IN THE SUPREME COURT OF TENNESSEE
AT NASHVILLE
October 6, 2016 Session

STEPHEN MICHAEL WEST ET AL. V. DERRICK D. SCHOFIELD ET AL.

Appeal by Permission from the Chancery Court of Davidson County
No. 13-1627-I Claudia C. Bonnyman, Chancellor

No. M2015-01952-SC-RDM-CV – Filed March 28, 2017

The Plaintiffs, each convicted of first degree murder and sentenced to death,[1] brought this declaratory judgment action seeking to have declared facially unconstitutional the written protocol by which the Tennessee Department of Correction carries out an execution by lethal injection. After a lengthy evidentiary hearing, the trial court denied relief. The Plaintiffs appealed and, following a motion by the Defendants,[2] this Court assumed jurisdiction over this matter. The Plaintiffs assert three grounds for relief in their brief to this Court: (1) the protocol is unconstitutional because it creates a substantial risk of serious harm; (2) the protocol is unconstitutional because it creates a substantial risk of a lingering death; and (3) the trial court erred by dismissing their claim that the protocol is unconstitutional because it requires the State to violate federal drug laws. We hold that the trial court did not err in concluding that the Plaintiffs failed to carry their burden of demonstrating that the protocol, on its face, violates the constitutional prohibitions against cruel and unusual punishment. We also hold that the trial court did not err in dismissing the Plaintiffs' claims that the protocol requires violations of federal drug laws. Accordingly, we affirm the trial court's judgment.

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[1] The condemned inmates include the following: Stephen Michael West, David Earl Miller, Nicholas Todd Sutton, Larry McKay, Billy Ray Irick, Abu Ali Abdur'Rahman, Byron Black, Andre Bland, Kevin Burns, Tony Carruthers, Walter Caruthers (since deceased), Gary Cone (since deceased), James Dellinger, Jon Hall, Kennath Henderson, Henry Hodges, Stephen Hugueley, David Ivy, Don Johnson, David Keen, Donald Middlebrooks, Pervis Tyrone Payne, Gerald Lee Powers, William Glen Rogers, Oscar Smith, Andrew Thomas, Charles Wright, Edmund Zagorski, Lee Hall, Nikolaus Johnson, David Jordan, Richard Odom, and Corinio Pruitt (spellings pursuant to pleadings in this case).

[2] The following persons were named defendants in the Plaintiffs' complaint: Derrick D. Schofield, in his official capacity as Tennessee's Commissioner of Correction; Wayne Carpenter, in his official capacity as Warden of Riverbend Maximum Security Institution; Tony Mays, in his official capacity as Deputy Warden of Riverbend Maximum Security Institution; Jason Woodall, in his official capacity as Deputy Commissioner of Operations; Tony Parker, in his official capacity as Assistant Commissioner of Prisons; John Doe Physicians 1–100; John Doe Pharmacists 1–100; John Doe Medical Examiners 1–100; John Doe Medical Personnel 1–100; and John Doe Executioners 1–100.

Tenn. Code Ann. § 16-3-201(d)(1) Appeal by Permission;
Judgment of the Chancery Court Affirmed

JEFFREY S. BIVINS, C.J., delivered the opinion of the Court, in which CORNELIA A. CLARK, SHARON G. LEE, HOLLY KIRBY and ROGER A. PAGE, JJ., joined.

Stephen M. Kissinger, *pro hoc vice*, and Helen Susanne Bales, Assistant Federal Community Defenders, Knoxville, Tennessee, for the appellants, Stephen Michael West, Nicholas Todd Sutton, Larry McKay, and David Earl Miller.

Gene Shiles, Jr., and William J. Rieder, Chattanooga, Tennessee, for the appellant, Billy Ray Irick.

Kelley J. Henry, Supervisory Assistant Federal Public Defender, and Michael J. Passino, Assistant Federal Public Defender, Nashville, Tennessee, for the appellants Edmund Zagorski, Abu-Ali Abdur'Rahman, Charles Wright, Don Johnson, David Keen, Andre Bland, Kevin Burns, James Dellinger, David Ivy, Byron Black, Pervis Tyrone Payne, William Glen Rogers, Oscar Smith, Stephen Hugueley, Kennath Henderson, Jon Hall, Andrew Thomas, Henry Hodges, Gerald Lee Powers, Tony Carruthers, and Donald Middlebrooks.

Kathleen Morrison, Nashville, Tennessee, for the appellants, Lee Hall, Jr., Nikolaus Johnson, David Jordan, Richard Odom, and Corinio Pruitt.

Herbert H. Slatery III, Attorney General and Reporter; Andrée S. Blumstein, Solicitor General; Jennifer L. Smith, Associate Solicitor General; Scott C. Sutherland, Deputy Attorney General; and Linda D. Kirklen, Assistant Attorney General, for the appellees, Derrick Schofield, Wayne Carpenter, Tony Mays, Jason Woodall, Tony Parker, and John Doe Physicians, Pharmacists, Medical Examiners, Medical Personnel, and Executioners.

OPINION

Procedural Background

On September 27, 2013, the Tennessee Department of Correction ("TDOC") adopted a new lethal injection protocol providing that inmates sentenced to death be executed by the injection of a lethal dose of a single drug, pentobarbital ("the Protocol").[3]

[3] The prior lethal injection protocol required the use of three drugs, sodium pentothal, pancuronium bromide, and potassium chloride. See Abdur'Rahman v. Bredesen, 181 S.W.3d 292, 300 (Tenn. 2005).

See Tenn. Code Ann. § 40-23-114(c) (2012) ("The department of correction is authorized to promulgate necessary rules and regulations to facilitate the implementation of [executions by lethal injection]."). The TDOC has since amended the Protocol twice. On September 24, 2014, the Protocol was amended to specify that the lethal injection drug to be used would be compounded pentobarbital rather than manufactured pentobarbital. On June 25, 2015, the Protocol was amended by incorporating a contract between the TDOC and a pharmacist for the provision of the compounded pentobarbital. Our references to the Protocol include these amendments.

On November 20, 2013, Stephen Michael West, Billy Ray Irick, Nicholas Todd Sutton, and David Earl Miller filed a declaratory judgment action in the Chancery Court for Davidson County, Tennessee, against the Defendants with regard to the Protocol. Additional death row inmates later were allowed to intervene and file complaints, eventually resulting in a total of five complaints setting forth essentially identical claims (collectively, and as subsequently amended, "the Complaint"). The Complaint sought a declaration that, for various reasons, the Protocol violates the United States and Tennessee Constitutions.

During the course of the litigation, the parties became embroiled in a discovery dispute, which eventually resulted in this Court's March 10, 2015 decision, West v. Schofield, 460 S.W.3d 113 (Tenn. 2015). In this first interlocutory decision, we, *inter alia*, made clear that the Plaintiffs' declaratory judgment action was limited to challenging the Protocol on its face, as opposed to any as-applied challenges. Id. at 131–32. This Court issued a second interlocutory decision after the Plaintiffs amended their complaint to challenge the constitutionality of a 2014 statute that designated electrocution as an alternative method of execution. See West v. Schofield, 468 S.W.3d 482, 484–85 (Tenn. 2015) (holding that, because the Plaintiffs "are not currently subject to execution by electrocution and will not ever become subject to execution by electrocution unless one of two statutory contingencies occurs in the future, their claims challenging the constitutionality of the 2014 statute and electrocution as a means of execution are not ripe" and reversing the trial court's denial of the Defendants' motion to dismiss these claims). In between these two decisions, the trial court dismissed the Plaintiffs' claims that the Protocol requires the State to violate state and federal drug laws, violates the federal Supremacy Clause, and constitutes a common-law civil conspiracy ("Count V"). Subsequently, the litigation proceeded to trial.

After carefully evaluating the considerable amount of proof adduced by the litigants, the trial court issued a comprehensive order setting forth its findings of fact and conclusions of law. Based upon these findings and conclusions, the trial court denied relief to the Plaintiffs. The Plaintiffs appealed, and we granted the Defendants' motion to accept jurisdiction pursuant to Tennessee Code Annotated section 16-3-201(d)(1) (2009).

