient notice and arguing that a last-minute drug substitution would make it impossible for ADC to comply with the protocol's training requirement, thus subjecting him to a substantial risk of pain and suffering. This Court denied injunctive relief, concluding that the lack of practice with pentobarbital was insufficient to demonstrate a risk of serious harm in light of the protocol's safeguards ensuring the prisoner's anesthetization prior to administration of pancuronium bromide and potassium chloride. *Beaty v. Brewer*, 791 F.Supp.2d 678, 684 (D. Ariz.), *aff'd*, 649 F.3d 1071 (9th Cir.), *cert. denied*, 131 S. Ct. 2929 (2011).

C. Arizona's Protocol

ADC Department Order 710 establishes the procedures for planning and carrying out the execution of a person sentenced to death in Arizona. Department Order 710 states that it "shall be followed as written unless deviation or adjustment is required, as determined by the Director of the Arizona Department of Corrections." The order further states, "This Department Order outlines internal procedures and does not create any legally enforceable rights or obligations." Under section 710.02, subsection 1.1, the

Division Director is responsible for the planning and overall direction of all pre-execution, execution, and post-execution activities. Robert Patton has been ADC's Division Director of Offender Operations ("Division Director") during the past five executions.

Attachment F to Department Order 710 governs the preparation and administration of chemicals when carrying out an execution as well as the composition and duties of the Medical Team.⁴ Any Medical Team member must be a physician, physician's assistant, nurse, emergency medical technician ("EMT"), paramedic, military corpsman, phlebotomist, or other medically trained personnel including those trained in the United States Military. All Medical Team members also must have at least one year of current and relevant professional experience in their assigned duties on the Medical Team. Section 710.04, subsection 1.9.5.1 of Department Order 710 states that the Medical Team shall consist of volunteers whose primary duties include administering IVs as part of their employment. Two Medical Team members ("IV team") will be assigned the responsibility of inserting IV catheters.

Selection of the Medical Team members must include a review of the proposed team member's professional qualifications, training, experience, professional licenses and certifications, criminal history, and personal interview. Licensing and criminal history reviews must be conducted prior to contracting, annually, and upon the issuance of an execution warrant. In addition, IV team members and non-medically licensed team members must participate in a minimum of ten execution rehearsals per year and at least two rehearsals prior to participating in an actual execution. Any documentation

⁴On September 15, 2009, a revised version of Department Order 710, including Attachment F, took effect. On May 12, 2011, ADC revised Department Order 710, but not Attachment F. On June 10, 2011, and again on September 12, 2011, ADC revised Attachment F.

establishing qualifications and training of Medical Team members shall be maintained by the Department Director or designee.

IV team members are to site and insert a primary IV catheter and a backup IV catheter in two separate locations in the prisoner's peripheral veins utilizing appropriate medical procedures. The insertion sites in order of preference are: arms, hands, ankles, and feet, as determined to be medically appropriate by the Medical Team Leader. If in the opinion of the Medical Team Leader it is not possible to reliably place a peripheral line, a Medical Team member may utilize a percutaneous central line in the inmate's femoral vein in the thigh. Upon issuance of a warrant, the inmate shall be physically inspected to predetermine appropriate venous access locations. During an execution, the IV catheter in use shall not be covered and shall remain visible throughout the procedure.

Prior to an execution, an assigned Medical Team member shall be responsible for preparing and labeling the sterile syringes, affixing two labels to each syringe. Once the drugs are prepared and the syringes labeled, the Medical Team Leader is required to attach two complete sets of the syringes to the 3-Gang, 3-Way manifold. A member of the Special Operations Team shall serve as Recorder for each execution and is responsible for completing Form 710-9, Sequence of Chemicals. The Recorder shall document the amount of each chemical administered, confirm that it was administered in the order set forth in the Chemical Chart, and document that the full dose contained in each syringe was administered. The Recorder shall also observe the disposal of all chemicals that were not administered and document the chemical name, syringe number, amount disposed, date disposed, and the time.

D. Medical Team

Two Medical Team members participated in the executions of Jeffrey Landrigan, Eric King, Donald Beaty, Richard Bible, and Thomas West: Medical Team Member IV ("MTM-IV") and Medical Team Leader ("MTL"). ADC Director Charles Ryan has admitted that he conducted the last five executions with full knowledge that at least one

of the Medical Team members did not hold a medical license and did not administer IVs in his current employment.

MTM-IV is currently employed with ADC and has been a correctional officer since 1996. His primary duties do not include administering IVs or preparing drugs as part of his regular employment. MTM-IV served as a corpsman from 1988 until 1996 and was also an EMT while in the military. MTM-IV has no specific recollection of his corpsman or EMT training but does recall learning how to set an IV line. ADC maintained no documentation concerning MTM-IV's qualifications and did not conduct a professional license or criminal history check before selecting him to participate on the Medical Team or before each execution. MTM-IV was charged with DUI in 2008 and paid a fine for reckless driving. He was also arrested for consuming liquor in public in 2000 and for writing a bad check in 1984 or 1985.

Before Landrigan's execution, MTM-IV received a telephone call from his warden and ADC Director Ryan asking whether he knew how to start an IV and whether he would have a problem doing it for an execution. MTM-IV was not asked any other questions. Division Director Patton believed MTM-IV was qualified to be part of the IV team based on his training as a medical corpsman.

MTL recently has been a physician at a clinic where he sees adult patients with medical problems such as diabetes, heart disease, and high blood pressure. His primary duties as a clinic physician do not include placing femoral central lines, administering IVs, or preparing sodium thiopental. For many years, MTL served as an emergency room physician and regularly placed central lines. ADC maintained no documentation concerning MTL's qualifications and did not conduct a professional license or criminal history check before selecting him to participate on the Medical Team or before each execution.

