IN THE CHANCERY COURT OF DAVIDSON COUNTY, TENNESSEE

STEPHEN MICHAEL WEST,	)	
	)	
Plaintiff,	)	
	)	**No. 10-1675-I**
	)	**DEATH PENALTY CASE**
v.	)	
	)	
GAYLE RAY, in her official capacity as Tennessee's Commissioner of Correction, et al	)	**EXECUTION DATE: November 30, 2010**
	)	
	)	
Defendants.	)	

PLAINTIFF'S TRIAL BRIEF IN SUPPORT OF HIS COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

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TABLE OF CONTENTS

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Comes the Plaintiff, Stephen Michael West, and hereby files this trial brief, in anticipation of the proof that will be presented to this Court on November 18 and 19, 2010

I. STATEMENT OF FACTS

The default method of execution prescribed by Tennessee law is lethal injection. TENN. CODE ANN. § 40-23-114. The State of Tennessee, through Defendants, seeks to execute Mr. West on November 30, 2010, by lethal injection using the Current Protocol described *infra*. (Plaintiff's Exhibit 7).

A. The Development of Tennessee's Current Lethal Injection Protocol

Tennessee's current Protocol, "Tennessee's Execution Procedures for Lethal Injection," dated April 30, 2007, (Plaintiff's Exhibit 4)[1] contains the lethal injection protocol to be used for

[1]Citations to "Plaintiff's Exhibit __" refers to the exhibits attached to Plaintiff's Amended Complaint, filed on October 25, 2010. Documents attached to this trial brief will appear on Plaintiff's Exhibit List with a notation that it is "Attachment ___ to trial brief."

Mr. West's execution. It replaced the protocol in effect prior to February 1, 2007, which, on that date, was unilaterally revoked by Governor Bredesen. (Plaintiff's Exhibit 3).

The following facts will be presented to this Court during the scheduled hearing or are stipulated by the parties, are contained within prior sworn testimony of the parties and/or are within the published opinion or public court record of *Harbison v. Little*, 511 F.Supp.2d 872 (M.D.Tenn. 2007), where an evidentiary hearing was held from September 4 through September 7, 2007, to determine the merits of Mr. Harbison's lethal injection claims.[2] "[T]he narrow issue before the [federal] court [wa]s whether the specific lethal injection protocol adopted by the Tennessee Department of Corrections on April 30, 2007, which will be used in the execution of Edward Harbison on September 26, violates the Eighth Amendment's prohibition against cruel and unusual punishments. Simply stated, this court must decide whether the new protocol involves the unnecessary and wanton infliction of pain." *Id.* at 874.

The same facts are equally applicable to the method of execution intended for Mr. West. At the *Harbison* federal court hearing:

> All prospective participants in Harbison's execution testified, as well as most members of the committee appointed by Corrections Commissioner Little pursuant to Governor Bredesen's Executive Order directing the review and adoption of new execution protocols. In addition, numerous expert witnesses testified for both sides, as well as Dr. Michael Higgins, Chief of Anesthesiology at Vanderbilt University Medical Center, appointed by the court as an impartial expert under Rule 706, FEDERAL RULES OF EVIDENCE.

* * *

The Protocol Committee

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[2]All hearing testimony references are to the official transcript page number ("TR ___"). The transcript was filed in Case No. 3:06-01206 as Docket Nos. 138, 139, 142 and 143, with continuous pagination from volume to volume.

On February 1, 2007, Tennessee's Governor, Phillip N. Bredesen, signed Executive Order Number 43,[3] which revoked the current protocols for executions by lethal injection and by electrocution ... , so that Tennessee's Commissioner of Corrections could complete the following activities no later than May 2, 2007: ...initiate immediately a comprehensive review of the manner in which death sentences are administered in Tennessee. ... In completing this review, the Commissioner is directed to utilize all relevant and appropriate resources, including but not limited to scientific and medical experts, legal experts, and Correction professionals, both from within and outside of Tennessee. As a component of this review, the Commissioner is further directed to research and perform an analysis of best practices used by other states in administering the death penalty. ...[T]he Commissioner of Corrections is directed to establish and provide to me new protocols and related written procedures for administering death sentences in Tennessee both by lethal injection and electrocution. In addition, the Commissioner is directed to provide me with a report outlining the results of the review... .(Plaintiff[Harbison] Exhibit 1) Pursuant to this Executive Order, Commissioner of Corrections George Little appointed his executive assistant, Julian Davis, to head a Protocol Committee (TR 402), the members of which would be Deputy Commissioner Gayle Ray, Assistant Commissioner of Corrections Roland Colson, Ricky Bell, Warden of Riverbend Maximum Security Institution ("Riverbend") (where death row is housed and where executions are administered), and General Counsel for the Department of Corrections, Debbie Inglis. (TR 402) Commissioner Little instructed Davis that the committee was to follow the Governor's Executive Order (TR 403); he gave the committee no other instruction. (TR 166)

The committee reviewed materials concerning problems with the three-drug protocol being used in Tennessee, including a recent article where the medical examiner who devised the three-drug protocol in 1977 stated, "It never occurred to me when we set this up that we'd have complete idiots administering the drugs." n2 (Plaintiff[Harbison] Ex. 15 at 3-4) (TR 404-406) Another article, furnished to the committee by Counsel Inglis (Plaintiff's [Harbison] Ex. 16) discusses, among other things, the risk under the three-drug protocol if the inmate is not totally unconscious when the second drug is administered: ...when potassium chloride is used as an additional third chemical, pancuronium bromide serves no real purpose other than to keep the inmate still while potassium chloride kills. Therefore, pancuronium bromide creates the serene appearance that witnesses often describe of a lethal injection execution, because the inmate is totally paralyzed. The calm scene that this paralysis ensures, despite the fact that the inmate may be conscious and suffering, is only one of the many controversial aspects of this drug combination.(Plaintiff[Harbison] Ex. 16, at 13-14) (TR 408) The committee also reviewed Oregon's Death With Dignity Act, which provides

[3](Plaintiff's Exhibit 3).

for euthanasia by a single dose of oral barbituate. (Plaintiff[Harbison] Ex. 17)

FOOTNOTES

n2 The court does not join in this overblown, defensive rhetoric expressed by the promulgator of the three-drug protocol. The court's impression of all of the participants who carry out lethal injection executions in Tennessee is that they are performing their assigned tasks in a somewhat stressful environment in good faith, to the best of their ability, given the limited training they have received and the experience they possess.

Mr. Davis testified that, during its meeting of March 16, 2007, the committee consulted with an anesthesiologist named Dr. Derek Payne. (TR 413) The minutes of that meeting (Plaintiff[Harbison] Ex. 20) reflect that Dr. Payne informed the committee that the second drug "prevents the ability to tell if a person is waking up" and that, if the dose of the first drug is not sufficient, "a person could wake and not be able to breathe." (Plaintiff[Harbison] Ex. at 2) Further, Dr. Payne advised the committee, with regard to mixing the sodium thiopental (the first drug), "You need someone who knows how to show them how to mix--a pharmacist, a nurse, or an anaesthesiologist." (Id. at 3) He also recommended a physical examination before the execution, which would give "the person who will insert the IV an opportunity to determine which veins are good before the execution." (*Id.* at 4)

Mr. Davis further testified that, at its meeting on April 9, 2007, the committee conferred with another anaesthesiologist, Dr. Mark Dershwitz, by telephone. (TR 419) The committee discussed with Dr. Dershwitz a one-drug protocol, using only sodium thiopental (TR 428), and the next day Mr. Davis sent an e-mail to Dr. Payne asking his opinion of this one-drug protocol (TR 428). (Plaintiff[Harbison] Ex. 21) Mr. Davis testified that the minutes of the April 12, 2007 committee meeting (Plaintiff[Harbison] Ex. 4) accurately reflect that Deputy Commissioner Ray stated that, "Dr. Dershwitz suggests the one-drug protocol" and that, at this meeting, the committee was consulting with the physician who functions as Physician A under Tennessee's protocol (the one who pronounces death). (Docket Nos. 428-29) That physician concurred in the use of one drug, sodium thiopental, with a wait of five minutes between each dose of the drug. (TR 429) Mr. Davis stated that the minutes of this meeting accurately reflect that Dr. Dershwitz "recommended that the committee adopt a one-drug protocol which provided for the administration of 5 grams of sodium thiopental, ... and a waiting period of five minutes before the physician came in and confirmed death." Then, "if the inmate were still alive, a second 5 gram dose of sodium thiopental could be administered." (Docket Nos. 430-31)

Following this meeting, Mr. Davis drafted, from the committee's discussions, a

document that summarized the "pros" and "cons" of a one-drug protocol, a two-drug protocol and a three-drug protocol. (TR 449) The one-drug protocol calls for a 5 gram dose of sodium thiopental to be followed by a second such dose of the same drug, "if needed." The advantages and disadvantages of that protocol were listed as follows:

Pros

. Easier to defend by AG Office

. Simplicity

. Peaceful to witnesses

. Similar to animal euthanasia

. All physicians have agreed

. Less chance of error

. Eliminates Pavulon & Potassium Chloride

. No other state does it

. Changes procedures

. Drug procurement tracking

. No downside to vein issue if needed to switch sites

Cons

. No other state does it

. Changes procedures

States that use an EKG/ECG might not want to do this because of potential longer time to pronounce death. No issue with stethoscope.(Plaintiff[Harbison] Ex. 7 at 1)

The pros and cons of the three-drug protocol, using the same three drugs as the old protocol, separated by injections of saline, were as follows:

Pros

. We have the experience and know it works

. No change from the current protocol

. Peaceful to witnesses

. Other states do it

. Successfully defended in state court

Cons

. Most subject to legal challenge

. Most complicated

. Would likely need to add a method of ascertaining consciousness after Sodium Pentothal

. Courts have required additional checks in some states

. Most difficult to account for drugs

. Must refrigerate Pavulon

(*Id.* at 2)

Mr. Davis also testified about language in a document admitted as Plaintiff[Harbison] Exhibit 26 that provided for the sodium thiopental to be inspected every 15 to 20 minutes "to ensure that the first syringe, Pentothal, does not become cloudy, form any particles and remains completely clear." (Plaintiff[Harbison] Ex. 26 at 1) He testified that both doctors stated that this could happen to the sodium thiopental (TR 447)[4] and that, if it became cloudy, "it could possibly clog up the line." (TR 448) He did not remember why this language was taken out of this document, thought it was important, but believes they "worded it a different way." (TR 448)

Gayle Ray, the Deputy Commissioner of Corrections, also a member of the Protocol Committee, confirmed much of Mr. Davis' testimony. She testified that one of the goals of the committee was to come up with a protocol that would assure that "the inmate does not wake up prior to the administration of the

[4]*See also* Attachment A, Hospira, Inc. 2005 Pentothal information, p.6, 7, 8, 9.

potassium chloride." (TR 519) She testified that Dr. Dershwitz told the committee that the one-drug protocol was the way animals are euthanized (TR 529), and Deputy Commissioner Ray was aware that the use of pancuronium was not permitted in Tennessee for animal euthanasia. (TR 530) Dr. Dershwitz also informed the committee that "there was no possibility that 5 grams of sodium pentothal would not cause death." (TR 532) He also told them that if one dose did not work, another dose of sodium thiopental could be given as "a very plausible back-up." (TR 533) She testified that Physician A preferred one dose of sodium thiopental, a wait of five minutes, and then a second dose of sodium thiopental and then check for death. (TR 541) She testified that Dr. Dershwitz "encouraged the committee to write a protocol that states if 5 grams are used, then wait five minutes, then check for circulation, heart beat. If death does not occur, wait another five minutes and check again. If death does not occur, administer 5 more grams." (TR 544) She further testified that the last "con" listed on Mr. Davis' summary for the one-drug protocol did not really apply as a con because Tennessee uses the stethoscope to confirm death and that, therefore "the length of time isn't an issue with the one-drug protocol when a stethoscope is used to declare death." (TR 546-47)

Ms. Ray testified that she and some of the other committee members traveled to Virginia in March as part of their efforts to review "best practices of the other states." (TR 549) They learned that Virginia had revised its three-drug protocol in the following ways: (1) it eliminated the cut-down provision because it was not done anymore; (2) they quit using 5 grams of sodium thiopental because "it slows the ability of the other drugs"; (3) they instituted a medical examination five days before the execution and review the inmate's medical records before the execution; and (4) they assess the inmate's veins a few hours before the execution. (TR 550-51) None of these "best practices" instituted in Virginia under the three-drug protocol were included in Tennessee's revised three-drug protocol, Ray testified. (TR 553-54) Deputy Commissioner Ray further testified that it was the goal of the committee "to find the most humane and professional protocol" (TR 560) and that their recommendation to Commissioner Little was the one-drug protocol. (TR 559) n3 Ray testified that, although the elements that were used in the new three-drug protocol were discussed with the physicians, "... none of the physicians were ever presented with the new protocol [for review]." (TR 566)