We now address the Plaintiffs' contentions that (1) the Protocol is unconstitutional because it creates a substantial risk of serious harm; (2) the Protocol is unconstitutional because it creates a substantial risk of a lingering death; and (3) the trial court erred by dismissing Count V. We begin our analysis with a brief review of salient portions of the Protocol, a document that is 98 pages long, including the three-page contract between Riverbend Maximum Security Institution ("Riverbend") and the pharmacist who is to provide the lethal injection drug ("the Contract").

The Protocol

After receiving a court order setting an execution date, the warden of Riverbend ("the Warden") or his designee is to contact a physician to obtain a physician's order for the lethal injection chemical, pentobarbital, described in the Protocol as "[a]n intermediate-acting barbiturate" and consisting of "[a] lethal dose of 100 ml of a 50 mg/mL solution (a total of 5 grams)" ("the LIC"). The Warden or his designee is to submit the physician's order to the licensed pharmacist pursuant to the Contract for the provision of the LIC. The Contract obligates the pharmacist to (1) provide the LIC; (2) compound the LIC "in a clean, sterile environment"; (3) "[a]rrange for independent testing of the [LIC] for potency, sterility, and endotoxins"; and (4) "[p]erform all services rendered under [the Contract] in accordance [with] professional standards and requirements under state and federal law."

Upon receipt of the LIC, the Warden and another member of the Execution Team, as that group is defined in the Protocol, place the LIC in a small, locked refrigerator. There is only one key to the refrigerator, "issued permanently to the Warden." The Protocol requires all delivered LIC to be "monitored for expiration dates." The Protocol also contains provisions for monitoring the security of the LIC.

As to the preparation of the LIC for administration to a condemned inmate, the Protocol provides as follows:

> 1. Prior to an execution, a minimum of two members of the Execution Team bring the LIC from the armory area [where the refrigerator is kept] directly to the Lethal Injection Room. The amount of chemical and saline is sufficient to make two complete sets of three (3) syringes each. One set is color coded red and the back-up set is color coded blue. The second set, however, need not be drawn into the syringes unless the primary dose proves insufficient for the procedure. Each syringe is numbered in the order it is to be administered and labeled with the name of its contents. Only the Warden and one member of the Execution Team have a key to the Lethal Injection Room.

2. The LIC is drawn into syringes by one member of the Execution Team. Another member of the Execution Team observes and verifies that the procedure has been carried out correctly.

3. Only one syringe is prepared at a time. As they are prepared, the two sets of syringes are positioned in specific holding places in two separate trays color coded red and blue. The syringes are numbered, labeled, and placed in the order they will be administered. One member of the Execution Team will perform this procedure while another member of the Execution Team observes and verifies that the procedure has been carried out correctly. The Chemical Preparation Time Sheet will document the preparation of the LIC.

4. Instructions for preparation of one set of syringes:

a. **Pentobarbital**: The member of the [E]xecution [T]eam draws 50 cc of Pentobarbital (50 mg/mL solution) in each of two syringes, for a total of 5 grams of Pentobarbital.[4] These syringes are labeled **Pentobarbital** with numbers one (1) and two (2), respectively.

b. **Saline**: The member of the Execution Team draws 50 cc of saline solution from the IV bag into a syringe, which is labeled **Saline** with the **number three (3)**.

5. The tray is placed on the workstation in the Lethal Injection Room.

6. **IF NECESSARY THIS PROCESS WILL BE REPEATED FOR THE SECOND SET OF SYRINGES.**

7. When the execution is complete, all syringes and any of the prepared but unused LIC are sent to the Medical Examiner's office with the body.

(Footnote added).

As to the administration of the LIC to the condemned inmate, the Protocol provides that a three-member team of certified emergency medical technicians will conduct the insertion and monitoring of the IV lines by which the LIC will be injected into the condemned inmate. After the successful placement of two IV catheters into the inmate, and after the Warden gives the signal to proceed, the Executioner is given syringe number one by a member of the IV team and connects it to the IV line. The Protocol continues:

[4] A "cc," or cubic centimeter, is the equivalent of one milliliter.

> The Executioner pushes on the plunger of the **#1 syringe (red)** with a slow, steady pressure. Should there be or appear to be swelling around the catheter or if there is resistance to the pressure being applied to the plunger, the Executioner pulls the plunger back. If the extension line [to the IV] starts to fill with blood, the execution may proceed. If there is no blood, the Executioner discontinues with this line. He starts the process on the other line with the back-up set of syringes starting with syringe #1 (blue) . . . .

The Protocol provides that the injection sequence is one syringe containing 50 cc of the LIC, a second syringe containing 50 cc of the LIC, and a third syringe containing 50 cc of a saline solution as a "flush." Two members of the IV team monitor the process throughout while in the Lethal Injection Room.[5] Monitoring of the catheter sites is accomplished via a pan-tilt zoom camera "which displays the exact location of the catheter(s)."

The Protocol continues:

> Following the completion of the lethal injection process, and a five-minute waiting period, the blinds to the official witness room are closed, the closed circuit TV camera is disengaged, and the privacy curtain is closed. The Warden then asks the physician to enter the room to conduct an examination. The physician reports his findings to the Warden or designee.

If the physician pronounces the inmate deceased, the Warden or his designee informs the Commissioner that the sentence has been carried out.

If, however, the physician determines that the inmate is not deceased after the initial dose of LIC has been injected, the physician returns to the waiting area and the Warden instructs the Executioner to repeat the lethal injection procedure with the second set of syringes. After the second dose of LIC is injected, the physician returns and again checks for signs of life.

The Protocol requires that "[t]he Execution Team's Officer in Charge and/or the Assistant Officer in Charge conducts a training session at least once each month at which time all equipment will be tested. The training includes a simulated execution (i.e. IV lines, IV Drip)." The simulated execution uses a saline solution. Additional training is conducted two weeks prior to a scheduled execution. The Executioner receives additional training from a qualified medical professional.

[5] The inmate is strapped to a gurney in the Execution Chamber, adjacent to the Lethal Injection Room.

Relevant Proof

Initially, we note that the trial court allowed the Plaintiffs to adduce proof about a variety of things that might conceivably go wrong in a compounded pentobarbital lethal injection execution as well as proof about the consequences of the Protocol being carried out in accordance with the Protocol's specific provisions. For instance, the Plaintiffs elicited expert proof about the risks associated with the LIC if it was compounded, transported, or stored improperly, i.e., in contravention of the Protocol, including the Contract. However, we view this proof as more appropriate to an as-applied challenge to the Protocol because the Protocol, on its face, does not provide for the improper preparation, transportation, or storage of the LIC. As the United States Court of Appeals for the Sixth Circuit has recognized, "[s]peculations, or even proof, of medical negligence in the past or in the future are not sufficient to render a facially constitutionally sound protocol unconstitutional." Cooey v. Strickland, 589 F.3d 210, 225 (6th Cir. 2009).

Certainly, there are risks of error in every human endeavor. Indeed, as the United States Supreme Court has recognized, "[s]ome risk of pain is inherent in any method of execution—no matter how humane—if only from the prospect of error in following the required procedure." Baze v. Rees, 553 U.S. 35, 47 (2008) (plurality opinion). However, "'accident[s], with no suggestion of malevolence' [do] not give rise to an Eighth Amendment violation." Id. at 50 (citation omitted) (quoting Louisiana ex rel. Francis v. Resweber, 329 U.S. 459, 463 (1947)).

Again, this lawsuit consists of a facial challenge to the Protocol. A facial challenge does not involve a consideration of the Plaintiffs' list of things that *might* go wrong if the Protocol is not followed. Therefore, we need not itemize the substantial amount of proof in the record before us that relates only to potential risks that might occur from a failure to follow the Protocol rather than the proof of risks that are inherent in the Protocol itself. We turn, then, to a brief summary of the relevant proof adduced at trial.