In May 2007, MTL participated as an observer in the lethal injection execution of Robert Comer and was deposed in October 2008 as part of the *Dickens* litigation.

Director Ryan called MTL approximately four to six weeks prior to Landrigan's scheduled execution to solicit his participation; Division Director Patton was not involved in the selection of MTL. MTL went to the prison to practice two days prior to Landrigan's execution.

E. 2010-2011 Executions

Five prisoners were executed by lethal injection between October 2010 and July 2011. At the direction of those responsible for administering these executions, ADC failed to follow certain components of its execution protocol.

Although the protocol requires MTL to attach the syringes to the manifold, for each execution the Special Operations Team undertook this task and MTL only inspected the attachments afterward. In each execution, the Recorder only documented information as dictated by the Special Operations Team Leader and did not specifically record that a "full dose of each syringe was administered." None of the Recorders in the five executions filled out the Chemical Disposition Form, which functioned as the required Sequence of Chemicals form; rather, another member of the Special Operations Team filled out this form based on information from the Recorder's log and a piece of scratch paper kept by this team member during the execution. In the Landrigan and King executions, the Recorders did not observe the disposal of drugs not used in the execution and did not record the disposal of such drugs. In the Beaty, Bible, and West executions, the Recorders did not record the disposal of unused drugs.

Upon issuance of the warrant, no IV team member physically inspected Landrigan, King, or Beaty to predetermine appropriate venous access, as required by the version of Attachment F then in effect. Upon issuance of the warrant for Bible and West, neither ADC's medical staff nor the IV team physically inspected either prisoner to predetermine appropriate venous access, as required by the version of Attachment F then in effect.

In all five executions, MTL placed a femoral central line using an ultrasound, which was usually held by MTM-IV during the procedure. In King, Bible, and West, an

arm peripheral line was also placed. The drugs administered during the executions of Landrigan, King, Beaty, and Bible were administered through the femoral central line. The drugs in the West execution were delivered through the peripheral line. MTL did not survey the veins of Landrigan, King, Beaty, or Bible before placing the femoral central line; in King and Bible, the peripheral line was set by MTM-IV after the femoral central line had been placed. MTL prefers to administer the lethal drugs through a femoral central line because in his opinion "it's more reliable" and "would be less likely to cause discomfort to the inmate." MTL also believes the first chemical, a barbiturate, is "a caustic chemical which is known to cause discomfort when given through an IV."

When setting the femoral central lines in Landrigan and King, MTL punctured the skin at least twice and did not administer additional lidocaine after the first attempt at setting the line was unsuccessful. On the morning of West's execution, Director Ryan asked MTL to use a peripheral line as the primary line in compliance with the expectations of the Court of Appeals expressed in its order denying a stay of that execution. West v. Brewer, 652 F.3d at 1061. MTL did not want to administer the drugs through the peripheral line because he was concerned West would experience discomfort from administration of pentobarbital or thiopental through a peripheral vein. MTL discussed with Director Ryan cases in other states where a peripheral IV had blown out during an execution, causing caustic chemicals to infiltrate subcutaneous tissue.

Throughout the executions of Landrigan, King, Beaty, and Bible, the femoral central line was not visible to the Medical Team members or the Special Operations Team Leader, as required by Attachment F. For all five executions, Warden Carson McWilliams remained in the execution room and could observe both the prisoner and the central line IV site throughout the execution. Although Warden McWilliams was not trained regarding potential problems or complications with the femoral line, he observed whether the line was disconnected and whether there was leakage or some other type of obvious distress with the prisoner.

After administration of the anesthetic drug in each execution, MTL conducted a consciousness check that included checking corneal reflex with a sterile swab, checking the gag reflex in the back of the throat, and squeezing a finger as hard as possible. He also re-checked the primary IV site before the remaining drugs were administered.

F. Importation of Lethal Drugs

On September 21, 2010, a warrant was issued for the execution of Jeffrey Landrigan. On this same date, the Arizona Supreme Court ordered ADC to inform the court by October 1, 2010, whether or not ADC had in its possession the drugs necessary to complete the execution. Because of a domestic shortage, sodium thiopental was not available in September 2010 through ADC's typical pharmaceutical drug source, Minnesota Multistate Contracting Alliance for Pharmacy ("MMCAP"). On September 22, 2010, Director Ryan learned that the Arkansas Department of Corrections had purchased sodium thiopental from Dream Pharma, Ltd., a distributor located in the United Kingdom, and that the shipment had been detained by the Food and Drug Administration ("FDA") the day before. Deputy Director Charles Flanagan was tasked with searching for the chemicals necessary for the Landrigan execution. Between September 23 and 29, 2010, ADC purchased and imported sodium thiopental, potassium chloride, and pancuronium bromide from Dream Pharma.

Deputy Director Flanagan first contacted Dream Pharma on September 22, 2010, and the next day sought the assistance of Dr. Sara Turnbow, MMCAP's senior pharmacist and primary pharmaceutical procurement representative. MMCAP informed ADC it could not order the drugs from Dream Pharma, and Dr. Turnbow advised Flanagan that Dream Pharma's website "leaves something to be desired; it is nothing like the pharmaceutical wholesale distribution websites we use here in the United States." She further noted, "It makes me wonder whether Dream Pharma is reputable and where exactly the medication would be coming from" and that the sodium thiopental offered for sale "pretty likely" was not approved by the FDA. She also warned Flanagan that there is

a "gray' market in the pharmaceutical industry and in this particular instance, you need to be sure that the product is actually thiopental and that it is going to work."