FOOTNOTES

n3 Ray disagreed with the testimony of Julian Davis about the danger of sodium thiopental getting cloudy while sitting in the syringes for up to three hours. Whereas Mr. Davis had testified that two physicians had told them of this danger, Ms. Ray testified that this provision of inspecting the syringes every 15 to 20 minutes for cloudiness was removed from what originally had been practiced because either Dr. Payne or Dr. Dershwitz told them that this was unnecessary

because "once pentothal is mixed appropriately, that is dissolved, suspended. Everything is good to go for several days." (TR 563)

Although Julian Davis had testified that Deborah Inglis, as General Counsel to the Department of Corrections, was an "adviser" to the committee, she testified that she was a "part" of the committee. (TR 570) She drafted several versions of the report that was to be delivered to Commissioner Little by the committee. (TR 576) The last draft prepared by her states the committee's thinking that the one-drug protocol "has the advantage of eliminating both of the drugs which if injected into a conscious person would cause pain. It is similar to the humane process used in animal euthanasia." (TR 577) This draft contains the further statement, with regard to the three-drug protocol, that, "Incorporating a method for monitoring anesthetic depth would address allegations that condemned inmates may be conscious and experience pain from the affects of pancuronium bromide and potassium chloride prior to death, but would not be practicable or feasible." (Plaintiff[Harbison] Ex. 40 at 7) (TR 584) After some confusion, Ms. Inglis ultimately testified that the continuous monitoring of anesthetic depth through the use of equipment was what she meant by not being "practicable or feasible." (TR 582) She did confirm that a physician had told the committee practical ways for confirming whether or not the inmate was unconscious during the administering of the drugs (TR 581, 582) and that all of the medical experts had told the committee that it was important for the first drug to render the inmate unconscious before the administration of the second and third drugs. (TR 583) Ms. Inglis testified that "our ultimate recommendation was for the one-chemical protocol." (TR 595)

George Little, the Tennessee Commissioner of Corrections, testified to the appointment of the committee and that he gave them no instructions other than to carry out Executive Order 43. (TR 10-11) He made the "conscious decision not to involve [himself] with the committee's direct deliberations,"...but he was "updated periodically and kept in the loop as they made progress." (TR 29)

After the April 12 committee meeting, Commissioner Little met with the Protocol Committee's Chairman, Julian Davis, and Deputy Commissioner Gayle Ray and discussed the pros and cons as set out in the summary prepared by Mr. Davis (Plaintiff's Ex. 7). (TR 35-36) He was "intrigued" by the one-drug protocol and asked them to find out whether anyone else was using it and what was the "legal landscape" concerning it. (TR 36) The ultimate decision on which protocol would be adopted was his. (TR 39) Commissioner Little testified that he was aware that the pancuronium bromide, the second drug in the three-drug protocol, paralyzes and makes the inmate unable to breathe and that "if felt," the third drug, potassium chloride, would burn as it passed through the veins of the body. (TR 50-51)

Commissioner Little read the report of the Florida Governor's Commission on Administration of Lethal Injection, which was attached in the Appendix of the Final Report on Administration of Death Sentences in Tennessee issued by his department in April of 2007 (Plaintiff[Harbison] Ex. 41). (TR 51) He was aware that that report recommended the development and implementation of procedures to ensure that the condemned inmate is unconscious after administration of the first drug, before initiating the second and third drugs in the three-drug protocol. (TR 51-52) He "felt that the direct observation by the warden and the execution team was sufficient to provide for that." (TR 52) He was aware that Dr. Dershwitz, an anaesthesiologist who made recommendations to the committee, had told them that the people who administer and monitor the administration of the drugs and the IV site "should be people who do this as part of their daily job and that they should be able to troubleshoot and that only comes with experience," but conceded that no one who performs these tasks under the new protocol has this experience or these qualifications. (TR 52-54) He was aware that the Florida Commission recommended that, a week prior to the execution, the inmate be "individually assessed by appropriately trained and qualified persons to determine the most suitable method of venous access concerning the individual circumstances of the condemned inmate," but the new protocol makes no allowance for that assessment. (TR 57-58) He is aware that Dr. Dershwitz has said that the sodium thiopental is a "very pleasant way to go to sleep" and that, properly administered, it causes no pain (TR 64), but he rejected the one-drug protocol, in part, because "there might be more suffering" if it took the person longer to die. (TR 63) n4

FOOTNOTES

n4 No medical testimony supports the proposition that the one-drug protocol causes any suffering or that it prolongs the pronouncement of death.

Commissioner Little at first denied that the Protocol Committee recommended to him the one-drug protocol (TR 17-18). He testified that he was "not aware" that any of the physicians consulted had recommended any one protocol over the other. (TR 32) He testified that he did not receive any information that indicated that the experts believed that one protocol would pose less of a risk of pain than another protocol, "if properly administered." (TR 39) He ultimately admitted that the committee recommended the one-drug protocol. (TR 43) In discussing this recommendation with Steve Elkins, the Governor's Legal Counsel, he told him that he did not want "Tennessee to be at the forefront of making the change from the three-drug protocol to the one drug protocol," that he thought adoption of the one-drug protocol could lead to "political ramifications" and that, if the three-drug protocol were held unconstitutional, Tennessee "could always fall back on the one-drug protocol." (TR 25-26)

> Steve Elkins, the Governor's Legal Counsel, confirmed Commissioner Little's testimony about conversations with Elkins from his own notes. He added that Commissioner Little told him that he had asked the committee "to add a step to the protocol to explicitly go over and check the level of sedation after the first drug," but he is aware that that did not end up in the final protocol. (TR 89-90)
>
> Julian Davis had kept Commissioner Little somewhat informed of the committee's proceedings but, when he presented to Commissioner Little the committee's recommendation of a one-drug protocol, Mr. Davis described the Commissioner's reaction as "a little surprised." (TR 452) The Commissioner stated that the one-drug protocol was "unproven," that more research needed to be done on it, and he rejected the committee's recommendation within a day or two. (TR 453) Davis testified that Commissioner Little had not been present for any of the input from the three physicians that the committee consulted and had not participated in any of the committee's discussions. (TR 454)

Harbison v. Little, 511 F. Supp. 2d at 874-880.

B. Defendants' Execution Protocols

1. Participants

Under the current Protocol, an execution by lethal injection requires the participation of the Commissioner (Defendant Ray), the Deputy Commissioner (Defendant Mills), Assistant Commissioner of Operations (Defendant Hodge), the Warden (Defendant Bell), the Deputy Warden (Defendant John Doe Executioner and/or Defendant John Doe), the Lethal Injection Recorder, the Death Watch Supervisor, a Chaplain, MIS Security Systems Technicians, (Defendants John Does), an Extraction Team (Defendants John Does). A Physician and associate (Defendants John Doe Physician 1 and 2) await in an area designated as a "garage" until after the procedure is completed. (*Harbison*, 511 F.Supp. 2d at 883; TR 120, 478, 495). The IV Team (Defendants John Does Medical Personnel) consists of two emergency medical technicians designated as "IV-A" and "IV-B," and corrections officer "IV-C / Executioner A." (*Harbison,* 511 F.Supp.2d at 882; TR 100-101). The Executioner (Defendant John Doe

Executioner), "Executioner A" mixes the lethal injection drugs and draws them into syringes. (*Harbison*, 511 F.Supp.2d at 897; TR 304-305). The Execution Team (Defendants John Does Executioner) responsible for the lethal injection procedure are corrections officers designated as "Executioner A," "Executioner B," and "Executioner C." (*Harbison*, 511 F.Supp.2d at 887 n11; TR 101). Executioner B injects the syringes into the IV line. (*Harbison*, 511 F.Supp.2d at 882; TR 197). Executioner C hands full syringes to Executioner B, receives empty syringes from Executioner B, and observes the inmate and television monitor. (*Harbison*, 511 F.Supp.2d at 892; TR 217-218; Plaintiff's Exhibit 4 p.2, 63).

2. Three-drug procedure

"Tennessee's new protocol requires the administration of three drugs--sodium thiopental, pancuronium bromide, and potassium chloride--through an intravenous catheter, in a rapid-fire series of eleven large ('bolus') injections. (Defendant[Little] Ex. 8 at 44; TR 958)." *Harbison*, 511 F.Supp.2d at 882. The stated explanation for the use of sodium thiopental is that "[i]t works by depressing the central nervous system, causing sedation or sleep, depending on the dose."[5] (Plaintiff's Exhibit 4 p.35). The stated explanation for the use of pancuronium bromide is that "[i]t will assist in the suppression of breathing and ensure death." (*Id.*) The stated explanation for the use of potassium chloride is that "[a] high dose of potassium chloride administered intravenously causes cardiac arrest and rapid death." (*Id.*)

The Current Protocol prescribes the sequence of events surrounding an execution as follows: On day one, the condemned inmate is moved to Death Watch and designated personnel

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[5]Sedation is defined as, "the calming of mental excitement or abatement of psychological function, especially by the administration of a drug." Random House Webster's Unabridged Dictionary, New York 1998.

check execution-related equipment (closed-circuit TV, telephones, intercom, etc.); on day two, the condemned inmate chooses his last meal, and on day three, the lethal injection chemicals are delivered to the Lethal Injection Room (Plaintiff's Exhibit 4 p.60-62). The Protocol is silent as to whether the inmate is provided medication before the execution and fails to caution about potential contraindications or reduced effectiveness of the sodium thiopental if such medication is given.

The Protocol directs the Execution Team to bring the Lethal Injection Chemicals to the Lethal Injection Room three hours before an execution. Each chemical is prepared by corrections officer "Executioner A" for being drawn into syringes. Two sets of eleven syringes are made. (Plaintiff's Exhibit 4 p.38).

Under the Current Protocol, the drugs to be used are:

a.	Syringes 1-4	sodium thiopental (5 grams: 5000 mg diluted by 200 cc sterile water)
b.	Syringe 5	Saline (50 cc)
c.	Syringes 6 & 7	pancuronium bromide (50 cc each of 100 mg/mL)
d.	Syringe 8	Saline (50 cc)
e.	Syringes 9 & 10	potassium chloride (50 cc each of 100 mg/mL of 2 mEq/mL)
f.	Syringe 11	Saline (50 cc)

(Plaintiff's Exhibit 4 p.38-39).

Under the Protocol, ten boxes of 500 mg sodium thiopental are used to make 5 grams. "Executioner A" injects 20 cc of sterile water into the powder. The powder is dissolved into the water. He repeats the process nine more times, using the remaining nine boxes. He then draws

the solution into four syringes. (Plaintiff's Exhibit 4 p.38). This process is repeated for the second set of syringes (Plaintiff's Exhibit 4 p.38-39).

> Before the injection process begins, catheters are inserted in both of the inmate's arms by two paramedic technicians. n5 (Defendant[Little] Ex. 8 at 41; TR 348, 374) A third "IV team member," who is neither a paramedic nor an emergency medical technician (TR 303, 315), assembles the IV lines, which run from the catheters inserted into the inmate into the separate Executioner's Room. (TR 161).

Harbison, 511 F.Supp.2d at 882.

The protocol does not recommend the shortest possible length for the IV setup. Instead, it indicates that the Solution Sets are 85 inches long but may be purchased longer or shorter; extensions into the first port should be 18 to 24 inches in length; extensions are added to each end of the Solution Set until it reaches the desired length; the ends should reach from head to toe of the condemned inmate (Plaintiff's Exhibit 4 p.40). The IV line is connected to the catheter *via* extensions "added to each end until it reaches the desired length" (Plaintiff's Exhibit 4 p.40). "The line is taped to the port (where the syringe is inserted) in place. The remainder of the line is placed out of the ports in the window" of the Lethal Injection Room and taped in place (Plaintiff's Exhibit 4 p.40).

Preparation of the two IV lines begins with securing the inmate's arms to the gurney. A tourniquet is placed around the limb or body part above the vein to be used. The protocol does not instruct or designate a person to remove the tourniquet. The IV Team inserts a catheter into the right arm, in the anticubital fossa area, and attaches a Solution Set line from a sodium chloride bag (located in the lethal injection room) to the catheter (Plaintiff's Exhibit 4 p.41-42). The protocol contains other locations for insertion of the catheter if it cannot be inserted into a

vein in the antecubital fossa area. The order of the locations is: forearm, wrist, back of the hand, top of the foot, ankle, lower leg, or other locations as determined by the EMTs. (Plaintiff's Exhibit 4 p.41). If "none of these veins are usable, the physician is called into the Execution Chamber to perform a cut-down procedure" (Plaintiff's Exhibit 4 p.41). The protocol alleges that a cut-down is "an ultimate and last option" (Plaintiff's Exhibit 4 p.20) but also allows the Physician to "choose[] a different method to find an IV site" (Plaintiff's Exhibit 4 p.67). The protocol is silent as to the Physician's qualifications, training and experience to perform such functions.

The process is repeated for the left arm (Plaintiff's Exhibit 4 p.41-42). Then the inmate's hands are taped in place, palms up, and the IV Team Members leave the Execution Chamber (Plaintiff's Exhibit 4 p.43).

> Once the lines have been established, the paramedics leave the execution chamber and remain in an area where they cannot see the inmate. (TR 358) The only person with the inmate in the execution chamber at the time the drugs are administered is the warden of Riverbend Maximum Security Institution ("Riverbend"), Ricky Bell. (TR 53, 119)
>
> FOOTNOTES
>
> n5 The second line is a back-up, in case the first fails for some reason.