Dr. David A. Lubarsky, Professor and Chair of the Department of Anesthesiology at the University of Miami and board certified in anesthesiology, explained that pentobarbital is a sedative hypnotic drug that, in a sufficient dose, represses the brain's respiratory impulses, causing the body to become oxygen deficient and resulting in the cessation of cardiac activity.

Dr. Lubarsky opined that the 100 milliliter bolus injection called for by the Protocol[6] was "a very large volume for a bolus injection" and that, in a medical setting,

[6] As noted above, one cubic centimeter (one "cc") is the equivalent of one milliliter. The two 50

such volumes were usually injected using a central IV line as opposed to a peripheral IV line as called for in the Protocol. Dr. Lubarsky explained that using a peripheral IV line for injecting such a large volume of fluid increased the risk of the fluid migrating from the vein into the surrounding tissue ("extravasation"). Such extravasation of pentobarbital would be "very painful." Dr. Lubarsky also opined that the risk of the pentobarbital leaching into the tissue surrounding the vein was increased because the injection was being administered by someone other than a medical professional and because the IV line was being monitored by camera rather than by a bedside medical professional. This risk of extravasation was also increased by the extended length of the IV tubing called for in the Protocol. Dr. Lubarsky also stated that the risk of extravasation increased if the LIC contained precipitate, i.e., particulate matter.

Dr. Lubarsky defined death as "the point where you have cardiac function that is irreversibly stopped." He stated that his review of eight pentobarbital executions conducted in Arizona indicated that "it did not appear that all the inmates had ceased cardiac electrical activity when the [electrocardiogram] was turned off and the inmate declared dead." He added, "Actually, there was electrical activity continuing in a couple of cases when the machine was turned off and apparently the inmate was declared dead." According to Dr. Lubarsky, "as long as there's electrical activity [i]t's potentially possible that the heart, again, not only could restart but, specifically in cases of drug overdose, the declaration of death has to be amended, if you will, to go beyond physical signs and symptoms because physicians can be fooled and that is so noted, especially as regards pentobarbital." He stated, "you can't use physical signs and . . . actually you are not allowed to actually declare death or brain death in people who have a massive amount of barbituates coursing through their body because the signs [of heartbeat and breathing] are known to be unreliable." Thus, he was concerned after reviewing execution records from Arizona "that the inmates are being declared dead before they meet the criteria for being declared dead."

On cross-examination, Dr. Lubarsky acknowledged that a properly administered dose of 5 grams of pentobarbital is likely lethal, and he acknowledged that each time this dose has been used in an execution it has resulted in the inmate's death. He also acknowledged that the proper administration of the LIC would result in a quick and complete loss of consciousness. Tellingly, Dr. Lubarsky had this to say during his cross-examination:

> I don't believe that lethal injection can be carried out in a humane fashion because I don't believe that we have the trained people to do the procedures the way they need to be done, nor the quality control, process control, or

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cc injections of the LIC provided for by the Protocol therefore equal 100 milliliters.

> testing of the hypotheses that these methods will work *perfectly* before they're applied to human beings.

(Emphasis added).

Dr. James Hoffman Ruble, Associate Professor at the University of Utah College of Pharmacy, testified about the differences between manufactured and compounded drugs. Manufactured drugs are regulated by the Food and Drug Administration, but compounded drugs are not. Dr. Ruble explained that manufactured pentobarbital "is not available in the United States for purposes of lethal injection."

After a number of people died from the injection of contaminated compounded drugs, the United States Pharmacopeia adopted General Chapter 797 ("USP 797"). USP 797 regulates the compounding of sterile pharmaceutical preparations. The LIC called for in the Protocol is a compounded sterile pharmaceutical preparation. To prepare the LIC, the compounding pharmacist must begin with bulk powdered pentobarbital.[7] This chemical is then mixed with "a liquid vehicle," most likely water. "In addition, compounding pharmacies may be including other inactive ingredients, e.g., propylene glycol, alcohol, hydrochloric acid, sodium hydroxide. Small amounts of these ingredients may be added, for example, to adjust pH, tonicity, and solubility of the finished preparation." According to Dr. Ruble, "The manual combination or mixing of these ingredients, that is, the 'compounding' process, must be carried out under specific environmental conditions, using equipment that is properly calibrated and maintained, and performed by personnel that are highly trained and whose competency and aseptic technique is verified at regular intervals."

Dr. Ruble expressed concern about a provision in the Protocol at the bottom of page 35, a page entitled "Procurement, Storage, Accountability, and Transfer of the Chemical." The provision states, "**NOTE: The chemical manufacturer may change the concentration of the chemical solution without notification. The label should be carefully checked.**" Dr. Ruble testified, "I believe that there is a risk of error in the protocol as a result of that process."

Dr. Ruble opined that the Protocol "fails to provide sufficient safeguards to maintain the stability and potency of compounded pentobarbital and creates a substantial risk that the drug will precipitate or otherwise be unfit for intended use" and that the "[i]njection of a solution which contains precipitated pentobarbital salt would be

[7] According to Dr. Ruble, "pentobarbital [active pharmaceutical ingredient] in bulk powder form is not currently available for sale for purchase by compounding pharmacies in the U.S. for use in compounded pentobarbital preparations." Dr. Ruble did not explain how other states have been able to execute persons with injections of compounded pentobarbital.

expected to be extremely painful upon administration and expected to cause a pulmonary embolism which is known to be extraordinarily painful."

Dr. Ruble's written report was admitted into evidence and contains the following statements regarding his review of the Protocol:

> For purposes of evaluation of the protocol you [the Plaintiffs' attorneys] have asked me to assume that the Tennessee Department of Correction and Pharmacist do only those things that are written down and I am not to read into the protocol actions which are not contained therein. With these assumptions in mind, it is my professional opinion that the Tennessee Lethal Injection protocol fails to provide sufficient safeguards to maintain the stability and potency of compounded pentobarbital and creates a substantial risk that the drug will precipitate or otherwise be unfit for intended use. . . .
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> Problems with the Tennessee Lethal Injection Protocol include:
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> 1) The protocol addresses expiration dates, but does not address beyond use dates. Beyond use dates are not the same as expiration dates.
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> 2) The protocol allows the chemical manufacturer (the pharmacist) to change the chemical concentration of the compounded solution without warning or notice; but fails to provide direction to the individual charged with administering the drug as to how to correct for such a change in concentration. Instead, the individual is specifically instructed to draw up a set amount of solution into a syringe. This provision of the protocol creates a substantial risk of a subpotent amount of drug being administered to the inmate.
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> 3) The protocol requires procurement of the compounded pentobarbital "upon receipt of an order setting an execution date." I am informed that Tennessee law requires that the execution date be no less than 7 days from the date of the order scheduling the execution but that no execution date has been on such a short time frame since the execution of Robert Coe in 2000. The drug is refrigerated, not frozen, according to the protocol. As previously stated, the [beyond use date] for refrigerated pentobarbital is three days and that assumes that the drug is kept refrigerated from manufacture through administration.
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> 4) The protocol permits the drug to be transported at room temperature for an indeterminate amount of time.

5) The protocol provides that the drug will be removed from the refrigerator on Day 3[8] and thus will come to room temperature for an indeterminate amount of time.

6) The protocol does not require temperature logs from the time the drug leaves the compounding pharmacy through the storage and use of the drug. As such, there is no way to determine that the drug has been maintained at the proper temperature.

7) The protocol does not provide for packing and transport of the compounded pentobarbital in accordance with USP 797 standards.

8) The protocol does not provide for training of staff charged with procurement, storage, and administration of compounded pentobarbital as required by USP.

(Footnote added). Dr. Ruble's written report also states generally that a "beyond use date" is defined by USP 797 as "'the date or time after which a [compounded sterile product such as the LIC] shall not be stored or transported'" and that, "[i]f not stored properly, [compounded sterile products] can be damaged and rendered unusable." His report also acknowledges that the USP guidelines on which he relies are aimed at the preparation of pharmaceutical products "for *medicinal use*." (Emphasis added).