Subsequently, Flanagan instructed an ADC procurement officer and others at ADC that "there may be an issue with FDA approval, so we need to do everything possible to process this and all of the other orders." On September 23, Flanagan sought information from Phoenix FDA investigator David Thomas and the next day hired Arizona Customs Brokers ("ACB") to assist with importation of the lethal injection drugs. Flanagan and Thomas worked with Robert Hornyan, president of ACB, to facilitate and expedite the importation process. Thomas recognized that the three drugs purchased by ADC constituted a non-compliant shipment because although Dream Pharma was registered with the FDA, it was not authorized to import these specific drugs. Thomas notified his supervisor of the impending shipment.

On September 24, Flanagan provided certain "essential directions" to Dream Pharma: (1) Fed Ex was not to use its own customs broker; (2) the Port of Entry "shall be Phoenix, Arizona without fail"; and (3) if Fed Ex shipped the drugs through Memphis on their way to Phoenix, Memphis "shall only be the Port of Unladen, not the Port of Entry." Flanagan required that Phoenix be the Port of Entry "to make sure that the people we spoke to here in Phoenix were the people who cleared [the shipment] because they're the ones who had all of the communications from us."

ACB filled out the U.S. Customs and FDA documentation for ADC's shipments. An import supervisor at ACB made a "clerical error" while inputting the FDA product codes in the computerized customs interface system and mistakenly marked the drugs as products intended for use on non-human animals.

On September 24, Thomas informed Flanagan that the FDA would conduct no inspection of ADC's import shipment. Nonetheless, on September 29, after the shipment was flown into Phoenix after being mistakenly routed from Fed Ex's Memphis facility to its Los Angeles facility, Thomas inspected the shipment "to ensure that the product was

actually—actually what it was purported to be" and determined that the drugs were for human use. Thereafter, Thomas physically released the shipment to ADC.

On September 30, Thomas recommended to Flanagan that he ask ACB's Hornyan about "informal entry." On October 13, Flanagan directed a procurement officer to place a new order for sodium thiopental with Dream Pharma and said the order must be split into three separate shipments, each totaling not more than \$1,500. Three orders were placed the next day, and the procurement officer directed Dream Pharma to ship direct from London to Phoenix. Flanagan also contacted Dream Pharma with directions to prominently mark the shipments as "Informal Entry."

On May 24, 2011, the day before Beaty's scheduled execution, the Department of Justice informed ADC that its supply of sodium thiopental was imported without compliance with the Controlled Substance Act. ADC had failed to fill out Form DEA-236, "Controlled Substances Import/Export Declaration," which is required to import a Schedule 3 controlled substance, such as sodium thiopental. Neither the FDA nor ACB ever informed ADC that Form DEA-236 was necessary for importation of sodium thiopental. In addition, although ADC holds DEA registration certificates permitting ADC to handle Schedule 3 drugs, it was not authorized by the DEA to import controlled substances and ADC did not use a licensed importer sanctioned by the DEA to import the drug. The Department of Justice offered to provide ADC with a list of registered importers or to expeditiously process a request from ADC to become a registered importer.

Dream Pharma is registered, regulated, and inspected by the United Kingdom's regulatory body, the Medicines and Healthcare products Regulatory Agency ("MHRA"), and holds a wholesale dealers license. In all four of its inspections, Dream Pharma was deemed to be in compliance with the requirements of the relevant UK medicines legislation. The MHRA records show that in 2006 Dream Pharma had been involved in trading falsified medicinal product, sourced from the United States and sent to Andorra.

The MHRA determined there was no evidence that Dream Pharma had been aware that the medicinal product was falsified.

V. Findings of Fact and Conclusions of Law

A. Cruel and Unusual Punishment

Plaintiffs contend that Defendants' failure to follow numerous core provisions of ADC's written lethal injection protocol, use of a femoral central line despite availability of a peripheral line, insufficient consciousness checks, willingness to violate federal law in order to carry out executions, and refusal to adopt a one-drug protocol create a substantial, objectively intolerable risk of harm that is likely to cause needless suffering and severe pain during an execution, in violation of the Eighth Amendment.

1. Protocol Deviations

In *Dickens*, the Ninth Circuit recognized that a court must "look beyond the facial constitutionality of an execution protocol when presented with evidence of improper administration." *Dickens*, 631 F.3d at 1146. However, to succeed on an implementation challenge, the prisoner must demonstrate "there is a substantial risk that he will be improperly anesthetized *despite* the Protocol's safeguards." *Id.* "In addition, the evidence must show more than a single accident or mistake or failure to follow the Protocol." *Id.*

Judicial Estoppel

Plaintiffs assert that judicial estoppel bars Defendants from arguing that deviations from ADC's lethal injection protocol lack constitutional significance because Defendants obtained a favorable ruling in *Dickens* by promising protocol changes sufficient to meet the constitutional standard in *Baze* and now argue that these changes are not constitutionally significant.

Judicial estoppel is an equitable doctrine that is applied if (1) "a party's later position is 'clearly inconsistent' with its original position;" (2) "the party has successfully persuaded the court of the earlier position;" and (3) "the inconsistent position would

allow the party to 'derive an unfair advantage or impose an unfair detriment on the opposing party." *United States v. Ibrahim*, 522 F.3d 1003, 1009 (9th Cir. 2008) (quoting *New Hampshire v. Maine*, 532 U.S. 742, 750-51 (2001)). Here, the doctrine of judicial estoppel does not apply because Defendants are not arguing a position contrary to its position in *Dickens*. Although in *Dickens* Defendants reached an agreement with Plaintiffs to modify the protocol in response to Plaintiffs' concerns, the modifications were not made at the direction of the Court. Furthermore, although the Court referenced some of the modifications in determining that ADC's amended protocol satisfied the *Baze* standard, the Court did not conclude that such modifications were constitutionally necessary.