Harbison, 511 F.Supp.2d at 882.

Under the Protocol, "IV-C / Executioner A" joins Executioner B and Executioner C in the lethal injection room. The Warden gives the signal to proceed and corrections officer "Executioner B" begins to administer the first chemical into a long length of tubing in the Injection Room that feeds through the wall and into the catheter inserted in the inmate. (*Harbison*, 511 F.Supp.2d at 882; TR 196) Executioner B chooses the right or left IV line. No

time frame is given in the protocol regarding administration of the drugs. (Plaintiff's Exhibit 4 p.43). The Executioner inserts and twists each syringe into the extension line, until all eleven syringes are injected (Plaintiff's Exhibit 4 p.43-44). The Current Protocol does not provide for a test of the inmate's level of consciousness after the sodium thiopental is injected.

> A single executioner injects all three drugs (along with intervening saline flushes), which are dispersed in eleven different syringes, into an IV line. (Defendant[Little] Ex. 8 at 44) Each syringe contains 50 cc's of liquid, and the injections into the line must be performed slowly, with even pressure to prevent a number of possible complications. (Id.; TR 213, 644) This action is performed by the executioner in a tiny room ("the Executioner's Room"), which is lit by a small lamp, a television monitor, and some light that is emitted through a heavily-tinted, one-way window from the execution chamber, where the inmate is strapped to a gurney. (Defendant[Little] Ex. 8 at 9; TR 196, 312, 313, 314) A second executioner hands the first executioner each syringe in order, taking from him at the same time the previous syringe, which has been emptied into the IV line. (TR 199, 311) This second executioner is also charged with observing the injection site where the catheter is inserted in the inmate by watching the television monitor and by periodically looking through the one-way glass. (TR 198-99) A third executioner stands in the tiny room, apparently observing the other two. (TR 198)
>
> * * *
>
> The executioner first injects five grams of sodium thiopental, which the protocol states should be dispersed into four syringes at a concentration of 2.5 percent, with 1.25 grams of the drug in each syringe. (Defendant[Little] Ex. 8 at 44) Sodium thiopental is a rapid-acting barbiturate commonly used in anaesthesia. (Id. at 35) The drug suppresses the central nervous system and slows circulation. (Id.) In medicine, sodium thiopental is most often administered in smaller amounts to induce unconsciousness rapidly, while other measures are then used to deepen the level of unconsciousness. (TR 668) Under Tennessee's new protocol, the primary purpose of the sodium thiopental dosage is to render the inmate unconscious before he is injected with the second two drugs. (TR 583)
>
> Following a saline flush, the executioner injects 100 mg of pancuronium bromide into the IV lines. (Defendant[Little] Ex. 8 at 44) Pancuronium bromide is a muscle paralytic. (Id. at 35) The drug completely paralyzes the diaphragm such that the inmate cannot breathe. (TR 50) By itself, 100 mg of pancuronium bromide would be sufficient to kill a person by suffocation. (TR 953) Its stated purpose in the protocol is to "assist in the suppression of breathing and ensure death." (Def. Ex. 8 at 35) An additional purpose extensively discussed at the

> hearing is that pancuronium bromide eliminates the involuntary muscle movements that could be caused by the operation of the third drug, potassium chloride, in the inmate's body. (TR 760-61) Due to the risk that pancuronium bromide could cause an animal to suffocate to death while paralyzed but fully awake, the use of the drug on animals for purposes of euthanasia is prohibited in Tennessee by the Nonlivestock Humane Death Act. Tenn. Code Ann. § 44-17-301, et seq.
>
> Following a second saline flush, the executioner injects the third and final drug, potassium chloride, in the amount of 200 mEq. (Defendant[Little] Ex. 8 at 44) The purpose of this drug is to cause cardiac arrest. (Id.) This is achieved by altering the ph consistency of the inmate's myocardial cells, rendering them incapable of carrying the electric charge that causes the heart to beat. (TR 69-71) One of the plaintiff's expert witnesses testified that 200 mEq might not be sufficient to cause the desired effect, considering that (1) dosages of potassium chloride are most often injected directly into the heart during bypass surgery, and (2) decreased circulation caused by the first drug would reduce the effectiveness of intravenous administration. However, the other expert witnesses who were posed this question testified that 200 mEq should be sufficient to stop the heart. (TR 248-49, 786) All of the expert witnesses agreed that, if conscious, the inmate would suffer a burning pain throughout his body when the potassium chloride is injected, followed by a cardiac arrest. (See TR 249)
>
> After all of the syringes have been injected into the IV line, the executioner injects a final saline flush. (Defendant[Little] Ex. 8 at 44) Then the executioner closes the IV line, opens the drip chamber, and signals to Warden Bell that all eleven syringes have been emptied into the lines. (Id.) Physician A, who has been waiting in a garage, emerges to declare the inmate dead by the use of a stethoscope. (TR 472, 478)

Harbison, 511 F. Supp. 2d at 882-83.

If the inmate's heart is still beating the process is repeated with the second set of syringes. (Plaintiff's Exhibit 4 p.67).

Under the Current Protocol, no one except Defendant Bell is present in the Execution Chamber during the administration of the three chemicals. The Protocol does not require the warden to observe the inmate or the catheter and IV lines. (Plaintiff's Exhibit 4 p.12). No one is at the inmate's side monitoring the IV lines, the IV drip or the inmate's vital signs or level of

consciousness. There is no procedure for ensuring that the anesthetic agent is properly flowing into the prisoner, nor any procedures for ensuring that the prisoner is properly sedated prior to the administration of the second and third chemicals (as would be required in any medical or veterinary procedure before the administration of a neuromuscular blocking agent, such as pancuronium bromide, or the administration of a painful, burning potassium chloride overdose).

II. THE RISK OF PAIN IF THE PLAINTIFF IS NOT PROPERLY ANAESTHETIZED

> It is undisputed that, without proper anaesthesia, the administration of pancuronium bromide and potassium chloride, either separately or in combination, would result in a terrifying, excruciating death. The basic mechanics are that the inmate would first be paralyzed and suffocated (because the paralysis would make him unable to draw breath), then feel a burning pain throughout his body, and then suffer a heart attack while remaining unable to breathe. Dr. David A. Lubarsky, an expert for the plaintiff [Harbison], testified that an insufficiently anaesthetized inmate would suffer unnecessary pain and suffering under the new protocol. Dr. Lubarsky stated that, apart from the effects of the pancuronium bromide, being injected with potassium chloride "is a grotesquely painful experience." Dr. Michael S. Higgins, an impartial expert appointed by the court, testified that administering pancuronium bromide to an individual with consciousness "would be nothing short of terror, as I think most of us can easily imagine with suffocation" and also that "[t]he administration of potassium [chloride] in that large a dose, large concentration through a peripheral IV would be painful." (TR 718) Dr. Bruce Levy, the Medical Examiner for the State of Tennessee and a defense witness, testified that, without sufficient anaesthesia, pancuronium bromide would cause pain because "a conscious person who is paralyzed would be unable to breathe. And suffocating to death would be a most violent form of death." (TR 718) No witness contradicted this testimony.

Harbison, 511 F. Supp. 2d at 882-884.

Unquestionably, this constitutes severe, serious, substantial pain that qualifies as cruel and unusual punishment under Article 1, section 16 of the Tennessee Constitution and the Eighth Amendment of the United States Constitution.

III. ANESTHESIA AND CONSCIOUSNESS WITH SODIUM THIOPENTAL

The Supreme Court's order queried about the level of sodium thiopental "necessary to

ensure that a prisoner is at a level of unconsciousness where he or she will be unable to feel severe pain at the time the second and third drugs are administered." *West v. Ray*, No. M2010-02275-SC-R11-CV, Order, p.3 (Tenn. Nov. 6, 2010).

Anesthesia is the process of blocking the perception of pain and other sensations, creating insensibility to pain. There are differing levels of anesthesia, and thus consciousness. Sodium thiopental (Pentothal) is an ultra-short acting barbiturate wherein the induction of anesthesia occurs quickly, but its effect wears off in a matter of minutes. It is used as an anesthetic in surgery because it enables an anesthesiologist to quickly awaken a patient should complications arise. It is usually used only during the preliminary phase of anesthesia administration and not for general anesthesia. (*See* Attachment A., p.4).

"Individual response to the drug is so varied that there can be no fixed dosage. The drug should be titrated against patient requirements as governed by age, sex and body weight." (Attachment A, p.3). When used for the rapid induction of anesthesia, an initial dose of 210 to 280 mg (3 to 4 mg/kg) is usually required for the average adult (70 kg [or 154 lbs]). *Id.* p.4. When Pentothal is used as the sole anesthetic agent, the desired level of anesthesia can be maintained by injection of small repeated doses or by using a continuous intravenous drip whereby the depth of anesthesia is controlled by adjusting the rate of infusion. *Id.*

The way the human body reacts to various stimuli differs depending upon the level of anesthesia. The following chart illustrates the serum thiopental levels required to produce a 50/50 chance that a person will have the corresponding state of unconsciousness:

15.6 mg/L ± 1.1: Loss of purposeful movement in response to verbal stimulation

30.3 mg/L ± 3.8: Loss of purposeful movement in response to tetanic nerve stimulation

39.8 mg/L ± 3.3: Loss of purposeful movement in response to trapezius muscle squeeze

50.7 mg/L ± 2.9: Loss of movement in response to larangoscopy

78.8 mg/L ± 7.4: Loss of movement in response to intubation

(Plaintiff's Exhibit 31, Orlando R. Hung, M.D., John R. Varvel, M.D.,Steven M. Shafer, M.D., and Donald R. Stanski, M.D., *Thiopental Pharmacodynamics*, 77 ANESTHESIOLOGY at 240 (1992)).

Upon administration of sodium thiopental, EEG brain activity peaks at 13.3 mg/L, after which it drops back to normal activity at 31.2 mg/l, and zero brain waves per second occurs only with serum levels above 50 mg/L.

IV. ALL ASPECTS OF DR. LUBARSKY'S OPINION THAT MR. WEST WILL BE CONSCIOUS DURING HIS EXECUTION IS FULLY SUPPORTED BY WELL-ESTABLISHED SCIENCE

The only way to address whether sodium thiopental, as used in Tennessee's Protocol, does not ensure unconsciousness so as to create an objectively intolerable risk of severe pain during the execution process[6] is to look to the science of anesthesiology and the pharmacokinetics and pharmacodynamics of sodium thiopental,[7] as well as anecdotal evidence from lethal injection executions. With respect to the science, established scientific principles as well as the study of available data are required to determine the efficacy of the use of sodium thiopental as directed by Tennessee's Protocol. The available, testable evidence consists of

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[6]This is the second enumerated question contained in *West v. Ray*, No. M2010-02275-SC-R11-CV, order (Nov. 6, 2010),

[7]"Pharmacokinetics may be simply defined as what the body does to the drug, as opposed to pharmacodynamics which may be defined as what the drug does to the body." Leslie Z. Benet, *Pharmacokinetics: Basic Principles and Its Use as a Tool in Drug Metabolism*, p.199 in: *Drug Metabolism and Drug Toxicity*, JR Mitchell and MG Horning (eds.), Raven Press, New York (1984).

blood drawn during state-conducted autopsies of executed inmates; specifically Robert Coe, Phillip Workman and Steve Henley.

A. Dr. Lubarsky's opinion regarding whether Coe, Workman, and Henley were suffocated and in extreme pain while they were conscious is based upon well-established scientific principles.

As an initial point, the *Lancet* study[8] meets all of the criteria governing the admission of expert opinion as set forth in *McDaniel v. CSX Transp.*, 955 S.W.2d 257, 264-265 (Tenn. 1997), as well as the federal criteria governing the admission of expert opinion contained in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The scientific evidence revealed by the *Lancet* study has been tested, it has been subjected to peer review and been published, a potential rate of error is known, the evidence is generally accepted in the scientific community as no similar evidence of equal caliber has disputed it, and the research was conducted independent of litigation.

The science behind the *Lancet* study in which Dr. Lubarsky participated is far from controversial. As discussed further below, the serum sodium thiopental levels necessary to render a person unconscious have been established through peer-reviewed studies in which researchers directly monitored thiopental levels in human subjects while simultaneously testing the subjects to determine their state of consciousness.[9] Similarly, Dr. Lubarsky and his fellow

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[8]Plaintiff's Exhibit 35, *Inadequate anesthesia in lethal injection for execution*, 365 THE LANCET 1412 (2005), referred to herein as "the *Lancet* study."