On cross-examination, Dr. Ruble acknowledged that Tennessee had adopted USP 797 and that pharmacists licensed by Tennessee must comply with USP 797 when compounding sterile pharmaceutical preparations. He acknowledged that the Contract required the pharmacist to compound the LIC in compliance with USP 797. He also acknowledged that USP 797 imposed handling, transporting, and labeling requirements for the LIC. He agreed that, if the LIC were prepared, handled, transported, and labeled as required, there was a low risk that the LIC would precipitate or be unfit for use, "[a]ssuming that the pharmacist has the adequate experience in compounding and understanding of the regulations." Importantly, he also acknowledged that, in rendering his opinion that the Protocol failed to provide sufficient safeguards, he presumed that USP 797 was not going to be entirely complied with.

Dr. Larry D. Sasich, a faculty member at Idaho State University's Pharmacy Program and a member of the Federal Drug Administration's Advisory Committee, also testified on behalf of the Plaintiffs. He stated that compounding the LIC could result in a dose contaminated with bacteria, fungi, and "cross-contaminants." Dr. Sasich also

[8] The Protocol sets forth a three-day "Death Watch period." On Day 1, among other things, "[t]he condemned inmate is moved to Death Watch status in Building 8." On Day 2, among other things, the inmate "orders his last meal." The execution takes place on Day 3.

explained that pentobarbital "is one of those drugs where the acidity is very critical to insure that it stays in solution because you don't want to—if it doesn't stay in solution, then it clumps." The danger of clumping, or precipitate forming in the compounded pentobarbital solution, was that "[i]t would probably block the blood supply. It would be a catastrophic event. And . . . it could be extremely painful."

Dr. Sasich opined that, based on his review of the Protocol, there was a likelihood that the compounded LIC would be out of date and/or improperly stored, rendering the LIC unsuitable for use. He also opined that the outside testing of the LIC required by the Contract was unreliable.

Dr. Lance B. Becker, the Director of the Center for Resuscitation Science and the Division Chief of Emergency Critical Care within the Department of Emergency Medicine at the University of Pennsylvania, testified that "it would be pretty straightforward and simple to fully revive an individual right after" he was executed according to the Protocol and declared dead by the physician. He maintained that the scientific evidence suggested that half of condemned inmates could be restored to life thirty minutes after being declared dead following an execution according to the Protocol. Dr. Becker explained that CPR and related resuscitative steps would be required to restore the executed inmate to life.

The Plaintiffs also called Debra K. Inglis, the TDOC's general counsel, to testify about the development of the Protocol. Asked about the Protocol's provision that the LIC's "chemical manufacturer may change the concentration of the chemical solution without notification. The label should be carefully checked," Ms. Inglis indicated that this provision was left over from the previous protocol that utilized manufactured drugs. With respect to a compounded LIC, the Protocol required the compounding pharmacist to provide the "specific thing ordered by the physician." Ms. Inglis stated, "That can't be changed." Thus, the provision "really doesn't have a lot of application when we are dealing with a compounded chemical for a particular person in response to a particular physician's order."

The Defendants called Dr. Feng Li, the Acting Medical Examiner for Davidson County, Tennessee, and board certified in clinical and forensic pathology. Dr. Li testified that the LIC called for by the Protocol was 25 to 50 times greater than the regular therapeutic dose of pentobarbital.[9] He stated that the large dose, coupled with the speed of its administration, would cause an individual to "lose consciousness very, very

[9] If the inmate is not declared dead after the first set of syringes is administered, the Protocol calls for the injection of the second set of syringes. According to Dr. Li, the administration of the second set of syringes would equal 50 to 100 times the clinical dose of pentobarbital.

quick[ly]." Dr. Li opined that, after injection of the LIC, the inmate's brain would suffer irreversible damage in a "very short period of time."

Dr. Li's written report was admitted into evidence and includes the following:

> 4. . . . In the execution context, the dose and rate of administration [of the pentobarbital] will have a rapid and profound effect on consciousness, respiratory and circulatory functions. The inmate will quickly lose consciousness and become comatose. Respiration and circulation will be depressed resulting in death. Unconsciousness is a state when the ability to maintain an awareness of self and the environment is lost. In this state, the inmate completely lo[ses] responsiveness to people and other environmental stimuli.
>
> 5. It is my opinion, to a reasonable degree of medical certainty, in the execution context, that the intravenous administration of 5 grams of pentobarbital will render the inmate unconscious within seconds and, for an average human being will result in death within minutes and that the Protocol's contingency provision for the administration of an additional 5 grams of pentobarbital will certainly result in death.
>
> 6. It is my opinion, to a reasonable degree of medical certainty, that there is a negligible risk that a condemned inmate to whom 5 grams of pentobarbital is properly administered pursuant to the Protocol will experience any pain and suffering associated with the execution process.

Dr. Li reviewed the records associated with thirty pentobarbital executions conducted in Georgia, Ohio, and Texas.[10] All of these executions resulted in the inmate being declared dead within thirty minutes of the first injection of pentobarbital. Based on

[10] Three of these executions were conducted by Georgia in December 2014 and January 2015. The records of these executions admitted as exhibits do not indicate the source of the pentobarbital used in these executions. However, the United States Court of Appeals for the Eleventh Circuit has indicated that, as of December 8, 2015, Georgia had executed seven inmates using compounded pentobarbital. See Terrell v. Bryson, 807 F.3d 1276, 1279 (11th Cir. 2015), petition for cert. docketed, (U.S. Dec. 8, 2015).

Ten of these executions were conducted by Ohio between March 2011 and September 2013. The records of these executions admitted as exhibits do not identify the source of the pentobarbital.

Seventeen of these executions were conducted by Texas between October 2013 and March 2015. The records of these executions admitted as exhibits do not identify the source of the pentobarbital. However, the United States Court of Appeals for the Fifth Circuit has stated that "Texas has used compounded pentobarbital to execute thirty-two prisoners since 2013 . . . ." Wood v. Collier, 836 F.3d 534, 537 (5th Cir. 2016).

the records Dr. Li reviewed, only one inmate spoke: Jose Villegas in Texas stated as the first injection began, "It does kind of burn. Good-bye." Mr. Villegas gasped several times and then ceased moving.

The Defendants also called Dr. Roswell Lee Evans, Jr., the dean of, and professor in, the Department of Pharmacy Practice at Auburn University. Dr. Evans stated that he is a pharmacist licensed in Georgia. Dr. Evans opined that the proper intravenous administration of five grams of pentobarbital "would induce a coma and death shortly thereafter." He also opined that it was "unlikely" that the inmate "would experience very much pain and suffering at all that would be beyond a needle stick."

Dr. Evans described the process of compounding pentobarbital in accordance with USP 797:

> [T]he raw product or the active ingredient would be provided, purchased and in a powdered form. That compound would then be weighed according to the volume of the injection that's going to be made and the right concentration.
>
> The drug would be dissolved in sterile water, adjusted for appropriate pH, filtered into a sterile vial, and stored in an appropriate environment. In this case it should be refrigerated.
>
> A sample of that compound, whether it's a duplicate of that compound, in other words, you might make two samples in the same way, some—that compound needs to be tested for sterility, for concentration, for pyrogenicity by outside laboratories.

Dr. Evans explained that a "pyrogen" was "something that would create a toxic reaction."

Dr. Evans also testified that "this is a really simple compound to make," and that "any pharmacist could actually formulate, regardless of whether they are compounding or not, could formulate this drug and create a solution that would be a 50-milligram per milliliter concentration." When asked whether he would be "confident" that the LIC would be equivalent to manufactured pentobarbital if a pharmacist prepared the LIC pursuant to the Contract, including adhering to USP 797, Dr. Evans responded, "In terms of concentration, yes."

Dr. Evans testified that the compounding pharmacist "is actually responsible for the appropriate transportation under appropriate temperature conditions, . . . including all the appropriate labeling for storage."

Dr. Evans reviewed the "execution logs" of seventeen executions that took place in Texas and three executions that took place in Georgia, each of which utilized the single drug, compounded pentobarbital. Nothing in these logs indicated to him that the inmates suffered any pain or suffering.