Thus, the doctrine of judicial estoppel does not capture what happened here. Defendants mooted some aspects of Plaintiffs' facial challenge by promising to follow a written protocol that was amended to closely conform to the protocol approved in *Baze*. Whether any of the amendments were constitutionally required was not adjudicated, but Defendants told this Court and the Court of Appeals that they would follow the protocol "as written." And they did not. Nor did they amend the written protocol to conform to what they actually were doing. Instead, they seek shelter in Department Order 710's statement: "These procedures shall be followed as written unless deviation or adjustment is required, as determined by the Director of the Arizona Department of Corrections." This Court did not interpret this single sentence to render the remainder of the written protocol meaningless in *Dickens* and will not do so here. It is expected that the Director will exercise his discretion to deviate from the written protocol when safety, security, or medical issues in individual circumstances require temporary deviation from the written protocol. It is further expected that the written protocol will be amended, in writing, when the Director determines that ADC no longer intends to follow the protocol as currently written. For this litigation, however, the Court will determine whether each of the deviations in practice from the protocol as written present a substantial, objectively

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intolerable risk of harm that is likely to cause needless suffering and severe pain during an execution, in violation of the Eighth Amendment.

Medical Team

As noted by the appellate court in *Dickens*, "it is critical for Arizona to follow the procedures set forth in the Protocol when conducting an execution." *Dickens*, 631 F.3d at 1149. ADC admittedly failed to conduct license and criminal background checks on MTM-IV and MTL, failed to document their qualifications to serve on the IV team, and failed to select Medical Team members with current and relevant professional experience in their assigned duties on the Medical Team. ADC agreed to these protocol requirements during the *Dickens* litigation to minimize the risk of enlisting unqualified personnel on the Medical Team.

Director Ryan's assertion that the failure to conduct license and criminal background checks was inadvertent and Division Director Patton's testimony describing the lack of compliance as an oversight on his part are credible. Ryan testified that he has now assigned the responsibility of conducting license and background checks to ADC's Inspector General, who will document such efforts in a written record. But the Court does not countenance ADC's failure to conduct the promised background checks of its Medical Team members even if such failure was due to inadvertence and oversight.

Baze counsels that "an isolated mishap alone does not give rise to an Eighth Amendment violation, precisely because such an event, while regrettable, does not suggest cruelty, or that the procedure at issue gives rise to a 'substantial risk of serious harm." Baze, 553 U.S. at 50 (quoting Farmer, 511 U.S. at 842). Here, too, ADC's failure to conduct license and background checks does not suggest cruelty or give rise to a substantial risk of serious harm. The risk of serious harm arising from the failure to conduct license and background checks is remote if in fact the Medical Team members have relevant knowledge and experience in setting IVs. See Dickens, 631 F.3d at 1148 (finding no objectively intolerable risk of harm from ADC's failure to interview and

screen an operations team member where no evidence suggested the person was unqualified or that any problems arose from his participation). At the time MTM-IV was asked to participate in the 2010-2011 executions, he had been employed by ADC for 15 years and thus was not a person about whom ADC lacked any background information. According to Division Director Patton, all staff in core positions receive criminal background checks. In addition, MTL was employed as a practicing physician and thus presumably held a valid medical license.

But Arizona's protocol also requires that members of the Medical Team administer IVs as part of their current employment and have at least one year current and regular practice placing such lines. MTM-IV has not administered IVs as a primary duty of employment since leaving the military in 1996. MTL does not administer IVs as a primary duty of his most recent employment, but he had extensive experience as a full-time emergency room physician for years. The team selection plainly did not satisfy written protocol requirements.

The Court finds credible Director Ryan's testimony that obtaining qualified Medical Team members is very difficult due to fears of professional repercussions from participating in executions. Although ADC has medical staff experienced in setting IVs, none are willing to participate in executions. Given the difficulty in locating qualified individuals, and in light of the MTM-IV's and MTL's IV knowledge and experience, Director Ryan's deviation from the written qualification requirements of the protocol was reasonable. It would have been better, however, to have amended the protocol's qualifications to state what is necessary and practicably attainable, rather than what may be merely aspirational.

With respect to MTM-IV, approximately fifteen years had passed since he last placed a peripheral IV while in the military, but he had served as a corpsman for eight years, setting IVs on a weekly basis. He thus had extensive, albeit not recent, experience with peripheral IV lines. Division Director Patton interviewed MTM-IV prior to his

selection, ADC administered a psychological fitness exam, and MTM-IV participated in numerous training exercises before each execution. There also is no evidence that any problems arose during the past five executions due to MTM-IV's participation.

At the time MTL was first contacted by ADC about participating in the Comer execution, he was employed as an emergency room physician and regularly placed central IV lines. Shortly thereafter, he became a clinic physician but continued to work once a month in the emergency department for some months. Director Ryan first spoke with MTL by telephone and accompanied him to Florence for the practice sessions preceding Landrigan's execution in October 2010. Based on his conversations with MTL, Ryan was satisfied that MTL was qualified, and MTL in fact had ample knowledge and experience needed to set a central line.

Thus, ADC's failure to conduct license and criminal background checks on MTM-IV and MTL, document their qualifications to serve on the IV team, and select Medical Team members with current and relevant professional experience in their assigned duties on the Medical Team is neither justified nor condoned. It is, however, explained in the specific circumstances in which it occurred, and it did not impose a substantial risk of serious harm during any of the past five executions. Now that ADC is acutely aware of its oversight, however, it is expected that ADC will either comply with its written protocol in the selection of Medical Team members or amend it to conform to actual practices.