[9]*Inadequate anesthesia in lethal injection for execution*, 365 THE LANCET 1412-14, at fn 7 (2005), *citing* Hung, OR, Varvell, JR,Shafer SI, Stanski DR, *Thiopental Pharmacodynamics II, Quantitation of Clinical and Electroencephalographic Depth of Anesthesia*, 77 ANESTHESIOLOGY 237-44 (1992).

researchers supported their conclusions with well-accepted scientific studies.[10] The conclusions were that neither the thiopental levels[11] nor the potassium chloride[12] levels reported from the autopsies of condemned inmates were sufficient to conclude that either drug was the agent causing condemned inmates' deaths. Not surprisingly, no one has ever questioned the science underlying either of Dr. Lubarsky's published medical articles. Indeed, both articles were peer-reviewed by appropriate experts in the field before publication. The challenges, rather, came in the form of criticizing the authors for relying on data which the critics deemed incomplete and therefore unreliable.[13]

In Mr. West's case, however, Dr. Lubarsky does not rely on data from the *Lancet* study. Instead Dr. Lubarsky's opinion relies upon its unchallenged scientific basis, to wit: (1) the time honored and non-controversial studies regarding the relationship between serum sodium

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[10]Zimmers TA, Sheldon JP, Lubarsky DA, Lopes-Munoz F, Waterman L, Weisman R, Koniaris LG: *Lethal Injection for Execution: Chemical Asphyxiation?* 4 PLOS MEDICINE 1-8 (2007).

[11]*Supra* note 10 at fn 20, *citing* Abbott Laboratories, *Pentothal for injection, USP (Thiopental Sodium)* Reference 06- R10 (Nov. 1993); *supra* note 3 at fn 21, *citing* Werner HW, Pratt TW, Tatum AL, *A comparative study of several ultrashort-acting barbiturates, nembutal, and tribromethanol.* 60 J. PHARMACOL. EXP. THER. 189-97(1937); *supra* note 3 at fn 22, *citing* Robinson MH, *The effect of different injection rates upon the AD50, LD50 and anesthetic duration of pentothal in mice, and strength-duration curves of depression, 85* J. PHARMACOL. EXP. THER. 176-91 (1945).

[12]*Supra* note 10 at fn 28, *citing* Wetherton AR, Corey TS, Buchino JJ, Burrows AM, *Fatal intravenous injection of potassium in hospitalized patients,* 24 AM. J. FORENSIC MED. PATHOL. 128-31 (2003).

[13]Because of this criticism, some of the members of the Court in *Baze*, stated that the *Lancet* study did not, in and of itself, meet a Plaintiff's Eighth Amendment burden of establishing a substantial risk of unnecessary pain, an observation in which the Tennessee Supreme Court joined. Slip Opinion, November 6, 2010, *West v. Ray et al.*, Case No. M2010-02275-SCR11-CV at page 3, fn. 1.

thiopental levels and consciousness in human beings; (2) the only peer-reviewed study of the relationship between post-mortem and ante-mortem sodium thiopental levels showing post-mortem serum thiopental levels to approximate ante-mortem serum thiopental levels; (3) the uncontested scientific fact that post-mortem thiopental levels in samples obtained from the heart and/or central vessels are up to twice as high as pre-mortem thiopental levels; and, (4) published studies on the bolus injection of thiopental in laboratory animals.[14] As a renowned expert in anaesthesiology, Dr. Lubarsky applies this body of science to the autopsy reports prepared by Dr. Bruce Levy and the results of toxicology testing on post-mortem blood samples obtained from Messrs. Coe, Workman, and Henley to reach the conclusion that there is a substantial likelihood that Mr. West will be conscious during his execution. Dr. Lubarsky's opinion rests upon established science and clearly meets the *McDaniel* criteria.

Moreover, here, there is no uncertainty about the data upon which Dr. Lubarsky relies. The time between the death of these Tennessee inmates and when their blood samples were taken is known. The location from which each of the samples were drawn is known. Rather than uncertainty, Mr. West's complaint presents a straight forward question of whether these facts, when applied to recognized scientific principles, support Dr. Lubarsky's opinion.

B. Post-mortem serum thiopental levels are the best available data to study an inmate's state of consciousness at the time of death.

The use of a paralytic agent in a three-drug lethal injection protocol means that after the paralytic is administered any outward signs of consciousness are masked. This leaves toxicological results as the primary data to examine the reliability of the anesthetic. If this Court

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[14]Teresa A. Zimmers, *et. al.*, *Lethal Injection for Execution: Chemical Asphyxiation?*, 4 PLOS MEDICINE 0005-0006 (April 2007) (citing studies).

determines that the post-mortem thiopental levels approximate what would be the levels at the time of death, then Tennessee's Protocol does not render condemned inmates unconscious. Since Defendants are faced with serum thiopental levels for executed Tennessee inmates which are inconsistent with their claims that Tennessee inmates are unconscious during executions, they have little choice but to argue that the Court should hold that post-mortem thiopental levels are unreliable as a matter of law. This position is based on a theory that post-mortem thiopental blood levels decrease over time. This so-called "post-mortem redistribution" theory is unsupported by established scientific principles, nor does it satisfy *McDaniel*.

The only peer-reviewed, published study of an injected anaesthetic with properties similar to sodium thiopental shows that serum levels increase after death.[15] The only peer-reviewed, published study examining postmortem sodium thiopental levels of executed inmates found no significant relationship between the time of collection after death and serum thiopental levels.[16] The Hung Study is widely accepted as the standard for measuring consciousness in relation to serum sodium thiopental levels. The body of science behind these studies is what Dr. Lubarsky rests his opinion on.

Defendants' contrary position, that postmortem thiopental levels are unreliable is based on Dr. Dershwitz's untested, non-peer-reviewed "opinion-piece" published in a law journal. Although this journal article is not properly before the Court,[17] a few points are required to show

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[15]Watson WA, Godley PJ, Garriott JC, Bradberry JC, Puckett JD, *Blood Pentobarbital Concentrations During Thiopental Therapy*, 20 DRUG INTEL. CLIN. PHARMACY 283-86 (1986).

[16]*Author's Reply*, 366 THE LANCET 1074-75 (Sept. 2005).

[17]Dr. Li's attempt to simply adopt Dr. Dershwitz's non-peer reviewed law journal article regurgitating testimony Dr. Dershwitz offered at the behest of the Defendants in the *Harbison* case is flatly improper. Dr. Dershwitz refuses to submit himself to cross-examination on the

that Dr. Dershwitz's theory is not accepted science nor even extrapolated from accepted scientific principles. Dr. Dershwitz's article discusses "paired" blood samples taken from executions in other states after death and then again after a lapse of time. Critical information about this data renders the conclusions drawn from its meaningless. For example, the site of collection for the "paired samples" is unknown. This or other factors can account for the different values. The samples taken closer to the time of death contained a higher concentration of thiopental than the samples taken at a time more remote from death. None of the six sodium thiopental levels which Dr. Dershwitz claimed were obtained immediately after executions conducted in other states (and therefore, he claims, are reliable) were consistent with a probability greater than 50/50 that the condemned inmates did not suffer the excruciating pain of suffocation.[18] Yet Dr. Dershwitz posits that the decrease of serum thiopental in the second samples indicates that blood samples taken later in time are not reliable indicators of the level of consciousness at the time of death.

Dr. Dershwitz refuses to acknowledge the scientific study demonstrating that thiopental levels increase postmortem. More importantly, Dr. Dershwitz fails to acknowledge that even the highest thiopental levels he discusses are not adequate to anesthetize a person subjected to a three-drug lethal injection procedure. Finally, this law journal article is based on Dr. Dershwitz's courtroom testimony and has not been subjected to peer-review. Now that Dr.

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issue of bias and, indeed, so refused during *Harbison*. In addition, during *Harbison*, Dr. Dershwitz altered the records of the Tennessee Protocol Committee in such a way as to remove language which could be read to indicate that he undertook actions on behalf of the Committee even though such actions violated his oath as a physician and the ethical rules governing the practice of anaesthesiology.

[18]11 Fordham Urban L. J.931, 951 (July 2008) (table of data).

Dershwitz has publicly published his opinion-piece it does not qualify for the peer-review process and thus will never be scrutinized by the medical community at-large. Accordingly, the existence of this opinion does not render postmortem serum thiopental levels *per se* unreliable.[19]

Dr. Lubarsky's reliance on postmortem thiopental levels has been accepted by the medical community. If there is any error in the science applied by Dr. Lubarsky, it would be that the postmortem blood thiopental level is higher than it was at the time of death.[20] This would mean that the error would result in a greater probability of unconsciousness (an error theoretically in Defendants' favor).

Not only does the scientific basis of Dr. Lubarsky's opinion meet *McDaniel*, the scientific basis for his reliance on the post-mortem thiopental levels obtained after Tennessee executions meets *McDaniel*. It must be considered by the court.

Not only does the scientific basis of Dr. Lubarsky's opinion meet *McDaniel*, the scientific basis for his reliance on the post-mortem thiopental levels obtained after Tennessee executions meets *McDaniel*. It must be considered by the court.

C. A three-drug execution protocol must produce a serum sodium thiopental concentration of at least 50 mg/L ± 2.9 mg/L in order to adequately anaesthetize a condemned inmate. Tennessee's Protocol does not produce such a concentration.

The serum sodium thiopental level necessary to render a patient unconscious has been the subject of at least one definitive and completely unchallenged study.

In Hung, OR, Varvell, JR,Shafer SI, Stanski DR, *Thiopental Pharmacodynamics II,*

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[19]Illogically, Dr. Dershwitz asserts his use of postmortem thiopental levels is acceptable as part of his courtroom testimony that executed inmates have been adequately anesthetized.

[20]366 PLOS MEDICINE at 1075.

Quantitation of Clinical and Electroencephalographic Depth of Anesthesia, 77 ANESTHESIOLOGY 237-44 (1992), Plaintiff's Exhibit 31, hereinafter "Hung Study," researchers inserted one arterial catheter for the purpose of continuous monitoring and blood sampling and an intravenous catheter for the purpose of administering sodium thiopental in 26 subjects. *Id.* at 238. They then conducted the following operations:

> A 5-min baseline recording of the EEG was obtained with the patient's eyes closed and with the patient breathing 100% oxygen through the anesthetic circuit and face mask. The CCIP then rapidly achieved and maintained the first target thiopental concentration randomly assigned between 10 and 30 μg/ml.[21] After maintaining this target concentration for 5 min to allow serum:brain equilibration of thiopental, the patient was tested for verbal responsiveness. If the patient was still verbally responsive for an additional 2 min, the thiopental target concentration was increased to the second target level. If the patient was unresponsive to verbal command, several noxious stimuli of 10-s duration were applied at 1-min intervals. These consisted of a 50-Hz constant electrical current that generated 50 mA to the forearm using a peripheral nerve stimulator to create neuromuscular tetanus (tetanic nerve stimulation), trapezius muscle squeeze, and direct laryngoscopy without intubation. Following these stimuli, a second, higher target serum thiopental concentration randomly assigned between 40 and 90 μg/ml was then rapidly achieved with the CCIP and maintained for 5 min. The same three noxious stimuli were repeated at 1-min intervals, followed by a laryngoscopy and intubation.

Id.

Even though none of the subjects had a serum thiopental level less than 10 mg/L and some had thiopental levels as high as 30 mg/L, six out of twenty-six subjects were actually aroused by a verbal command.[22] *Id.* at 239. The study further revealed that a thiopental level of 15.6 mg/L ± 1.1 mg/L would have to be achieved before there was even a 50% chance that the subjects would be anaesthetized sufficiently enough to not respond to verbal stimulus. In

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[21]1 μg/ml is equivalent to 1 mg/L.

[22]Mr. Coe's serum sodium thiopental level was 10 mg/L; Mr. Workman's was 18.9 mg/L, and Mr. Henley's was only 8.31 mg/L.

addition, the study determined that the more painful the stimulus, the higher the concentration required to sufficiently anaesthetize the subject. *Id.* at 240, Table 1. For example, the next step, a mild electrical shock, required a thiopental level of 30.5 mg/L ± 5.8 mg/l before there was a 50% chance that the subjects were anaesthetized sufficiently. Hung Study at 240, Table 1.

Condemned inmates in Tennessee are not just spoken to or mildly shocked, they are paralyzed, suffocated, and injected with potassium chloride which causes excruciating pain. Tennessee's own Chief Medical Examiner, Dr. Bruce Levy, described this event as a "most violent form of death." (Dr. Levy at TR. 718, 920-21). Dr. Michael Higgins, a neutral court-appointed expert anaesthesiologist who testified in the *Harbison* case, called it "nothing short of terror." (Dr. Higgins at TR. 953). If the pain and horror of conscious suffocation is the equivalent of a squeeze of the trapezius muscle, Tennessee's protocol would have to achieve a serum sodium thiopental level of 39.8 mg/L ± 3.3 mg/l before Tennessee officials could claim that there was less than a 50/50 chance that the inmate would be sufficiently unconscious. If conscious paralyzation, suffocation and injection of the noxious substance potassium chloride produces suffering equivalent to a direct laryngoscopy,[23] a serum sodium thiopental level of 50.7 mg/l ± 2.9 mg/l would be required to achieve a 50/50 chance that the inmate was unconscious. If it were the equivalent of intubation, a serum sodium thiopental level of 78.8 mg/l ± 7.4 mg/l would have to be achieved.

Even allowing state officials the benefit of every reasonable, or perhaps even every possible, doubt, Tennessee's execution protocol would have to achieve a serum sodium

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[23]n direct laryngoscopy, a flexible, fiber-optic endoscope is threaded through the nasal passage and down into the throat. *Encyclopedia of Nursing and Allied Health*, http://www.enotes.com/nursing-encyclopedia/laryngoscopy

thiopental level of at least 50 mg/l ± 2.9 mg/L before state officials could claim that condemned inmates were sufficiently anaesthetized to prevent them from experiencing the "most violent form of death" caused by Tennessee officials' subsequent injection of the paralytic drug, pancuronium bromide. None of Tennessee's executed men had a serum sodium thiopental level greater than 19 mg/L.