On cross-examination, Dr. Evans agreed that the Protocol did not require stability testing of the LIC, but he stated that stability would "show up as a result of the potency" testing required.

Trial Court's Ruling

The trial court found that the medical and pharmacy experts who testified agreed "that the injection of five grams of pentobarbital, if compounded properly and if administered properly, will likely cause death with minimal pain and with quick loss of consciousness." The trial court noted that Tennessee's current one-drug Protocol lowered the possibility of pain that was present in the prior three-drug protocol and that, in Baze, the United States Supreme Court had determined that Kentucky's three-drug protocol was, nevertheless, constitutional. The trial court also noted several safeguards set forth in the Protocol that were similar to those examined in Baze, including the Protocol's requirement that the IV lines be established by "emergency medical technicians who are trained to administer venipuncture in IV fluid therapy."

The trial court determined that, "[e]xcept for precipitation that can occur in compounding, [it] must find that if the licensed pharmacist complies with USP 797 as the compounding pharmacist is required to follow a sedative should work as intended." As to the possibility of precipitate forming in the LIC, the trial court found that this potential problem does not cause "a serious risk of severe pain because the [P]rotocol requires the IV team to continuously monitor the injection sites and assure the clear and unobstructed flow of the drug through the long tubing." Additionally, the trial court found that the Defendants "demonstrated that numerous one-drug executions have taken place without discernible painful muscle infiltration from an imperfect IV." The trial court found that "although perfect IV delivery of pentobarbital may not occur following the [P]rotocol, accidents such as those about which Dr. Lubarsky has genuine concern did not occur during the execution of inmates in Ohio, Georgia, and Texas." Indeed, the trial court noted that "[t]he execution of Mr. Villegas of Texas was the only execution among the numerous executions discussed using pentobarbital that raised the spectrum [sic] of visible pain."

The trial court rejected the Plaintiffs' claims about the LIC's possible lack of potency "because there are two lethal doses of the drug if one [dose] is not adequately potent to kill the inmate." The trial court also concluded that "[t]he State is reasonably

relying upon pharmacist direction for transport, storage, and days for use" and that "[r]isk of poor storage conditions is minimal."

Based on these findings, the trial court concluded that it could not find that the possibility of an accident in the compounding or administration of the LIC "causes the [P]rotocol to violate the Eighth Amendment prohibition against cruel and unusual punishment." The trial court also concluded that the Plaintiffs "did not identify an alternative method of execution that is feasible, readily implemented, and which significantly reduces a substantial risk of severe pain; nor did the Plaintiffs demonstrate that no lethal injection protocol can significantly reduce the substantial risk of severe pain."

The trial court also determined that the Plaintiffs "did not carry their burden to establish that Tennessee's use of pentobarbital in its protocol entails a substantial risk of lingering death" because they did not "demonstrate even a minimal risk that inmates will awake" after being declared dead following a lethal injection execution. The trial court also stated that there was "no authority" for it to decide that "death over 30 minutes without pain is a lingering death and a violation of the Eighth Amendment." Finally, the trial court rejected the Plaintiffs' contention that the State imposes cruel and unusual punishment by failing to attempt resuscitation after pronouncing the inmate dead and his sentence served following injection of the LIC.

Analysis

Standard of Review

The resolution of a constitutional claim after an evidentiary hearing "generally presents a mixed question of law and fact." Abdur'Rahman v. Bredesen, 181 S.W.3d 292, 305 (Tenn. 2005). "On appeal, our standard of review is de novo with a presumption of correctness extended only to the lower court's findings of fact." Id.

Eighth Amendment Claims of Cruel and Unusual Punishment

The Eighth Amendment to the United States Constitution prohibits the infliction of "cruel and unusual punishments." U.S. Const. amend. VIII. The Plaintiffs contend that the Protocol violates this provision in two distinct ways: (1) by exposing them to a substantial risk of serious harm and/or (2) by exposing them to a substantial risk of a lingering death.

Risk of Serious Harm

The United States Supreme Court most recently considered an Eighth Amendment claim against a lethal injection protocol in Glossip v. Gross, 135 S. Ct. 2726 (2015).[11] In Glossip, condemned inmates in Oklahoma filed a civil rights action in federal court contending that the three-drug lethal injection protocol used by Oklahoma violated the Eighth Amendment because it created an unacceptable risk of severe pain. Id. at 2731. After an evidentiary hearing, the federal district court denied the inmates' application for a preliminary injunction, and the United States Court of Appeals for the Tenth Circuit affirmed. Id. The Supreme Court granted certiorari and affirmed. Id.

The Glossip Court reiterated and emphasized its earlier holding in Baze v. Rees, 553 U.S. 35 (2008) (plurality opinion), that an Eighth Amendment challenge to a lethal injection protocol based on the infliction of pain requires the complaining inmates to satisfy two prerequisites.[12] First, the inmates must establish that the protocol "presents a risk that is '*sure or very likely* to cause serious illness and needless suffering and give rise to sufficiently *imminent* dangers.'" Glossip, 135 S. Ct. at 2737 (quoting Baze, 553 U.S. at 50) (internal quotation marks omitted). "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.'" Id. (quoting Baze, 553 U.S. at 50) (internal quotation marks omitted). Second, the inmates "must identify an alternative [method of execution] that is 'feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain.'" Id. (quoting Baze, 553 U.S. at 52); see also Baze, 553 U.S. at 61 (stating that an inmate asserting an Eighth Amendment challenge to a state's lethal injection protocol must establish "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"). The Glossip Court affirmed the denial of relief to the inmates because they had failed to satisfy either prerequisite. Glossip, 135 S. Ct. at 2731.

For the same reasons, the Plaintiffs' Eighth Amendment claim in this case that the Protocol exposes them to a substantial risk of severe pain must fail. First, the proof does not preponderate against the trial court's conclusion that the Plaintiffs "did not carry their burden to establish [that] Tennessee's protocol using compounded pentobarbital imposed a substantial risk of serious harm and qualifies as cruel and unusual." The Plaintiffs'

[11] Glossip was filed on June 29, 2015. The trial court in this case began hearing proof on the merits on July 7, 2015.

[12] While the Baze opinion relied upon by the Glossip Court was a plurality opinion, the Glossip decision was a majority opinion. See Glossip, 135 S. Ct. at 2730.

proof on this point consisted of experts opining on the pain that an inmate would feel *if* the LIC infiltrated into the tissue surrounding the inmate's vein. Such an event could occur *if* the LIC had precipitated or *if* the IV line were not successfully placed or maintained or *if* the LIC were injected too quickly. We hold that these mere possibilities are not sufficient to satisfy the Plaintiffs' burden to establish a substantial risk of severe pain. See Baze, 553 U.S. at 62 (holding that "[t]he risks of maladministration [that the petitioners] have suggested—such as improper mixing of chemicals and improper setting of IVs by trained and experienced personnel—cannot remotely be characterized as objectively intolerable") (internal quotation marks omitted); see also, e.g., Wood v. Collier, 836 F.3d 534, 540 n.26 (5th Cir. 2016) (rejecting Eighth Amendment challenge to compounded pentobarbital and noting that "[t]he prisoners aver that, because the drug is produced by compounding pharmacies, it could be contaminated or perhaps be some drug other than pentobarbital. This argument does not close the distance between a mere possibility and a sure or very likely risk that contamination will occur and will bring extreme pain"); Zink v. Lombardi, 783 F.3d 1089, 1101 (8th Cir. 2015) (rejecting Eighth Amendment challenge to execution protocol using compounded pentobarbital because "[t]he prisoners rely on allegations of generalized harms resulting from the use of a compounding pharmacy to produce the pentobarbital and have failed to provide anything more than speculation that the current protocol carries a substantial risk of severe pain"); Terrell v. Bryson, 807 F.3d 1276, 1279 (11th Cir. 2015) (Marcus, J., concurring) (expert's opinion that there was a "real possibility" that compounded pentobarbital could have an undetected dangerous pH level or be invisibly polluted with contaminants and "could result in excruciating pain and suffering upon injection" does not meet the burden of proof imposed by Glossip/Baze) (internal quotation marks omitted), petition for cert. docketed, (U.S. Dec. 8, 2015); Wellons v. Comm'r, Ga. Dep't of Corr., 754 F.3d 1260, 1265 (11th Cir. 2014) (rejecting Eighth Amendment challenge to compounded pentobarbital because "speculation that a drug that has not been approved [by the Food and Drug Administration] will lead to severe pain or suffering 'cannot substitute for evidence that the use of the drug is sure or very likely to cause serious illness and needless suffering'" (quoting Mann v. Palmer, 713 F.3d 1306, 1315 (11th Cir. 2013))); Whitaker v. Livingston, 732 F.3d 465, 468 (5th Cir. 2013) (rejecting Eighth Amendment challenge to compounded pentobarbital when inmates "pointed to only hypothetical possibilities" that the state's choice of pharmacy, its lab results, and its training of its executioners were defective and were unable to "point to *some* hypothetical situation, based on science and fact, showing a likelihood of severe pain"), cert. denied, __ U.S. __, 134 S. Ct. 417 (2013); Whitaker v. Livingston, No. CV H-13-2901, 2016 WL 3199532, at *8 (S.D. Tex. June 6, 2016) (rejecting inmates' Eighth Amendment challenge to execution by compounded pentobarbital and holding that "[n]o allegation that rises above the speculative exists that maladministration—however generated—causes unintended suffering from Texas's use of compounded pentobarbital"); Owens v. Hill, 758 S.E.2d