Finally, Arizona's current lethal injection protocol does not require either or both members of the IV team to be licensed medical professionals. The joint report filed in *Dickens* summarized protocol amendments as requiring that IV lines will be placed "only by medically licensed individuals with at least one year current and regular practice placing such lines." However, the joint report expressly stated that the summary "in no way affects or changes the complete text of Defendants' agreed-upon changes," and the attached amended protocol did not require Medical Team members to have medical

licenses. Moreover, although ADC has been fortunate to enlist the services of a licensed physician, the Eighth Amendment does not require the participation of licensed medical professionals in lethal injection executions. *See generally Baze*, 553 U.S. at 64-66 (Alito, J., concurring) (describing execution-related ethical proscriptions adopted by the American Medical Association, the American Nurses Association, and the National Association of Emergency Medical Technicians).

Drug Administration⁵

At the time of the *Dickens* litigation, Arizona's protocol required insertion of a percutaneous central line catheter into the inmate's femoral vein for administration of the lethal chemicals. The *Dickens* plaintiffs challenged this practice, and ADC rendered the issue moot by agreeing to amend the protocol to provide that "the lethal chemicals will, by default, be administered through a peripheral intravenous line." Pl.'s Ex. 173 at 3. In an affidavit filed with the Court, Director Ryan stated: "While I believe that administration of the lethal chemicals through a central line catheter does not place the inmate in substantial risk of imminent pain, the Department is willing to amend the protocol to reflect the administration of the lethal chemicals by peripheral venous access." Pl.'s Ex. 172.

ADC subsequently amended its protocol as follows:

The IV Team members shall site and insert a primary IV catheter and a backup IV catheter in two separate locations in the peripheral veins utilizing appropriate medical procedures. The insertion sites in order of preference shall be: arms, hands, ankles and feet, as determined medically appropriate by the Medical Team Leader. Both primary and backup IV lines will be placed unless in the opinion of the Medical Team Leader it is not possible to reliably place two peripheral lines.

. . . .

⁵Addressed below is Plaintiffs' separate argument that default use of the femoral vein, outside the context of a protocol deviation, constitutes an Eighth Amendment violation.

Should it become necessary to use an alternate means of establishing an IV line because, in the opinion of the Medical Team Leader, it is not possible to reliably place a peripheral line in the inmate, a Medical Team member may utilize a percutaneous central line in the inmate's femoral vein in the thigh if, in the opinion of a qualified Medical Team member, such a line may be reasonably placed.

Pl.'s Ex. 85, Attach. F at 5-6.

Prior to the Landrigan, King, Beaty, and Bible executions, Director Ryan authorized MTL to place a central femoral line as the primary line to administer the lethal drugs. This deviation was authorized without first considering whether peripheral vein IVs could be reliably placed, as ADC had agreed to do during the *Dickens* litigation. Director Ryan believed it was within his discretion under the protocol to permit this change based on MTL's advice that a femoral central line is more reliable.

The Court concludes there is no significant risk of intolerable harm from ADC's failure to follow the written protocol with respect to placement of the IV lines. The evidence adduced at trial shows that use of a femoral central line reduces the risk of pain and suffering in three ways. First, because the femoral vein is larger than a peripheral vein, there is less chance the first drug will extravasate outside the vein and into surrounding tissue. This in turn reduces the risk of both pain from the leakage itself and, more importantly, an inadequate dose of the anesthetic. Second, use of the femoral vein reduces the risk a prisoner will experience a burning sensation from administration of a large dose of toxic chemicals, such as sodium thiopental or pentobarbital, through a small peripheral vein, even in the absence of extravasation. Third, use of the femoral vein allows a larger quantity of the drug being administered to reach the heart faster.

The evidence also showed, however, that placement of a femoral central line requires greater medical expertise than does placement of a peripheral IV line. It is appropriate that the written protocol requires that IV lines be placed in peripheral veins as a default because the medical expertise required for femoral central line placement exceeds that which ADC can expect to find. The inability to locate physicians willing to

participate in an execution is likely the reason most states administering lethal injection use peripheral IV lines by default.

Here, there is no significant risk of intolerable harm from ADC's failure to follow the written protocol with respect to placement of the IV lines because MTL had the training and experience necessary to site and insert a femoral central line. Although Plaintiffs take issue with MTL's technique in setting the central lines in the past five executions, arguing that he did not adhere to an "acceptable standard of care," there were no problems with those lines. Plaintiffs' expert's criticism of MTL's placement of femoral central lines from post-mortem photographs falls short of persuasion to this Court. His criticism of MTL's application of local anesthesia before inserting the central lines is similarly speculative. Even if the local anesthetization was less than ideal, it would not amount to severe pain and could not be cruel and unusual punishment. Plaintiffs have failed to establish "there is a substantial risk that [they] will be improperly anesthetized" if ADC continues to employ default placement of a femoral central line by an individual with appropriate training and experience. *Dickens*, 631 F.3d at 1146.

Director Ryan's decision to deviate from the literal requirements of the protocol with respect to IV placement was neither arbitrary nor made in bad faith. Director Ryan determined, based on MTL's advice, that a femoral central line would be safer and more reliable. He observed MTL put great effort into preparing each inmate for the central line and believed MTL instilled confidence in the inmates. It was not unreasonable for the Director to defer to MTL's training and expertise to ensure that the executions were carried out in the most humane manner possible, with the least amount of discomfort to the prisoners. When, as here, a state is able to enlist the services of a licensed physician to assist in an execution, the decision to deviate from the protocol's preference for peripheral access is reasonable in light of the advantages of using the femoral vein for administration of the lethal chemicals.