Based on the types of noxious stimuli used in the Hung Study, which may approximate the pain resulting from Tennessee's use of pancuronium bromide and potassium chloride, the answer to the Tennessee Supreme Court's third question,[24] would be a concentration of at least 50.7 mg/L ± 2.9 mg/L is required to anaesthetize against the pain caused by Tennessee's protocol. Accordingly, as to the Tennessee Supreme Court's second question,

> Whether the current amount and concentration of sodium thiopental mandated by Tennessee's current lethal injection protocol are insufficient to ensure unconsciousness so as to create an objectively intolerable risk of severe suffering or pain during the execution process?

the answer is, "Yes."

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[24]"At what level sodium thiopental is sufficient to ensure unconsciousness so as to negate the objectively intolerable risk of severe suffering or pain during the execution process? *West v. Ray et al.*, Case No. M2010-02275-SCR11-CV, order at p. 4 (Nov. 6, 2010).

V. THE RISK THAT SODIUM THIOPENTAL, AS USED IN THE TENNESSEE PROTOCOL, DOES NOT EFFECTIVELY ESTABLISH UNCONSCIOUSNESS.

The Supreme Court's order queried "whether Tennessee's three-drug protocol constitutes cruel and unusual punishment because the manner in which the sodium thiopental is prepared and administered fails to produce unconsciousness or anesthesia prior to the administration of the other two drugs." *West v. Ray*, No. M2010-02275-SC-R11-CV, Order, p.2 (Tenn. Nov. 6, 2010). The answer is yes.

Findings made as a result of the autopsy of Robert Coe show that his serum thiopental level was 10 mg/L. (Plaintiff's Exhibit 26, Coe Autopsy Bates p.13). This level is inadequate for unconsciousness (2007 Affidavit of Dr. Lubarsky, p.5-6 ¶20-21, Plaintiff's Exhibit 28). Philip Workman's serum thiopental level was 18.9 mg/L. (Plaintiff's Exhibit 27, Workman Autopsy Bates p.03, 07). This means he was not fully anesthetized during his execution (Plaintiff's Exhibit 32, 2010 Affidavit of Dr. Lubarsky, p. 5). Steve Henley's level was 8.31 mg/L, which is also inadequate to be fully anesthetized during the execution. (Plaintiff's Exhibit 29, Henley Autopsy Bates p.02, 06, 09; Plaintiff's Exhibit 32, 2010 Affidavit of Dr. Lubarsky p. 6).

These levels indicate that each man's brain activity would have been higher than normal. Additionally, both Coe and Henley were within the range of consciousness. There is a 50% chance that Workman was unconscious only to the point of losing purposeful movement in response to verbal stimulation; he would have had awareness of physical stimulation. *See* Section III, *supra.*

Accordingly, every autopsy performed following an execution under the Tennessee Protocol reveals levels of thiopental below those required to induce unconsciousness that would

prevent serious harm from the administration of pancuronium bromide and potassium chloride (Plaintiff's Exhibit 32, 2010 Affidavit of Dr. Lubarsky p.7-8). These past experiences of executions by the State of Tennessee shows a demonstrated substantial risk of severe pain; an objectively intolerable risk of harm. *Baze*, 553 U.S. at 50. There is a substantial risk, that cannot be ignored or ascribed as an accident, that the use of sodium thiopental under the Tennessee Protocol will not sufficiently anesthetize Mr. West. As a result, Mr. West will experience an excruciatingly painful and horrifying death as a result of the conscious asphyxiation caused by the use of pancuronium bromide and the painful internal burn and potential cardiac arrest caused by the introduction of potassium chloride.

A. Risks Regarding the Preparation of Sodium Thiopental

1. Manufacturer's instructions and warnings

500 mg kits of sodium thiopental should be stored at a controlled room temperature of 15 to 30°C (or 59 to 86°F). *See* http://www.rxmed.com/b.main/b2.pharmaceutical/b2.1.monographs/CPS-%20Monographs/CPS-%20(General%20Monographs-%20P)/PENTOTHAL.html.

Solutions of sodium thiopental should be prepared aseptically with either Sterile Water for Injection, USP, 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. (Attachment A, p.6). A 2.0% or 2/5% solution is most commonly used. *Id.*

> Since Pentothal contains no added bacteriostatic agent, extreme care in preparation and handling should be exercised at all times to prevent the introduction of microbial contaminants. Solutions should be freshly prepared and used promptly...
>
> Any solution of Pentothal [] with a visible precipitate should not be administered. The stability of Pentothal solutions depends upon several factors, including the diluent, temperature of storage and the amount of carbon dioxide from room air that gains access to the solution. ...

> ... The most stable solutions are those reconstituted in water or isotonic saline, kept under refrigeration and tightly stoppered. The presence or absence of a visible precipitate offers a practical guide to the physical compatibility of prepared solutions of Pentothal.

Id. at p.6. The manufacturer expressly cautions users to "[o]bserve aseptic precautions at all times in preparation and handling of Pentothal." *Id.* at p.2. The user is also warned to:

> Inspect reconstituted (mixed) solutions of Pentothal [] for clarity and freedom from precipitation or discoloration prior to administration. Use reconstituted solution only if is clear, free from precipitate and not discolored.

Id. at p. 9.

"This drug should be administered only by persons qualified in the use of i.v. anesthetics." *See* http://www.rxmed.com/b.main/b2.pharmaceutical/b2.1.monographs/CPS-%20Monographs/CPS-%20(General%20Monographs-%20P)/PENTOTHAL.html.

2. Information known by Defendants

a. Preparation of sodium thiopental

Dr. Payne advised the Committee that Tennessee needed a qualified person, "a pharmacist, a nurse, or an anaesthesiologist" to show the executioners how to properly mix sodium thiopental and also recommended a physical examination before the execution to give the paramedics "an opportunity to determine which veins are good before the execution." (Plaintiff[Harbison] Ex. 20 at 2, 4) (*Harbison*, 511 F.Supp.2d at 876). The Tennessee Department of Corrections did not adopt Dr. Payne's suggestion to employ a "qualified person" to show the executioners how to mix sodium thiopental. Instead, Executioner A--the executioner with the most experience in mixing the drug--learned by watching another executioner in Texas and cannot remember when he first mixed the drug. (TR 304-05, *Harbison*, 511 F.Supp.2d at 887)

Julian Davis testified that medical doctors had informed the Committee that sodium thiopental solution could become cloudy, and he felt this presented a problem because this drug can be mixed as much as three hours before the execution (TR 447-8); however, Ms. Ray testified that either Dr. Payne or Dr. Dershwitz had told the committee that this step was unnecessary. (TR 563. *Harbison*, 511 F.Supp.2d at 878 n3). This safeguard was removed.

b. Dosage of sodium thiopental

The Committee, including some of Defendants, which established the use of 5 grams of sodium thiopental to allegedly effect "general anesthesia" and death by "one lethal 5 gram dose" *(see* Plaintiff's Exhibit 4 p.35; Plaintiff's Exhibit 5 p.7), knew that "the effect and required dosage of sodium thiopental [is] less predictable and more variable... ." *See* Plaintiff's Exhibit 5 p.8. Nevertheless, the Protocol fails to address an individual prisoner's weight, medical condition and medical history as related to the dosage of sodium thiopental necessary to effectively anesthetize him, but just indicates that a 5 gram dose will be given (Plaintiff's Exhibit 4 p.35). Thus, the Committee has displayed deliberate indifference to the risk of pain and suffering by directing the use of one generic dose of sodium thiopental to supposedly achieve a proper level of anesthesia while at the same time knowing its effect upon the condemned is unpredictable.

c. Monitoring for effectiveness of sodium thiopental

The Tennessee Protocol Committee was "well aware of the necessity for checking consciousness under the three-drug protocol option." (*Harbison*, 511 F.Supp.2d at 885; (Plaintiff[Harbison] Ex. 7, 30).

> The April 19, 2007, minutes state that "Deputy Commissioner Ray also mentioned having something that would assure the unconsciousness of an inmate

(during the execution procedure)." (Plaintiff[Harbison] Ex. 29). In addition, those minutes reflect a conversation between Warden Bell and Physician A in which Warden Bell "inquire[d] about what would indicate that an inmate is unconscious after the first drug and a saline flush are given (three-drug protocol) so that he can give the signal to go ahead with the other drugs." Id. The physician suggested looking at the inmate's eyes but also "stated that constricted pupils are not a definitive sign of unconsciousness." Id. Therefore, he also advised "checking for an eyelash response by brushing a finger across them . . . lifting up the person's arm . . . [and] a pin prick or pinching the nipples." n9 Id.

FOOTNOTES

n9 In addition, Gayle Ray's notes labeled "4-12" (relating to a meeting that occurred on April 12, 2007) includes the sentence "What, if any, safeguards to ensure person is appropriately anesthetized" with an arrow pointing towards "Any monitoring by machine? medical personnel?" (Plaintiff[Harbison] Ex. 31 at 30)

However, when Commissioner Little chose to reject the Protocol Committee's recommendation of a one-drug protocol and to order the committee to draft a new three-drug protocol instead, he did not add a safeguard for checking consciousness. Instead, Commissioner Little testified that, although the new protocol contained no specific provision for ascertaining the inmate's consciousness before the administration of the second two drugs, continuous visual observation by Warden Bell "was sufficient." Commissioner Little also noted that the executioners would be able to watch the inmate through the one-way glass.

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FOOTNOTES

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> As Dr. Higgins and Dr. Lubarsky testified, in light of the potential pitfalls in administering sodium thiopental discussed below, the failure to check for consciousness greatly enhances the risk that the inmate will suffer unnecessary pain.

Harbison, 511 F.Supp.2d at 885-886.

Lack of monitoring, inadequately skilled personnel and the known risk of ineffectiveness of sodium thiopental have resulted in inadequate anestheia in executions in the United States, including jurisdictions considered by the Committee. Such botched executions, meaning inadequate anesthetic states when prison personnel administer sodium thiopental, were known or should have been known to the Committee. (*Harbison*, 511 F.Supp.2d at 901-904). Instead, the Committee deliberately ignored this information when it stated that "5 grams of sodium thiopental would render a person unconscious within a few seconds, and its anesthetic depth would continue until death" (Plaintiff's Exhibit 5 p.7).

3. The Protocol's instructions regarding sodium thiopental

The sodium thiopental is stored in the armory area of Building 7 at Riverbend Maximum Security Institution in an "unmovable heavy gauge steel container[]." (Exhibit 4, Protocol, p.36). Three hours before an execution the drugs are prepared. *Id.* at p.38.

> The Sodium Thiopental is in powder form and is mixed with sterile water. A box of Thiopental contains 500 mg of powder and a bottle of sterile water. 10 boxes of 500 mg of Thiopental are required to produce 5 grams of the chemical. The member of the Execution Team draws 20 cc of sterile water and injects it into the powder. The powder is dissolved into the water. Next, he repeats the process nine (9) more times, using the remaining 9 boxes for a total of 5 grams of the chemical. He then draws the solution into four syringes. The syringes are labeled Sodium Thiopental with consecutive numbers one (1) through (4).

(Exhibit 4, Protocol, p.83). The syringes are placed on a tray that will sit on the workstation in the Lethal Injection Room until the execution. *Id.* at p.39.

a. Significant shortcomings regarding preparation instructions

The Protocol uses 5 grams of sodium thiopental, dispensed in four syringes, for the purpose of "general anesthesia" (Plaintiff's Exhibit 4 p. 35). The Protocol fails to address an individual prisoner's weight, medical condition and medical history as related to the dosage of sodium thiopental necessary to effectively anesthetize him, but instead just indicates that a 5 gram dose will be given (Plaintiff's Exhibit 4 p.35).

The Protocol requires the use of 10 boxes of 500 mg. of thiopental (Plaintiff's Exhibit 4 p.38). The Protocol fails to include the proper instructions for mixing sodium thiopental: for example, it fails to identify what the sodium thiopental should be mixed in, whether it is to be mixed all together (10 boxes in one mixing container) or one box at a time, what instrument is to be used to actually mix the solution, how the syringes should be filled, how many syringes should be filled per box of powder, or what precautions are taken to avoid settling or contamination of the sodium thiopental (Plaintiff's Exhibit 4 p.38). Moreover, the requirement that ten boxes of sodium thiopental be used is unnecessary and increases the risk that the sodium thiopental will be improperly mixed, combined and administered. This procedure unnecessarily increases the risk of error regarding proper mixture and effectiveness of the chemical. The method of mixing the sodium thiopental, as described by Defendant Bell, is not medically accepted (2007 Lubarsky affidavit, Plaintiff's Exhibit 28, p.4-5 ¶17).