794, 802–03 (Ga. 2014) (rejecting inmate's attack on compounded pentobarbital because inmate's proof "that there is some risk that a lack of sterility could lead to symptoms that are irrelevant to a person being executed [and] that there is an undetermined risk that a compounding pharmacy acting in its routine role of producing a well-known medication according to the directions in a prescription will fail to produce an effective drug free of visible precipitates" "fall[s] far short of satisfying the legal standard applied under the Eighth Amendment, which involves a showing of a 'substantial risk of serious harm' that is 'sure or very likely to cause serious illness and needless suffering'" (quoting Baze, 553 U.S. at 49–50)).

The Plaintiffs also have failed to carry their burden of proving their claim that the Protocol's lack of specificity exposes them to a substantial risk of severe pain. As our Court of Appeals has recognized, "[a] lethal injection protocol is not constitutionally infirm simply because it does not specify every step of the procedure in explicit detail." Abdur'Rahman v. Bredesen, No. M2003-01767-COA-R3-CV, 2004 WL 2246227, at *17 (Tenn. Ct. App. Oct. 6, 2004) (citing LaGrand v. Lewis, 883 F. Supp. 469, 470 (D. Ariz. 1995), aff'd sub nom. LaGrand v. Stewart, 133 F.3d 1253 (9th Cir. 1998); Sims v. State, 754 So. 2d 657, 668 (Fla. 2000)), aff'd, 181 S.W.3d 292 (Tenn. 2005).

Second, the Plaintiffs failed to demonstrate "a known and available alternative method of execution that entails a lesser risk of pain." Glossip, 135 S. Ct. at 2731. Indeed, the Plaintiffs affirmatively abandoned any effort to satisfy this Eighth Amendment prerequisite. Apparently, the Plaintiffs concluded that they did not need to meet the second Glossip/Baze requirement based upon some language used by this Court in an order filed in a different case involving Plaintiff West, State v. Stephen Michael West, No. M1987-000130-SC-DPE-DD (Tenn. Nov. 29, 2010), which this Court referred to in passing in West v. Schofield, 460 S.W.3d 113, 117 n.2 (Tenn. 2015). In that 2010 order, this Court stated the following:

> In any proceedings on remand, the standards enunciated in the plurality opinion in Baze v. Rees, 553 U.S. 35, 51 (2008) apply. The burden is on Mr. West to prove that the revised protocol creates an "objectively intolerable risk of harm that qualifies as cruel and unusual." Baze v. Rees, 553 U.S. at 52. In order to carry this heavy burden, he must demonstrate that the revised protocol imposes a substantial risk of serious harm, *and* he must *either* propose an alternative method of execution that is feasible, readily implemented, and which significantly reduces the substantial risk of severe pain, Baze v. Rees, 553 U.S. at 52–53, *or demonstrate that no lethal injection protocol can significantly reduce the substantial risk of severe pain.*

State v. Stephen Michael West, No. M1987-000130-SC-DPE-DD, at 3 (Tenn. Nov. 29, 2010) ("the West Order") (final two emphases added). This Court cited to no authority in the West Order for the proposition that a condemned inmate may raise a successful Eighth Amendment challenge by proving that "no lethal injection protocol can significantly reduce the substantial risk of severe pain," and Glossip does not construe Baze in this manner.

This Court may not construe the Eighth Amendment of the United States Constitution in a manner that is contrary to the United States Supreme Court's interpretation. See, e.g., James v. City of Boise, Idaho, __ U.S. __, 136 S. Ct. 685, 686 (2016) ("The Idaho Supreme Court, like any other state or federal court, is bound by this Court's interpretation of federal law."); Marmet Health Care Ctr., Inc. v. Brown, 565 U.S. 530, 531 (2012) ("When this Court has fulfilled its duty to interpret federal law, a state court may not contradict or fail to implement the rule so established."). Glossip, which was filed after the 2010 West order but before the trial in this matter began, made clear the burden of proof that a condemned inmate must satisfy in Eighth Amendment challenges to a lethal injection protocol. The Plaintiffs did not satisfy that burden of proof.[13]

Because the Plaintiffs have failed to satisfy either prerequisite imposed by the Supreme Court for a successful Eighth Amendment challenge to an execution protocol on the basis that the Protocol creates an unacceptable risk of severe pain, we hold that the Plaintiffs are not entitled to relief under the Eighth Amendment on this basis.

Risk of Lingering Death

The Plaintiffs assert that the Protocol also violates the Eighth Amendment because it exposes them to an unacceptable risk of a lingering death. The Plaintiffs contend that this is a free-standing basis for an Eighth Amendment challenge, citing In re Kemmler, 136 U.S. 436, 447 (1890); Estelle v. Gamble, 429 U.S. 97, 102 (1976); Baze, 553 U.S. at 49; and Brown v. Plata, 563 U.S. 493, 510–11 (2011).

In Kemmler, the Supreme Court stated that "[p]unishments are cruel when they involve torture *or a lingering death*; but the punishment of death is not cruel within the meaning of that word as used in the [Eighth Amendment]." 136 U.S. at 447 (emphasis added). The high court reiterated this statement in Baze. See Baze, 553 U.S. at 49. In

[13] Moreover, we agree with the trial court that the Plaintiffs also failed to prove that *no* lethal injection protocol could significantly reduce the substantial risk of severe pain, even if that proof were relevant to their Eighth Amendment challenge.

Gamble, the Supreme Court recognized that a prison's failure to meet an inmate's medical needs might produce a "lingering death" in violation of the Eighth Amendment. Gamble, 429 U.S. at 103. Similarly, in Plata, the Supreme Court recognized that a prison's failure to provide "sustenance" to an inmate could result in a "lingering death" in violation of the Eighth Amendment.[14] Plata, 563 U.S. at 510.

The Plaintiffs contend in their brief to this Court that "[i]nmates executed under [the Protocol] will remain alive from 34 minutes up to over 1 hour after their executioners have finished injecting all required lethal injection drugs." The Plaintiffs base this statement on proof in the record that some of the inmates previously executed in other states with pentobarbital may have continued to experience some electrical activity in their hearts, even after having been declared dead by a physician. However, the Plaintiffs cite to no authority supporting the proposition that an execution requiring up to an hour for death to result is a "lingering death" prohibited by the Eighth Amendment, particularly when the inmate is unconscious for all but the first few seconds of the process.[15] Moreover, the Supreme Court's examples of state conduct that might produce a "lingering death" in violation of the Eighth Amendment—failure to provide medical care and failure to provide food—imply strongly that a "lingering death" is one that takes much longer than an hour and one during which the inmate is consciously suffering.