Other Deviations

The protocol provides that the IV catheter used to administer the chemicals remain uncovered. However, in Landrigan, King, Beaty, and Bible, the primary IV site was concealed from view of witnesses and execution team members. As evidenced by photographs presented at trial, the femoral central line used in these executions was placed in each prisoner's groin. Leaving this site uncovered likely would have left each prisoner's genitals partially exposed. To preserve the dignity of the inmates and any sensitivities of the witnesses, Director Ryan authorized the placement of a sheet tent over the femoral IV site, preventing the Medical Team members from observing the site from their position in the chemical room.

Director Ryan's decision to block the view of the femoral IV site was both within his discretion and not unreasonable. The safeguard provided by leaving the site uncovered was not arbitrarily abandoned and was satisfied by the presence, as also required by the protocol, of one staff member in the execution room. Warden Carson McWilliams had an unobstructed view of the femoral central line during each execution and testified it was his responsibility to make sure there were no problems with the line during the execution. In *Baze*, the plurality recognized, as a safeguard against maladministration of the first drug, the ability of non-medical staff to watch for signs of IV problems while in the execution chamber. *Baze*, 553 U.S. at 56 (citing expert testimony that "identifying signs of infiltration would be 'very obvious,' even to the average person, because of the swelling that would result"). Additionally, MTL rechecked the IV site when he entered the execution room to conduct the consciousness check after administration of the anesthetic. The Court concludes there is no substantial risk Plaintiffs will not be properly anesthetized if a femoral IV site is not left uncovered for observation by others in addition to the warden.

The protocol also requires the Medical Team to affix two labels to each syringe and attach the syringes to the manifold. During the 2010-2011 executions, Director Ryan

permitted the Special Operations Team to label and attach the syringes to the manifold. In addition, only one label was affixed to each syringe. Director Ryan explained that preparation of the chemicals is a time-consuming process for a two-man medical team and therefore he authorized assistance by the Special Operations Team because it was more expedient. This was not an arbitrary or unreasonable deviation from the written protocol.

The evidence presented at trial established that for each of the past five executions the Medical Team prepared the drugs and the Special Operations Team attached the syringes to the manifold board. MTL supervised the entire process, inspected the manifold after all syringes were attached, and checked the flow of the syringes prior to administration of the lethal chemicals. The manifold and syringe labels were color-coded for each chemical, the syringes were prepared in the order to be attached, and the Medical Team told the Special Operations Team the name of the chemical as each syringe was handed over. A Special Operations Team member then attached the syringe to the manifold and affixed the appropriate label.

The written protocol requires two labels "to ensure a label remains visible." Pl.'s Ex. 85, Attach. F at 3. However, Warden McWilliams explained that each syringe must be screwed into the manifold board and that the label is affixed afterward to ensure the label faces outward and is visible. There is no evidence of syringe mix-ups or other drug error during administration of the chemicals in the past five executions. The Court concludes there is no substantial risk Plaintiffs will not be properly anesthetized if the Special Operations Team continues to label and attach the syringes to the manifold and if ADC affixes only one label to each syringe after it is screwed into the manifold board. *See Baze*, 553 U.S. at 54 (finding no risk of improper administration of first drug from employment of "untrained personnel" in mixing and loading sodium thiopental into syringes).

The written protocol also requires accurate documentation regarding drug administration and disposal of any unused lethal drugs. There is no dispute that ADC's documentation contains minor errors and that ADC failed to document the disposal of chemicals not used in the executions. Nonetheless, the Court finds no substantial risk of maladministration of the anesthetic drug based on these recordkeeping deviations. *See Baze*, 553 U.S. at 50 ("an isolated mishap alone . . . does not suggest cruelty, or that the procedure at issue gives rise to a 'substantial risk of serious harm'").

Conclusion

Plaintiffs point to various failures by ADC to follow the protocol's literal requirements and argue in a conclusory fashion that Defendants have misled the public and created an intolerable risk of harm by disregarding important safeguards. Department Order 710 provides that ADC may deviate from or adjust written execution procedures as required. Although criminal background and professional license checks were omitted through inadvertence, the other deviations were authorized by Director Ryan and were neither unreasonable nor undertaken in bad faith. None of the deviations identified by Plaintiffs create a substantial risk Plaintiffs will not be properly anesthetized.

The responsibility of carrying out an execution is a weighty one. It is thus critically important that ADC adhere to its written protocol to minimize the risk of maladministration. However, the Eighth Amendment does not require inflexibility. Some deviation during implementation may be necessary when determined by the Director, in his discretion, to be in the best interests of carrying out a reliable and humane execution. Nothing presented at trial demonstrates that Director Ryan exercised his discretion in a manner that eliminated critical safeguards or heightened the risk of pain to the prisoners. To the contrary, the Court concludes that Director Ryan is highly cognizant of his responsibilities under the Eighth Amendment and finds genuine the concern expressed by Ryan, Division Director Patton, Warden McWilliams, and MTL to make the prisoner as comfortable as possible during the execution process.

2. Femoral Central Line

Plaintiffs argue that use of a femoral central line as the default method of administering drugs causes unnecessary pain and suffering because MTL failed to adhere to an "acceptable standard of care" when setting the femoral lines in the past five executions and because a peripheral line is a readily available alternative. However, the Eighth Amendment does not require adherence to an "acceptable standard of care" during an execution but rather avoidance of cruel and unusual punishment.