In contrast, the Protocol for execution by electrocution contains specific instructions for mixing a sodium chloride solution (Plaintiff's Exhibit 4 p.35). Such specific instructions are absent for mixing the sodium thiopental used for lethal injection, thus evincing deliberate indifference to the risk that the sodium thiopental will not be properly mixed and/or properly

drawn into the syringes and/or properly administered causing the condemned to not be properly anesthetized and unnecessarily suffer a painful and tortuous death by asphyxiation from pancuronium bromide while simultaneously feeling the extreme chemical burn from the injection of potassium chloride.

b. Risks regarding the storage of constituted sodium thiopental

Defendant Ray disagreed with the testimony of Julian Davis about the danger of sodium thiopental getting cloudy while sitting in the syringes for up to three hours. Whereas Mr. Davis had testified that two physicians had told them of this danger, Ms. Ray testified that this provision of inspecting the syringes every 15 to 20 minutes for cloudiness was removed from what originally had been practiced because either Dr. Payne or Dr. Dershwitz told them that this was unnecessary because "once pentothal is mixed appropriately, that is dissolved, suspended. Everything is good to go for several days." (TR 563, *Harbison*, 511 F.Supp.2d at 878 n3)

The Current Protocol requires the Lethal Injection Chemicals to be prepared three hours before an execution (Plaintiff's Exhibit 4 p.38). Because the execution can take place within 24 hours of the scheduled time, the sodium thiopental could be sitting in the tray, in solution form, settling and degrading for up to 25 hours and 59 minutes before being used in the execution. This length of time increases the risk that the thiopental will become compromised either as a result of not being refrigerated and/or tightly stoppered, as a result of the formation of particulate matter, and/or because the maximum amount of time for effectiveness is 24 hours. This unnecessarily increases the risk that the condemned will not be properly anesthetized and will unnecessarily suffer a painful and tortuous death by asphyxiation from pancuronium bromide while simultaneously feeling the extreme chemical burn from the injection of potassium

chloride.

B. The executioners' lack of training in preparing sodium thiopental

Experts told Tennessee officials that "with regard to mixing the sodium thiopental (the first drug), '[y]ou need someone who knows how to show them how to mix--a pharmacist, a nurse, or an anaesthesiologist.'" *Harbison*, 511 F.Supp.2d at 876; *See* Lubarsky testimony, *Harbison v. Little,* No. 3:06-cv-1206, Docket No.142, TR657 (M.D. Tenn.); *see* Physician A testimony, *id.* at Docket No.142, TR497, 503-04. Tennessee, instead, selected a person without training in mixing sodium thiopental but who had once watched a Texas executioner perform the same task. *Harbison*, 511 F.Supp.2d at 886-87, 897. The *Harbison* Court found this compounded the risk of harm in the three-drug protocol as implemented in Tennessee. *Id.*

The Current Protocol fails to indicate who prepares, mixes and administers the "Lethal Injection Chemicals" (other than "one member of the execution team") and what training, education, licensing, or screening any member of the Execution Team has in the preparation, mixing and combining of the chemicals, drawing the chemicals into syringes and the administration of the chemicals (Plaintiff's Exhibit 4 p.38). Based on the vague descriptions of the Execution Team, there is no one who has pharmaceutical training or knowledge of drug compounding to mix the drugs. Moreover, the Current Protocol provides only that "another member of the execution team observes and verifies that the procedure has been carried out correctly." *Id.* Again, the Current Protocol fails to indicate what training, education, or licensing, or any screening any Execution Team Member has for observing the mixing of the "Lethal Injection Chemicals," drawing them into the syringes and administering the chemicals to make sure it is done correctly. There is no quality control to assure that the chemicals have

actually been mixed correctly and at the proper dosage and that they are administered correctly. "The risk created by Tennessee's decision not to check for consciousness is compounded by Tennessee's choice of individuals to mix and inject the drugs and monitor the IV lines during executions." *Harbison*, 511 F.Supp.2d at 886.

The use of sodium thiopental by untrained personnel greatly increases the risk that a prisoner would not receive the necessary amount of anesthetic prior to being paralyzed and suffocated by the pancuronium bromide and then experiencing the painful internal burn of the potassium chloride.

The Protocol directs the Execution Team to practice with saline and not the Lethal Injection Chemicals (Plaintiff's Exhibit 4 p.33). This unnecessarily increases the risk that the sodium thiopental will not be mixed and combined properly at the time of an execution. It unnecessarily increases the risk that it will not be drawn properly into the syringes or properly pushed into the IV line. The result is an unnecessary risk that the condemned will not be properly anesthetized and will unnecessarily suffer a painful and tortuous death by asphyxiation from pancuronium bromide while simultaneously feeling the extreme chemical burn from the injection of potassium chloride.

C. Risks Regarding the Administration of Sodium Thiopental

The Protocol fails to educate its readers (the Execution Team) about the rate and time of sodium thiopental's onset, and also about its rapid withdrawal rate and that it is likely to cause pain and inflict burns if the drug is not properly dissolved or infiltrates to surrounding tissue. (Attachment A, p.6) (A 2.0% or 2.5% solution is most commonly used. A 3.4% concentration is

isotonic; concentrations less than 2.0% are not used because they cause hemolysis.)[25].

1. Set-up of IV lines

The Protocol does not recommend the shortest possible length for the IV setup. Instead, it indicates that the Solution Sets are 85 inches long but may be purchased longer or shorter; extensions into the first port should be 18 to 24 inches in length; extensions are added to each end of the Solution Set until it reaches the desired length; the ends should reach from head to toe of the condemned inmate (Plaintiff's Exhibit 4 p.40). The IV line is connected to the catheter *via* extensions "added to each end until it reaches the desired length" (Plaintiff's Exhibit 4 p.40). "The line is taped to the port (where the syringe is inserted) in place. The remainder of the line is placed out of the ports in the window" of the Lethal Injection Room and taped in place (Plaintiff's Exhibit 4 p.40).

> With regard to the task of injecting the drugs into the IV line, Dr. Higgins stated that using individuals with the level of training the executioners have received "would increase the risk of error." Specifically he testified: Of course, I've never administered drugs from quite that long of a line, but I know that we have certainly used extensions in many surgical procedures where we're a little more remote from the patient. It does reduce your ability to sense any resistance or obstruction in the line. That alone, coupled with the fact that you are using very large syringes, both make it more challenging and why, or course, I was very concerned about the low level of training for these individuals involved and their low experience in addressing--detecting and addressing problems. Because that, in this setting, would make it especially challenging.(TR 959)

Harbison, 511 F.Supp.2d at 889.

The protocol fails to provide for any monitoring of anesthetic depth as is necessary when using sodium thiopental (Plaintiff's Exhibit 4 p.43). The protocol does not require in the death chamber any personnel to monitor and determine if there is a blockage in the intravenous line or

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[25]Plaintiff's Exhibit 25, p.8-9.

to evaluate whether a prisoner is properly sedated before proceeding with the painful parts of the execution process. The design of the Execution Chamber and the Lethal Injection Room, the restraints, the dressing and tape obscure and/or distort any view of the catheter, surrounding body area and tubing. (Plaintiff's [Harbison] Exhibit 2, diagram of lethal injection room, TR 218).

2. The failure to check for consciousness

> Perhaps the most glaring omission in the new protocol is the failure to check for consciousness before the pancuronium bromide is administered. The testimony of expert witnesses at the hearing established that the failure to check for consciousness greatly increased the risk of pain because the pancuronium bromide would make it impossible for Warden Bell to determine if Mr. Harbison is suffering. Further, although other jurisdictions employ such measures, and Tennessee officials were aware of this, the new protocol does not contain procedures to check for consciousness.
>
> Dr. Higgins testified that the failure to include a check for consciousness posed a substantial risk of serious or unnecessary harm to the inmate "because the next drug to be administered is a rapidly acting paralytic agent." (TR 953) Dr. Lubarsky testified that checking for consciousness was "probably . . . the most critical step." (TR 658) It is for these reasons that other states who recently have reexamined their three-drug lethal injection protocols have adopted specific measures for checking consciousness. For instance, the Florida Department of Corrections, which adopted new lethal injection procedures effective for executions after May 9, 2007, n6 included the following procedure to immediately follow the sodium thiopental injections: At this point, a member of the execution team will assess whether the inmate is unconscious. The warden must determine, after consultation, that the inmate is indeed unconscious. Until the inmate is unconscious and the Warden has ordered the executioners to continue, the executioners shall not proceed to step (5). (Docket No. 63, Ex. 26 at 8) This provision appears to have been inspired by the Florida Commission on Administration of Lethal Injection's Final Report, n7 which recommended that Florida "[d]evelop and implement procedures to ensure that the condemned inmate is unconscious after the administration of the first lethal chemical, sodium thiopental, before initiating administration of the second and third lethal chemicals. Under no circumstances should the execution continue with the second and third lethal chemical without the Warden's authorization." (Docket No. 63, Ex. 18 at 12) Commissioner Little testified that he personally read the Florida Report, which was included in the Appendix to Tennessee's own Report on Administration of Death Sentences in Tennessee.

FOOTNOTES

n6 The new Florida procedures appear in the record at Docket No. 63, Ex. 26.

n7 The Florida Report is listed in the Appendix to the final Tennessee Report (Plaintiff[Harbison] Ex. 41), but the actual report is not attached to that exhibit. It appears in the record at Docket No. 63, Ex. 18)

In California's Lethal Injection Protocol and Review, which was issued on May 15, 2007, the California Department of Corrections' Review Team pointed out that earlier versions of its protocol "made no provisions for any objective assessment of consciousness of the condemned inmate following administration of the sodium thiopental, and prior to the administration of the other chemicals." State of California Lethal Injection Protocol Review, p. 20. n8 The California committee noted that "[t]here are reliable, but relatively uncomplicated methods for effectively assessing consciousness that have been incorporated into the [California] Lethal Injection Protocol. Among them are talking to and gently shaking the inmate, as well as lightly brushing the eyelash." Id. For that reason, "[c]hanges were made to the [California] protocol to place staff in close proximity to the condemned inmate throughout the execution to assess and confirm the condemned inmate is unconscious prior to and during the administration of the pancuronium bromide and the potassium chloride." Id.

FOOTNOTES

n8 The California Report is publicly available at:
http://www.cdcr.ca.gov/Communications/docs/ReportToCourt.pdf

In addition, drafts of the Tennessee committee's Report--drafts which ultimately recommended the one-drug protocol--stated that, although it had chosen to reject the three-drug protocol, "certain safeguards" could be incorporated to reduce the three-drug protocol's "slightly greater risk of error." (Plaintiff[Harbison] Ex. 36 at 7) Those safeguards included "[i]ncorporating a method for monitoring anesthetic depth," which would "address allegations that condemned inmates may be conscious and experience pain from the effects of pancuronium bromide and potassium chloride prior to death." Id. The drafts concluded (in apparent disagreement with the Florida and California reports) that those safeguards "would not be practicable or feasible." Id.

Indeed, the Tennessee Protocol Committee appears to have been well aware of the necessity for checking consciousness under the three-drug protocol option. In a document prepared by the chair of the committee, Julian Davis, that listed the "pros" and "cons" of the various options considered by the committee, the following phrase appears as a "con" under the three-drug protocol: "Would likely need to add a method of ascertaining consciousness after Sodium Pentothal."

(Plaintiff[Harbison] Ex. 7) The same phrase appears in the minutes of the April 12, 2007 meeting, along with the phrase "courts have required additional checks in some states." (Plaintiff[Harbison] Exhibit 30).

The April 19, 2007, minutes state that "Deputy Commissioner Ray also mentioned having something that would assure the unconsciousness of an inmate (during the execution procedure)." (Plaintiff[Harbison] Ex. 29). In addition, those minutes reflect a conversation between Warden Bell and Physician A in which Warden Bell "inquire[d] about what would indicate that an inmate is unconscious after the first drug and a saline flush are given (three-drug protocol) so that he can give the signal to go ahead with the other drugs." Id. The physician suggested looking at the inmate's eyes but also "stated that constricted pupils are not a definitive sign of unconsciousness." Id. Therefore, he also advised "checking for an eyelash response by brushing a finger across them . . . lifting up the person's arm . . . [and] a pin prick or pinching the nipples." n9 Id.

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However, when Commissioner Little chose to reject the Protocol Committee's recommendation of a one-drug protocol and to order the committee to draft a new three-drug protocol instead, he did not add a safeguard for checking consciousness. Instead, Commissioner Little testified that, although the new protocol contained no specific provision for ascertaining the inmate's consciousness before the administration of the second two drugs, continuous visual observation by Warden Bell "was sufficient." Commissioner Little also noted that the executioners would be able to watch the inmate through the one-way glass.

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Harbison, 511 F.Supp.2d at 884-886.

3. Failure to adequately monitor anesthetic depth

The only monitoring provided for by the Protocol is monitoring of the IV site *via* close-circuit camera, which is inadequate. *(Harbison*, 511 F.Supp.2d at 892) . There is no monitoring of the condemned for anesthetic depth. There is no monitoring of the IV lines and tubing during the administration of the drugs. In contrast, the Protocol for execution by electrocution requires monitoring for "visible muscle movement to determine the effectiveness of the electrocution (Plaintiff's Exhibit 4 p.74). No such monitoring with respect to the sodium thiopental is required. Thus, this procedure evinces deliberate indifference to the risk that the sodium thiopental will not be properly dosed, mixed and/or drawn into the syringes and administered causing the condemned to not be properly anesthetized and unnecessarily suffer a painful and tortuous death by asphyxiation from pancuronium bromide while simultaneously feeling the extreme chemical burn from the injection of potassium chloride.