The Plaintiffs acknowledge in their brief to this Court that their claim that the Protocol violates the Eighth Amendment by causing a "lingering death" "has never before been addressed by any court." But see Walker v. Johnson, 448 F. Supp. 2d 719, 724 (E.D. Va. 2006) (holding that Virginia's then three-drug protocol included sufficient safeguards, including the placing of two working IV lines, the high dosage of the lethal drugs, the manner in which the drugs were prepared and handled, the qualifications of the execution team members, and the repetitive training required of them, to avoid a lingering death). Respectfully, we decline to hold that a lethal injection protocol that causes unconsciousness within seconds violates the Eighth Amendment because it may take an hour or more for the inmate's heart to cease all electrical activity or because there may be some possibility that the inmate could be resuscitated after being declared dead. The intended result of an execution is to render the inmate dead. Therefore, as a result,

[14] Although we question whether the United States Supreme Court would consider a lingering-death claim without requiring the Plaintiffs to demonstrate a known and available alternative method of execution as set forth under Baze and Glossip, we will address the merits of the lingering death argument without deciding this issue.

[15] Indeed, one of the Plaintiffs' attorneys told the trial court that their lingering death claim is one of first impression: "A claim of lingering death has never been brought in any court at any time." The Plaintiffs' attorney explained to the trial court that "[t]he central part of the lingering death claim is [that the executed inmate pronounced dead] can be revived; therefore, he is not dead."

the State is under no obligation to attempt revival efforts. We hold that the Plaintiffs are not entitled to relief on this basis.

Claims under the Tennessee Constitution

Similarly to the federal constitution, the Tennessee Constitution provides that "excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." Tenn. Const. art. I § 16. The Plaintiffs request that this Court hold that the Protocol violates this state constitutional provision.

Preliminarily, we hold that this Court should apply a similar two-prong test as that adopted by the United States Supreme Court in Baze and Glossip to determine if there has been a violation of this provision of the Tennessee Constitution.[16] Accordingly, to prevail on this claim, the Plaintiffs must (1) establish that the Protocol "presents a risk that is '*sure or very likely* to cause serious illness and needless suffering, and give rise to sufficiently *imminent* dangers,'" Glossip, 135 S. Ct. at 2737 (quoting Baze, 553 U.S. at 50) (internal quotation marks omitted), and (2) "identify an alternative [method of execution] that is 'feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain,'" id. (quoting Baze, 553 U.S. at 52).

With regard to the first prong of this test, the Plaintiffs complain that the identity of the pharmacist who will compound the LIC has been withheld from them. They argue that they were "thus prohibited from learning or presenting evidence on the issue of whether the contract with the pharmacist . . . provides adequate protections against the substantial risks of serious harm presented by using a high-risk sterile compound for purposes of executions by lethal injection" and that "[i]t is cruel and unusual punishment under the Tennessee Constitution to put prisoners to death while asking all persons to pay no attention to that man behind the curtain." The Plaintiffs cite no authority for their proposition that the pharmacist's unknown identity creates a substantial risk of severe pain, and we have found none. Therefore, the Plaintiffs have failed to satisfy this first prong. Likewise, for the same reasons set forth above with regard to the federal constitutional claim, we conclude that the Plaintiffs have failed to identify a known and available alternative method of execution. As a result, we hold that the Plaintiffs are not entitled to relief on this basis under the Tennessee Constitution.

The Plaintiffs also ask this Court to declare that the death penalty violates the Tennessee Constitution in light of "evolved standards of decency." We respectfully

[16] We conclude that there is no difference in language between the United States Constitution and the Tennessee Constitution which would warrant application of a different standard under the Tennessee Constitution.

decline that request. The validity of the death penalty as a punishment is not at issue in this declaratory judgment action challenging the method of execution. The Plaintiffs are not entitled to relief on this basis.[17]

We have held that the Protocol, on its face, does not violate the Eighth Amendment. We now also hold that the Protocol, on its face, does not violate Article I, section 16, of the Tennessee Constitution.

Dismissal of Count V

The Plaintiffs devote a significant portion of their briefed argument to this Court challenging the trial court's dismissal of the claims they included in Count V of their complaint. These claims revolve around the Plaintiffs' theory that an execution pursuant to the Protocol violates federal laws regulating the provision and use of certain prescription drugs, specifically the federal Controlled Substances Act, 21 U.S.C. §§ 801–904 (2012) ("the CSA"). Pentobarbital falls within the ambit of the CSA. See 21 C.F.R. § 1308.12(e)(3) (2016) (listing Schedule II controlled substances). The CSA limits physicians to prescribing sodium pentobarbital for legitimate medical purposes. See 21 C.F.R. § 1306.04(a) (2005).

The trial court concluded that the Plaintiffs have no cause of action under the CSA and granted the Defendants' motion for judgment on the pleadings. We review the trial court's ruling de novo with no deference afforded to the trial court. Mortg. Elec. Registration Sys., Inc. v. Ditto, 488 S.W.3d 265, 275 (Tenn. 2015). We construe the dismissed claims in the Plaintiffs' favor, taking their factual allegations as true and giving them the benefit of the inferences that can reasonably be drawn from the pleaded facts. Id. (quoting Harman v. Univ. of Tenn., 353 S.W.3d 734, 736 (Tenn. 2011)).

The Plaintiffs acknowledge in their brief that "in actions brought by death sentenced inmates challenging lethal injection protocols, claims invoking the Controlled Substances Act have not been well received," citing Zink v. Lombardi, 783 F.3d 1089, 1113–14 (8th Cir. 2015) (per curiam) (rejecting condemned inmates' alleged right not to be executed by compounded pentobarbital in violation of CSA because the CSA does not create a private right of action); Durr v. Strickland, No. 2:10-cv-288, 2010 WL 1610592, at *2–3 (S.D. Ohio Apr. 15, 2010) (dismissing complaint that use of sodium thiopental violates the CSA because no private right of action exists under that Act), aff'd, 602 F.3d

[17] This Court repeatedly has upheld the death penalty as permissible under the Tennessee Constitution. See, e.g., State v. Henretta, 325 S.W.3d 112, 143 (Tenn. 2010); State v. Thacker, 164 S.W.3d 208, app. at 254–56 (Tenn. 2005); State v. Black, 815 S.W.2d 166, 187–91 (Tenn. 1991); and cases cited therein.

788, 789 (6th Cir. 2010); Irick v. Ray, No. 3:10-1004, 2010 WL 4810653, at *4 (M.D. Tenn. Nov. 19, 2010) (concluding that "no private right of action exists under . . . the CSA . . . , and therefore, any injury allegedly suffered by the [condemned inmate] cannot be redressed through a declaratory judgment action"), aff'd, 628 F.3d 787 (6th Cir. 2010); West v. Ray, No. CIV 3:10-0778, 2010 WL 3825672, at *4 (M.D. Tenn. Sept. 24, 2010) (dismissing request for declaratory judgment that lethal injection protocol violates the CSA because the CSA does not provide for a private right of action), aff'd, 401 F. App'x 72 (6th Cir. 2010); and Ringo v. Lombardi, No. 09-4095-CV-C-NKL, 2010 WL 3310240, at *2–3 (W.D. Mo. Aug. 19, 2010) (same); see also Jones v. Hobbs, 745 F. Supp. 2d 886, 892–94 (E.D. Ark. 2010) (declining to vacate judgment dismissing complaints that Arkansas lethal injection protocol violated CSA because CSA did not create a private cause of action), aff'd sub nom. Williams v. Hobbs, 658 F.3d 842 (8th Cir. 2011). Indeed, the Plaintiffs have not provided us with a single case in which a condemned inmate has successfully challenged a lethal injection protocol on this basis, and we have found none.