In *Baze*, the Court stated, "Simply because 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." 553 U.S. at 50. In addition, "a condemned prisoner cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative." *Id.* at 51. "To qualify, the alternative procedure must be feasible, readily implemented, and in fact *significantly* reduce a *substantial* risk of *severe* pain." *Id.* at 52 (emphasis added).

At trial Plaintiffs' expert described the process involved in placing a femoral central line. Unlike a peripheral IV, for which the needle and catheter are one unit and are placed just below the surface of the skin into a visible vein, a central line requires use of a larger needle to go through skin, subcutaneous tissue, and muscle to reach the larger femoral vein. An ultrasound is used to locate the vein and a local anesthetic (lidocaine) is applied. Once the needle reaches the vein, a guide wire is threaded into the vein, the needle is removed, the skin next to the wire is incised with a scalpel to enlarge the opening, a dilator slightly larger than the catheter is used to clear a wider path, and then the catheter is placed and secured with two sutures or staples. Unlike a peripheral IV, the placement of a central line requires an advanced level of training and is ordinarily undertaken only by a physician.

At most, the evidence at trial showed that a prisoner may experience some pain and discomfort during placement of a central line if the topical anesthetic is improperly administered before the skin is punctured. However, this pain, as Plaintiffs' own expert conceded, is difficult to quantify. The evidence at trial also demonstrated that none of the prisoners during the past five executions verbally complained of, or appeared to experience, any pain while MTL placed the central line.

Therefore, the Court finds that any pain attendant to placement of a central line, beyond that likely to accompany placement of a peripheral IV line, falls far short of the severity needed to trigger an Eighth Amendment violation. *Cf. Baze*, 553 U.S. at 53 (describing the "constitutionally unacceptable" pain from suffocation and cardiac arrest a prisoner would experience if not fully anesthetized prior to administration of pancuronium bromide and potassium chloride). Accordingly, the Eighth Amendment does not require that ADC administer the drugs through a peripheral vein whenever feasible. To find otherwise would in effect turn this Court into a "board[] of inquiry charged with determining 'best practices' for executions." *Id.* at 51.

3. Consciousness Check

Plaintiffs contend that the consciousness check performed by MTL is insufficient to protect prisoners from the risk of pain from maladministration of the first drug because MTL lacks the understanding necessary to ensure that a prisoner is sedated rather than paralyzed. However, MTL conducts the consciousness check only after administration of the anesthetic, not the paralytic. Thus, Plaintiffs' argument rests on the speculative assumption that the pancuronium bromide will be mistakenly administered before the sodium thiopental or pentobarbital.

As noted by the court in *Dickens*, Arizona's protocol provides even more safeguards against maladministration than the Kentucky protocol upheld in *Baze*, including requirements that the Medical Team monitor the inmate with a microphone and camera and physically confirm unconsciousness. *Dickens*, 631 F.3d at 1146, 1149. For the latter, MTL checks for a corneal reflex with a sterile swab, checks the inmate's gag reflex with a tongue depressor, and squeezes one of the inmate's fingers as hard as

possible. In addition, MTL is a licensed physician whereas the physical inspection in Kentucky is performed by the warden and deputy warden. *Baze*, 553 U.S. at 59. Finally, in rejecting the plaintiff's argument that Kentucky must employ a mechanism for monitoring anesthetic depth of the inmate, the *Baze* Court noted that administration of a proper dose of anesthetic "obviates the concern that a prisoner will not be sufficiently sedated." *Id.*; *see also Dickens*, 631 F.3d at 1149-50. Here, in four of the executions, the anesthetic drug was given through a femoral central line, thus even further reducing the risk of maladministration. Therefore, MTL's consciousness check does not violate Plaintiffs' rights under the Eighth Amendment.

4. Drug Importation

Plaintiffs assert that ADC's illegal importation of drugs from a potentially unsafe "gray market" foreign distributor creates a substantial risk of harm. The facts surrounding ADC's acquisition of drugs from Dream Pharma are undisputed and are summarized above. It is also undisputed that, although ADC still retains possession of these drugs, ADC has agreed not to use them in any execution absent express consent from the DEA. Furthermore, Director Ryan testified at trial that he just learned the DEA is delaying the processing of ADC's application to become an authorized importer until the DEA has possession of the drugs purchased from Dream Pharma. Ryan also stated that he intends to release the drugs to the DEA so that ADC's importer application can go forward. Based on these facts, Plaintiffs' claim that they are at risk of suffering substantial harm if executed using the drugs acquired from Dream Pharma is moot.

Plaintiffs also argue that ADC's actions with respect to the drug importation demonstrate a pattern of dishonesty and bad faith. This, they argue, is relevant to the question of whether ADC can be trusted to carry out its obligations under the protocol, especially in light of protocol deviations during the past five executions. Plaintiffs cast ADC's conduct as devious and reckless, but the Court concludes otherwise.

First, there is no evidence of purposeful concealment. From the outset, ADC notified both the FDA and Customs of their intent to import drugs for use in executions by lethal injection. During the entire importation process, the FDA consumer safety officer kept his chain of command informed of the non-compliant importation and ultimately released the shipment to ADC. Second, ADC took measures to verify the drugs it purchased from Dream Pharma came from a legitimate manufacturer and were not expired. Third, ADC hired a customs broker and relied on that person to navigate the complexities of importing pharmaceuticals. The Court concludes that it was reasonable for ADC to believe the FDA had "approved" the importation, that ADC was unaware of certain DEA requirements for importing sodium thiopental, and that ADC did not intentionally or knowingly import drugs unlawfully. Plaintiffs' contention that ADC cannot be trusted to carry out its protocol based on the importation issue is unpersuasive.