> Tied in with the deficiencies of the protocol in training the executioners is a deficiency involving a specific task that one executioner is charged with performing: monitoring the IV lines during the administration of the three drugs. Under the new protocol, the IV lines are monitored only visually, by looking through the one-way window and at a video screen in the separate executioners' room. Neither the executioners nor anyone else palpates the injection site. According to Dr. Higgins and Dr. Lubarsky, this is a significant problem. Dr. Higgins testified that Tennessee's decision to use only visual observation of the IV site to detect errors "would definitely increase the risk of error." (TR 945) At

his deposition, Dr. Higgins further elaborated on this risk, stating "visual observation is certainly better than none, but you can't sense some of the more subtle changes that really require tactile monitoring during injection. And again, these are relative levels of veracity or detection, but the highest level would be to actually be able to physically monitor the injection site during the injection processes with your hand on the site, which is what I do every time I induce a patient." (Court's Ex. A at 42-43) Especially in circumstances where the observers have only minimal training--as in the situation at hand--Dr. Higgins testified that visual observation "would not be adequate." (*Id.* at 44)

Similarly, Dr. Lubarsky testified that visual monitoring was "absolutely not" adequate, especially when the injection site is located in the arm, because "the body has various different compartments, especially in the arm," and the compartments are "not fully communicative with each other." (TR 646) Therefore, "[i]f the IV catheter is in one compartment and you're looking at a superficial compartment, that is the subcutaneous area, you might not see anything." (TR 647)

Dr. Dershwitz was somewhat less concerned about the visual monitoring but did testify that, "[i]f an error is going to occur in this whole process, the most likely error would be that the intravenous catheter is not in a vein." (TR 888) Dr. Dershwitz later added that "the visual inspection should be the first step. But if one detected or had a high suspicion that there might be a malfunction, one would also want to touch and palpate the IV site to check for things like a subcutaneous collection of fluid." n17 (TR 894)

FOOTNOTES

n17 Dr. Dershwitz further elaborated that, "if the person were conscious and thiopental was being injected subcutaneously, there's a high likelihood that the person would have significant pain at the injection site because of the high pH of the thiopental solution." (*Id.*)

Executioner B testified that the television screen used to visually monitor the inmate allows the executioners to "zoom in close enough to where you can count individual human hair[s] around the injection site." (TR 221) Dr. Lubarsky, however, testified that this zoom function "would not solve the problem" because "[t]he human eye is actually better than any camera. Especially in close proximity." (TR 647) Dr. Lubarsky described situations in which "even a trained physician" cannot determine whether an IV is working and must perform "all sorts of manipulations" to determine whether the drugs are actually entering a vein. He expressed concern that the protocol do not allow for this kind of troubleshooting. (*Id.*) Moreover, the executioner with the primary responsibility for monitoring the television screen is also charged with handing, in the proper order and in rapid fashion, eleven numbered syringes to the executioner who

injects them into the IV line, and with receiving back from him, in turn, the empty syringes. n18 (TR 198-99) Accordingly, it is difficult to imagine what level of monitoring actually occurs, regardless of the efficacy of the zoom function.

FOOTNOTES

n18 Executioner B testified that, in the Coe execution, Executioner C performed the dual functions of "watches the monitor, passes the syringes," while Executioner A mixed the drugs and observed them both. (TR 198) No testimony at hearing indicated that the division of responsibilities between the three executioners has changed since the Coe execution, although the assignment of an individual executioner to an individual role was subject to change.

In light of the lack of training provided to the executioners, the court finds that relying solely on visual monitoring of the IV lines increases the plaintiff's risk of unnecessary pain.

Harbison, 511 F. Supp. 2d at 892.

D. The Failure to Select Adequately Trained Executioners to Prepare and Administer the Sodium Thiopental

The risk created by Tennessee's decision not to check for consciousness is compounded by Tennessee's choice of individuals to mix and inject the drugs and monitor the IV lines during executions. Under the new protocol, two certified paramedic technicians insert the catheters into each of the inmate's arms, while a third, significantly less trained, "IV Team Member" puts the IV lines together. n11 Then the certified paramedic technicians leave the execution chamber and, from that point forward, are not in a position to observe the inmate or the executioners. The three executioners, all Corrections Department employees selected by Warden Bell (TR 100), are untrained in the duties they are expected to perform and, at hearing, were unable to identify potential pitfalls that the expert witnesses identified to be significant risks.

FOOTNOTES

n11 The paramedics and executioners testified anonymously behind a screen at the hearing and will not be identified by name in this opinion pursuant to provisions in state law that protect their identities. Instead, the paramedics will be identified as IV Team Members A and B. The executioners will be identified as Executioners A, B, and C. In addition, although he is not a trained paramedic or emergency medical technician, under the new protocol, Executioner A also serves as IV Team Member C.

Executioner A (who also serves as IV Team Member C) attended one thirty-two

hour IV therapy course in 1998 at Motlow State Community College, where he was instructed in the insertion of IV catheters, but not in setting up IV lines, administering drugs through IV lines or in monitoring the lines during a series of bolus injections. In 2003, Executioner A attended one four-hour intravenous catheterization refresher course, which also did not instruct him regarding setting up and administering drugs or monitoring IV lines, the actual functions of the executioners under the new protocol. In addition, Executioner A testified that he has gone to Texas to watch executions. (TR 304)

Executioner B attended the same two courses as Executioner A and has, likewise, received no training or instruction in setting up IV lines, administering drugs through IV lines, or in monitoring the lines. Executioner B has also gone to Texas to watch executions but did not receive much training from his Texan counterparts. n12 (TR 203-04)

FOOTNOTES

n12 Executioner B testified that the Texas officials: "were busy in their own effort. And they were kind enough to allow us access. And I didn't want to interfere, which would cause them problems. So I kept my questions very short, brief--you know, why this? How that? And their response would be just that, very brief, because they were concentrating on the job at hand for them." (TR 184)

Unlike his two co-executioners, Executioner C did not attend the thirty-two hour course at Motlow State Community College in 1998. His sole training has been attending the four-hour course in 2003 along with Executioners A and B. Warden Bell, who, under the new protocol, is the only person in the same room as the condemned inmate when the drugs are injected into the IV lines, testified that his only training consisted of viewing executions in Texas, visiting an execution site in Indiana, and talking with "some other states" about the process. (TR 97-98)

In addition to their training, Executioners A, B, and C, as well as Warden Bell, participate in monthly practice sessions wherein they and IV Team Members A and B inject saline solution into volunteers. However, the executioners do not receive any instruction at the training sessions from the paramedics or any other medically qualified individuals. n13 They do not troubleshoot potential problems that might occur, such as catheter infiltration, but simply practice performing their functions with saline solution.

FOOTNOTES

n13 In fact, IV Team Member B testified that he did not take part in any portion of the practice sessions except the portion where he inserted the IV catheter into the arm of the volunteer, and that the same was true for IV Team Member A. (TR 379-80)

The executioners and paramedics testified that they had not been screened for drug problems or psychological disorders before being hired and that Commissioner Little does not test any of the participants for drugs prior to the executions themselves. This is a particular issue because one of the paramedics--IV Team Member B--has a history of drug and alcohol addiction and psychological disorders. (TR 384-85) IV Team Member B testified that he did not take part in the Sedley Alley execution because he was hospitalized in an alcoholic treatment program during April, May and June of 2006. Further, IV Team Member B testified that he pled guilty to possession of a controlled substance in 1988 and again in 1998. While hospitalized in the Spring of 2006, IV Team Member B was diagnosed by a psychiatrist as suffering from a "deep-rooted" depression and, as a result, he is currently taking Paxil. (TR 385)

IV Team Member B stated that he never told Warden Bell about any of these issues because "[i]t never came up." (TR 385) This testimony was corroborated by Warden Bell himself, who testified that he did not screen the executioners or paramedics for drug or psychological problems before taking them in as members of his execution team. n14 Warden Bell stated that he did know about IV Team Member B's problems but that he was not concerned about them because he had observed IV Team Member B and had "not seen anything that appeared to be out of the ordinary." (TR 171)

FOOTNOTES

n14 Warden Bell affirmed that he did not do any background checks regarding the execution team members and that he "usually" asked for a copy of their credentials, "but not always." (TR 170) When asked whether he checked to see if their certifications had ever been suspended, Warden Bell answered "No." (TR 170)

In addition, Warden Bell testified that he did not require his execution team to actually read the new protocol unless they had come on board after its creation. Warden Bell testified that he had "conducted training using the protocol" and those members who "didn't get to sit through that have since read the manual itself." (TR 114)

The expert witnesses testified that employing individuals with the training that Executioners A, B, and C, have undergone to perform the functions that the protocol calls for them to perform is a severe problem. Dr. Dershwitz, an expert witness for the defendant, stated that "[s]ometimes intravenous catheters fail" and that if the only individuals who are trained in monitoring IV lines leave the room following insertion of the catheters--which is what the new protocol dictates--he "think[s] it is logical to assume that there's an increased risk." (TR 889) Dr. Dershwitz also testified that "the person who is primarily responsible for making sure that the IV is working should also have experience doing the same in their

usual and customary day job," and further elaborated that "I mean that all the steps involved in putting in and maintaining and checking an IV are best done by somebody who regularly does all of these parts or all of these steps as part of their day job" (TR 890-91), and also that "it would be best if somebody injected medications, again, as part of their day job." (TR 892) In identifying the things that could go wrong during the injection of the drugs, Dr. Dershwitz testified: Well, the person could inject the wrong drug. They could pick up the wrong syringe. I guess it's possible that if the system is using stopcocks, they could inject it in the wrong direction; although I don't think that is a very likely scenario. And certainly the IV itself can malfunction.(TR 891) Dr. Dershwitz testified that IV catheters, though properly inserted initially, did move from veins into outer tissue "once in a while," even in his own practice. (TR 892)

Dr. Higgins, the court-appointed expert, testified that, in his opinion, Tennessee's decision to use executioners with the training such as Executioners A, B, and C have received would generally increase the risk of pain incurred by the plaintiff. (TR 944) He agreed with Dr. Dershwitz that the persons who place the IV catheters, administer the drugs and monitor the process should be IV therapists, nurses or similar professionals who do these tasks as part of their everyday jobs so that they can troubleshoot problems. (Depos., Court Ex. A, at 29-37) (TR 946-47) Dr. Higgins stated that the decision to remove the paramedics from the execution chamber before the administration of the drugs "would certainly increase the risk" of pain. (Id. at 944) Dr. Higgins testified that errors such as catheter slippage occur in hospitals with highly trained professionals "with a fairly high frequency." (TR 945) He further stated that tactile monitoring of the IV site is very important and that visual observation by a minimally trained person is not adequate. (Depos., Court Ex. A, at 29-31, 34) With regard to the task of injecting the drugs into the IV line, Dr. Higgins stated that using individuals with the level of training the executioners have received "would increase the risk of error." Specifically he testified: Of course, I've never administered drugs from quite that long of a line, but I know that we have certainly used extensions in many surgical procedures where we're a little more remote from the patient. It does reduce your ability to sense any resistance or obstruction in the line. That alone, coupled with the fact that you are using very large syringes, both make it more challenging and why, or course, I was very concerned about the low level of training for these individuals involved and their low experience in addressing--detecting and addressing problems. Because that, in this setting, would make it especially challenging.(TR 959)

Dr. Lubarsky testified that he did not "believe that people who do not routinely do these activities and who are not trained to do these activities can accomplish a complex multi-step task that is basically the practice of medicine." (TR 634) Dr. Lubarsky testified that "[t]he point is that it's easy to make mistakes" and that the hands-on knowledge required to identify problems with IV administration "is absolutely lacking in correctional facilities." (TR 634) Dr. Lubarsky further

elaborated that "[t]here are tons of different reasons why even after following successful insertion or what appears to be a successful insertion, it can malfunction," and that "whenever you are doing large amounts of bolus injections, you run the risk of IV disruption much more than otherwise." (TR 641-42) Additional causes for concern were that the drugs are "being injected at a large distance without direct visual contact and without tactile contact," all of which were "set-ups for failure and mistakes." (TR 642)

Dr. Lubarsky was also troubled by the lack of training regarding the stopcock, a device used to set the directional flow of the IV The stopcock apparently can be turned the wrong way, with the result that the drug will flow into the IV bag instead of into the patient. Dr. Lubarsky testified that, reading the protocol, he saw "no guarantees around one-way valves, making sure that the injection stopcocks were turned the right way," and elaborated that "I've seen over and over again by inexperienced residents who are medical professionals and doctors, who do this on a daily basis. And still they turn the stopcock occasionally the wrong way when they're under stress and pressure." (TR 644-45)