The Plaintiffs contend, nonetheless, that they are asserting a viable Eighth Amendment claim on this basis under Brewer v. Landrigan, 562 U.S. 996 (2010). In Landrigan, the condemned inmate was facing execution pursuant to Arizona's three-drug protocol. Landrigan v. Brewer, No. CV-10-02246-PHX-ROS, 2010 WL 4269559, at *1–2 (D. Ariz. Oct. 25, 2010), aff'd, 625 F.3d 1144 (9th Cir. 2010), and vacated, 562 U.S. 996 (Oct. 26, 2010). The inmate sought a stay of his execution on the grounds that the sodium thiopental, the first drug to be administered pursuant to the protocol, had been "manufactured by a foreign source not approved by the FDA," thereby "creat[ing] a substantial and unnecessary risk of serious harm in violation of his rights under the Eighth Amendment." Id. at *4. The inmate produced an affidavit from a physician indicating that drugs produced by foreign manufacturers "are more likely to contain harmful contaminants." Id. at *10. In spite of the trial court's order requiring Arizona to provide information regarding the drug, Arizona "repeatedly refused to provide any of the underlying factual information necessary for resolution of [the inmate's] claims," even declining to submit "an affidavit stating that the drug was obtained through reputable sources and there was no reason to question that it would function as intended." Id. at *9. The trial court concluded that,

> [w]ithout the assurance of FDA-approval, the Court is left to speculate whether the non-FDA approved drug will perform in the exact same manner as an FDA-approved drug and whether the non-FDA approved drug will cause pain and suffering. This is not a factual issue the Court can resolve by adopting [Arizona's] assurances that sodium thiopental 'is

> simply a chemical compound' and the source of that compound is irrelevant.

Id. at *10. The trial court granted the inmate a temporary restraining order staying his execution "to allow the Court to fully consider his challenge to Arizona's use of sodium thiopental obtained from an unidentified, non-FDA approved source." Id. at *12.

Arizona subsequently sought to have vacated the district court's order. We recite here the full substantive text of the United States Supreme Court's memorandum decision granting the application to vacate and relied upon by the Plaintiffs in support of their Count V claims:

> The application to vacate the order by the district court granting a temporary restraining order, presented to Justice KENNEDY and by him referred to the Court, is granted. There is no evidence in the record to suggest that the drug obtained from a foreign source is unsafe. The district court granted the restraining order because it was left to speculate as to the risk of harm. See Order Granting Motion for a Temporary Restraining Order in Landrigan v. Brewer, 2010 WL 4269559, No. CV-10-02246-PHX-ROS (D. Ariz.), Doc. 21, p. 15 ("[T]he Court is left to speculate . . . whether the non-FDA approved drug will cause pain and suffering."). But speculation cannot substitute for evidence that the use of the drug is "'*sure or very likely* to cause serious illness and needless suffering.'" Baze v. Rees, 553 U.S. 35, 50, 128 S.Ct. 1520, 170 L.Ed.2d 420 (2008) (quoting Helling v. McKinney, 509 U.S. 25, 33, 113 S.Ct. 2475, 125 L.Ed.2d 22 (1993)). *There was no showing that the drug was unlawfully obtained, nor was there an offer of proof to that effect.* The motion to file documents under seal is denied as moot.

Landrigan, 562 U.S. at 996 (second emphasis added). The Plaintiffs claim that this opinion stands for the proposition that an Eighth Amendment claim is made out if there is a showing or an offer of proof that an execution drug is "unlawfully obtained." They further claim that compounded pentobarbital to be used in an execution is necessarily "unlawfully obtained" because the CSA mandates that pentobarbital be used only for a "legitimate medical purpose."

We disagree. In context, it appears to us that the Supreme Court in Landrigan used the term "unlawfully obtained" as referring to drugs obtained from black or grey market sources, the quality of which would obviously be subject to question, or imported from a legitimate source without administrative compliance with the relevant federal

laws, see West v. Brewer, No. CV-11-1409-PHX-NVW, 2011 WL 6724628, at *10 (D. Ariz. Dec. 21, 2011) (reciting the administrative errors the Arizona Department of Corrections made in importing sodium thiopental from a British source, resulting in the Department of Justice informing the Arizona Department of Corrections that its supply of the drug was imported without compliance with the CSA). However, the Arizona inmate in the Landrigan decision had made no showing that the sodium thiopental to be used in his execution had been obtained from such questionable sources, or had been obtained without compliance with the relevant laws. Rather, he had shown merely that Arizona had obtained the drug from a foreign source. Accordingly, the inmate had failed to satisfy Baze's requirement that Arizona's use of the foreign-sourced drug was "sure or very likely to cause serious illness and needless suffering."

In addition to rejecting the Plaintiffs' construction of Landrigan, we reject their attempt to utilize the CSA in this context. First, as indicated above, numerous courts have held that the CSA does not provide a private cause of action which would permit the Plaintiffs to enforce its provisions for their benefit. Second, as the United States Supreme Court has made clear, "the CSA 'repealed most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic in illicit drugs'" and "sought to 'conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'" Gonzales v. Oregon, 546 U.S. 243, 269 (2006) (quoting Gonzales v. Raich, 545 U.S. 1, 12 (2005)). State-sanctioned executions do not fall within the ambit of the legislative purpose embodied in the CSA. Indeed, the federal government allows the use of lethal injections for the execution of federal condemned inmates. See 18 U.S.C. § 3596(a) (providing that a death sentence imposed by a federal court is to be carried out "in the manner prescribed by the law of the State in which the [death] sentence is imposed"). Clearly, the federal government does not consider those of its own executions that are conducted by lethal injection to violate a regulatory scheme for the prescription and use of controlled substances. We are not persuaded that we should construe the CSA in a manner contrary to that of the federal government's interpretation.[18]

The Plaintiffs also alleged in Count V a cause of action under the Supremacy Clause of the federal Constitution. The trial court dismissed this claim as follows:

[18] In Gonzales v. Oregon, the Supreme Court concluded that "the CSA's prescription requirement does not authorize the Attorney General to bar dispensing controlled substances for assisted suicide in the face of a state medical regime permitting such conduct." 546 U.S. at 274–75. Analogously, Tennessee's statute permitting the TDOC to formulate the appropriate method for conducting an execution, including by lethal injection, does not authorize the United States Attorney General to bar the dispensing of compounded pentobarbital to the TDOC for execution purposes or to seek penalties against the doctors or pharmacists who assist the TDOC.

> The Supremacy Clause is not a source of any federal rights. It is a conflict of law provision that declares truth which flows immediately and necessarily from the institutions of a federal government. For this Court to find that there is a private right of action under the Supremacy Clause would substantively change the federal rule established by Congress in the [CSA], and as such, is disapproved.

We agree. See Armstrong v. Exceptional Child Ctr., Inc., 135 S. Ct. 1378, 1383 (2015) (stating that the Supremacy Clause "instructs courts what to do when state and federal law clash"); Chapman v. Houston Welfare Rights Org., 441 U.S. 600, 613 (1979) (recognizing that the Supremacy Clause "is not a source of any federal rights"); see also Michigan Corr. Org. v. Michigan Dep't of Corr., 774 F.3d 895, 906–07 (6th Cir. 2014). The Plaintiffs failed to establish any authority for a cause of action under either the CSA or the Supremacy Clause. Therefore, even reading these claims liberally in favor of the Plaintiffs, the trial court properly dismissed this claim.

Finally, Count V contained a claim that the Defendants engaged in a common-law civil conspiracy to violate the Plaintiffs' rights "by entering into an agreement to take their lives by unlawful means including, but not limited to, the commission of federal felonies in order to obtain and use controlled substances to kill them." These "federal felonies" allegedly arise from the Defendants' alleged violation of the CSA by obtaining the LIC. Because the Plaintiffs have no viable claim that the Defendants will commit any violation of the CSA, the trial court properly dismissed this claim.

In sum, we hold that the trial court did not err in dismissing the Plaintiffs' Count V claims and that the Plaintiffs are not entitled to relief on this basis.

Conclusion

We affirm the trial court's judgment.

JEFFREY S. BIVINS, CHIEF JUSTICE