5. One-Drug Protocol

Plaintiffs renew the contention raised in their complaint in *Dickens* that the Eighth Amendment requires Arizona to adopt a one-drug protocol because it is a feasible, readily-implemented alternative. Because Arizona's implementation of its three-drug protocol does not cause a substantial risk of serious pain, the Court disagrees. *See Rhoades v. Reinke*, ____ F.3d ____, No. 11-35940, 2011 WL 5574900, at *5 (9th Cir. Nov. 16, 2011) (observing that state is "free to choose to use the three-drug protocol if it does so in a way that is not likely to cause substantial risk of serious pain"); *Dickens*, 631 F.3d at 1150 (same).

B. Equal Protection

Plaintiffs contend that Defendants' pattern of "recklessly" deviating from the written lethal-injection protocol, combined with their willingness to violate federal law in order to carry out executions, treats each condemned inmate differently and arbitrarily denies Plaintiffs their fundamental right to be free from cruel and unusual punishment, in violation of the Fourteenth Amendment's Equal Protection Clause.

A state practice that interferes with a fundamental right or that discriminates against a suspect class of individuals is subject to strict scrutiny. *Massachusetts Bd. of Ret. v. Murgia*, 427 U.S. 307, 312 (1976). As discussed above, the Court has already determined that ADC has not implemented its lethal injection protocol in a manner that subjects Plaintiffs to a substantial risk of serious harm. Therefore, ADC's actions have not burdened Plaintiffs' fundamental right to be free from cruel and unusual punishment. In addition, Plaintiffs do not allege they belong to a suspect class. Therefore, Plaintiffs are not entitled to strict scrutiny review.

State action that does not burden a fundamental right or target a suspect class will be upheld as long as it is rationally related to a legitimate government interest. *Romer v. Evans*, 517 U.S. 620, 632 (1996). All that is needed to uphold state action under a rational basis test is a finding that there are "plausible," "arguable," or "conceivable" reasons which may have been the basis for the state's action. *Jackson Water Works v. Public Utilities Comm'n of State of Cal.*, 793 F.2d 1090, 1094 (9th Cir. 1986) (quoting *Brandwein v. California Board of Osteopathic Examiners*, 708 F.2d 1466, 1472 (9th Cir. 1983)). ADC has an interest in ensuring executions are carried out in an reliable and humane manner. *See DeYoung v. Owens*, 646 F.3d 1319, 1328 (11th Cir. 2011) ("The State has a legitimate interest in ensuring that its executions occur in a thorough manner with maximum inmate safeguards"). As already found with respect to Plaintiffs' Eighth Amendment claim, ADC had plausible reasons for deviating from the protocol's written directives. The deviations are therefore rationally related to ADC's legitimate interest in ensuring executions are carried out in an reliable and humane manner.

C. Due Process

Plaintiffs contend that Defendants' concealment and misrepresentation of their execution procedures, and willingness to violate federal law in order to carry out executions, constitute egregious official conduct that is constitutionally arbitrary, shocks the conscience, and is unsupported by any reasonable legitimate governmental objective.

Plaintiffs further allege a deprivation of their Fourteenth Amendment procedural guaranty of meaningful access to the courts by Defendants' practice of concealment and misrepresentation of its execution procedures.

To establish a due process challenge to executive action, as a threshold question Plaintiffs must show that Defendants' behavior was "so egregious, so outrageous, that it may fairly be said to shock the contemporary conscience." *Cnty. of Sacramento v. Lewis*, 523 U.S. at 847 n.8 (1998) (discussing abuse of executive action); *Fontana v. Haskin*, 262 F.3d 871, 882 n.7 (9th Cir. 2001); *see also Daniels v. Williams*, 474 U.S. at 328 ("We conclude that the Due Process Clause is simply not implicated by a *negligent* act of an official causing unintended loss of or injury to life, liberty, or property."). Plaintiffs have not shown that Defendants' conduct was egregious, let alone so egregious it shocks the conscience. ADC had plausible reasons for deviating from the written protocol, and none materially altered Arizona's lethal injection process, eliminated critical safeguards, or heightened the risk of pain to Plaintiffs.

To establish that he was denied meaningful access to the courts, a plaintiff must submit evidence showing that he suffered an "actual injury" as a result of the defendant's actions. *See Lewis v. Casey*, 518 U.S. 343, 348-49 (1996). An "actual injury" is "actual prejudice with respect to contemplated or existing litigation, such as the inability to meet a filing deadline or to present a claim." *Id.* at 348. Plaintiffs have made no attempt to demonstrate how the protocol deviations interfered with their ability to challenge implementation of the protocol as constitutionally objectionable. They have thus failed to show any actual injury.

VI. Relief

Plaintiffs seek a permanent injunction that, among other things, directs ADC to (1) conform its lethal injection procedures to Department Order 710 and Attachment F "as written," (2) provide the Court and Plaintiffs documentation sufficient to demonstrate that any planned execution will comply with Department Order 710 and Attachment F "as

1	written" or disclose any deviations, and (3) appoint a judicial monitor to ensure ADC's
2	compliance. Because the evidence before the Court in this litigation does not show a
3	violation of Plaintiffs' constitutional rights, however, the Court does not order the
4	injunctive relief Plaintiffs seek.
5	Based on the foregoing findings of fact and conclusions of law,
6	IT IS ORDERED that the Clerk of Court enter final judgment against Plaintiffs
7	Thomas Paul West, et al., and in favor of Defendants, Janice K. Brewer, et al. The Clerk
8	shall terminate this case.
9	DATED this 21 st day of December, 2011.
10	1/2'01/11/1
11	Neil V. Wake
12	United States District Judge
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