At his deposition, taken on August 29, 2007 and admitted into evidence as Court's Exhibit A, Dr. Higgins also noted potential issues that untrained individuals would not notice. (Court's Ex. A at 33-35) Dr. Higgins stated that IV catheters often slip out after they are properly inserted but that, nevertheless, swelling might not occur in surrounding tissue, and other signs of "infiltration" might not be present. (Id.) The "stopcock" might be turned the wrong way, and the catheter might slip solely due to the force of pressure from the injections, particularly where the IV tubing is very long (as it is here). (Id.) Also, a person inserting an IV might get "false positives" showing that an IV was inserted properly when, in fact, it was not. (Id. at 38) Dr. Higgins mentioned a specific issue with regard to injections in the antecubital fossa--the inside of the arm near the elbow--which is where the catheters are inserted under the new protocol, stating that "we generally discourage the placement of IV catheters in the antecubital fossa" because they have "a higher likelihood of not functioning." (Id. at 41) Dr. Higgins stated that the antecubital fossa site was a particular problem because there is actually a gap, or space ("fossa" means space), in that specific area where fluid can infiltrate unnoticed. (Id. at 81-82)

In fact, the executioners do appear to be largely ignorant of the potential pitfalls outlined by Dr. Lubarsky and Dr. Higgins. Executioner A testified that he could identify catheter infiltration by checking the flash chamber for blood, and although both Dr. Lubarsky and Dr. Higgins testified that such a test could produce "false positives," Executioner A identified no problem with this mechanism. (TR 323-24) Executioner B appeared to be unaware that the stopcock could be turned in two different directions. n15

FOOTNOTES

n15 In response to the question, "And have you ever done any practicing with how that stopcock can be used incorrectly so that the drugs go into the bag instead of into the person?" Executioner B responded, "Yes, ma'am. The stopcock--the stopcock is used as an adjust on the IV line. Using that, you can provide anything from a full flow to the drip--which is what we're looking for when the saline is going into the line--to shutting the line off. It's all accomplished with that one valve. So yes, ma'am, it's used regularly." (TR 224)

The paramedics were also unaware of certain risks identified by the expert witnesses. For instance, IV Team Member A could not identify any potential pitfalls with regard to the "stopcock," and testified that any swelling in the arm would be immediately apparent, and that "you would probably see" fluid "before you would ever feel it." (TR 372) IV Team Member B was also unable to identify these potential issues, stating that there was little worry of the catheter slipping from the vein so long as the patient was not moving, and that he could always test the IV for "flash back"--a test that Dr. Higgins identified as sometimes providing false positives. (TR 397)

To allay similar concerns with its own lethal injection protocol, the Florida lethal injection commission recommended that Florida "[d]evelop and implement a training program for all persons involved in the lethal injection process." (Docket No. 63 at 12) Among other specific recommendations, the Florida commission stated that "[a] procedure should be developed and implemented in which each training exercise is critiqued at all levels to address contingencies and the response to these contingencies," and recommended that Florida "review foreseeable lethal injection contingencies and formulate responses to the contingencies which are rehearsed in the periodic training." (Id.) In response, Florida's new lethal injection procedures provide for quarterly simulations which "shall anticipate various contingencies." n16 (Docket No. 63, Ex. 26 at 2)

FOOTNOTES

n16 In contrast, Warden Bell's monthly "practice sessions" do not address contingencies or troubleshoot in any other way. (TR 113)

Similarly, the California protocol review provides, under the heading "Screening of Execution Team Members": A panel of staff will be designated to review the qualifications of potential Lethal Injection Team Members. The Warden will chair an interview panel of at least three members, including the Associate Director, Reception Centers, to interview the candidates and make the selection of Lethal Injection Team Members . . . .State of California Lethal Injection Protocol Review, p. 12. Among other criteria, Team Members must "Have consistently demonstrated professional job performance and demeanor . . . Have no prior stress claims . . . [and] Have no history of Corrective Action within the preceding three years and no sustained disciplinary action during State employment." *Id.*

In addition, under the heading "Meaningful Training, Supervision, and Oversight of the Execution Team," the California protocol review provides that "[t]raining is designed to provide each Lethal Injection Team Member with specific knowledge of all aspects of OP 770 [the protocol], duties of their specific assignments, recent executions in other jurisdictions, current litigation, and potential problems with recommendations for avoidance or resolution." *Id.* at 13-14.

The Tennessee Protocol Committee, however, concluded that its selection and training of execution team members was sufficient. Commissioner Little testified, that although he was aware that Dr. Dershwitz told the committee that the person who monitors the administration of the drugs should have daily experience monitoring IV lines and should be able to troubleshoot potential issues, he did not provide for that skill level because "based on the information available, it's my opinion that the procedures we had were adequate for the purposes intended, inasmuch as these are not a medical procedure, per se." (TR 54)

Considering the weight of the expert witness testimony, the testimony from the executioners themselves, and the requirements recently adopted in other states, the court disagrees with Commissioner Little. The executioners have received only very limited instruction, and that instruction relates to the tasks of the IV Team Members, not the actions they are actually charged with performing. The court finds Dr. Higgins' testimony--supported at each side by Dr. Dershwitz's and Dr. Lubarsky's testimony--very compelling on this point. These are known risks--accidents which, given enough of an opportunity, will occur--for which the executioners are completely unprepared. In many cases, the executioners are not even aware that the risks exist. This is not a mere "risk of negligence" but a guarantee of accident, written directly into the protocol itself. ...

Harbison, 511 F.Supp.2d at 886-891.

VI. DEFENDANTS' KNOWING DISREGARD OF THE RISKS INHERENT IN THE PROTOCOL

The Tennessee Protocol Committee, after considerable research and consultation with medical experts, recommended a one-drug protocol to Commissioner Little. Because the one-drug protocol called only for the injection of sodium thiopental, it would have mitigated the risk of serious pain to the plaintiff outlined above. In addition, the Tennessee Protocol Committee studied the implementation of safeguards in other jurisdictions which serve to mitigate the risk of pain. However, Commissioner Little adopted neither the Committee's recommendation, nor the safeguards it studied. In so doing, Commissioner Little knowingly disregarded an excessive risk of pain to the plaintiff.

Harbison, 511 F. Supp. 2d at 895.

A. The One-Drug Protocol

Under the protocol recommended by the Committee, one dose of five grams of sodium thiopental would be administered to the inmate. (TR 595) Subsequently, a physician would assess whether or not the inmate was dead. (*Id.*) If he was not dead, another five grams of the drug would be administered. (*Id.*) In a draft of its recommendation, the Committee discussed the benefits of this method, stating: The primary advantage of the one-drug protocol is that it is much simpler to administer and provides an even lower risk of error in its administration. As compared to the two- and three-drug protocols, it has the advantage of eliminating both of the drugs which, if injected into a conscious person, would cause pain. It is similar to the humane process used in animal euthanasia. Using one drug that does not require refrigeration greatly simplifies the process of maintaining and accounting for the lethal injection drugs. Most importantly, all of the medical experts consulted by the State were very supportive of the one-drug protocol, and the 5 gram dose.(Plaintiff[Harbison] Ex. 36 at 6) In fact, if the Department of Corrections had adopted the Committee's recommendation, it would have greatly mitigated the plaintiff's risk of pain. As the Committee stated in its draft, the one-drug protocol would have eliminated the use of the second two drugs--pancuronium bromide and sodium thiopental--which, without proper anesthesia, would cause pain. Even if the sodium thiopental were improperly administered, the only result would be that the plaintiff would be given more sodium thiopental. Committee minutes, notes, and "pro" and "con" lists all, alluding to this intrinsic advantage, were introduced into evidence at the hearing. (See Plaintiff[Harbison] Ex. 7 at 1; Plaintiff[Harbison] Ex. 26 at 1; Plaintiff[Harbison] Ex. 31 at 24; TR 541; TR 544; TR 546-47) As Debbie Inglis testified, the Committee found that the only risk to the inmate under the one-drug protocol "is that the person might regain consciousness," after which more anesthesia would be given. (TR 577)

This advantage was highlighted by the medical experts consulted by the Committee. Dr. Payne highlighted the potential dangers of the three-drug protocol when he informed the Committee that the second drug "prevents the ability to tell if a person is waking up" and that, if the first drug is insufficient, "a person could wake and not be able to breathe." (Plaintiff[Harbison] Ex. 20 at 2) Gayle Ray, the Deputy Commissioner of Corrections, testified that Dr. Dershwitz later "encouraged the Committee to write a protocol that states if five grams are used, then wait five minutes, then check for circulation, heart beat. If death does not occur, wait another five minutes and check again. If death does not occur, administer five more grams." (TR 544) That is the one-drug protocol the Committee ultimately recommended.

Commissioner Little rejected that recommendation. Although he testified that he was aware that pancuronium bromide paralyzes the inmate and that potassium chloride would cause pain when it entered the body, if the inmate is not

unconscious, (TR 50-51), Commissioner Little chose not to adopt the protocol that would provide a "lower risk of error" because he did not want "Tennessee to be at the forefront of making the change from the three-drug protocol to the one drug protocol," was concerned about "political ramifications" and believed that, if the three-drug protocol was struck down in a court of law, Tennessee "could always fall back on the one-drug protocol." (TR 25-26)

Harbison, 511 F. Supp. 2d at 896.

B. Other Safeguards

In its draft, the Committee also noted that the risk of error associated with the three-drug protocol "can be minimized by adequate training of personnel and the incorporation of certain safeguards," principal among which was "[i]ncorporating a method for monitoring anesthetic depth." (Plaintiff[Harbison] Ex. 36 at 5) The Committee explored some of those safeguards with medical experts and even visited other jurisdictions that had implemented them. However, concurrently with its rejection of the one-drug protocol, the Department of Corrections failed to adopt any of the safeguards employed by these other jurisdictions.

Minutes from a March 16, 2007 meeting reflect that Dr. Payne advised the Committee that Tennessee needed a qualified person, "a pharmacist, a nurse, or an anaesthesiologist" to show the executioners how to properly mix sodium thiopental and also recommended a physical examination before the execution to give the paramedics "an opportunity to determine which veins are good before the execution." (Plaintiff[Harbison] Ex. 20 at 2, 4)

In addition, Gayle Ray testified that she and some of the other Committee members traveled to Virginia where they learned that, although Virginia continued to employ a three-drug protocol, it had implemented certain safeguards. (TR 549) Among those safeguards, Virginia had eliminated the cut-down procedure, instituted a medical examination five days before the execution, and also performed a second examination a few hours before the execution to assess the inmates' veins. (TR 550-51)

Later, the committee discussed specific methods by which a lay person could assess an inmate's consciousness with Physician A. (Plaintiff[Harbison] Ex. 29) In response to questioning by Ms. Ray and Warden Bell, the physician advised "checking for an eyelash response by brushing a finger across them . . . lifting up the person's arm . . . a pin prick or pinching the nipples." (*Id.*) In addition, Steve Elkins confirmed that he and Commissioner Little discussed "adding a step to the protocol to explicitly go over and check the level of sedation after the first drug." (TR 89-90)

Finally, the Florida Governor's Commission on Administration of Lethal Injection

issued a report, which was attached in the Appendix of the Tennessee Commission's final Report (Plaintiff[Harbison] Ex. 41), recommending numerous safeguards designed to reduce errors in its three-drug protocol. Commissioner Little confirmed that he had read this report and was aware of the recommendations in it. (TR 57-59) For instance, the Florida report recommended development of a procedure "which requires that the condemned inmate be individually assessed by appropriately trained and qualified persons at a minimum of one week prior to the scheduled execution." (Docket No. 36, Ex. 18 at 11-12) In addition, the Florida report recommended development of procedures "to ensure that unexpected event(s) are identified, including inability to access a venous site, problems with tubing, apparent consciousness of the inmate, etc." (Id. at 12)

As discussed above, the Florida report also recommended "procedures to ensure that the condemned inmate is unconscious" after the administration of sodium thiopental and training procedures "which review foreseeable lethal injection contingencies and formulate responses to the contingencies which are rehearsed in periodic training." (*Id.* at 12-13) The Florida Commission concluded with the following statement: [T]he Commission suggests that the Governor have the Florida Department of Corrections on an ongoing basis explore other more recently developed chemicals for use in a lethal injection execution with specific consideration and evaluation of the need of a paralytic drug like pancuronium bromide in an effort to make the lethal injection execution procedure less problematic.(Id. at 13) As an appendix, the Florida report included a "Physician's Statement" signed by three physicians who participated in Florida's revision to its protocol, Steve Morris, M.D., Peter Springer, M.D, F.A.C.E.P., and Dave Varlotta, D.O., concluding that "the inherent risks, and therefore the potential unreliability of lethal injection cannot be fully mitigated." (Id. at 16) Commissioner Little testified that he read this specific language. (TR 59)

The Tennessee Department of Corrections did not adopt Dr. Payne's suggestion to employ a "qualified person" to show the executioners how to mix sodium thiopental. Instead, Executioner A--the executioner with the most experience in mixing the drug--learned by watching another executioner in Texas and cannot remember when he first mixed the drug. (TR 304-05) The Tennessee Department of Corrections also did not adopt Dr. Payne's suggestion--implemented in Virginia and recommended by the Florida commission--to assess the inmate's veins a few hours prior to the execution. (TR 568) Neither did the Tennessee Department of Corrections adopt Virginia's other safeguards. (Id.) The new Tennessee protocol does not perform a medical examination at any time before the execution, and it continues to provide for the cut-down procedure if the paramedics cannot find a suitable vein. (Id.)

The Tennessee Department of Corrections also chose not to adopt any of the mechanisms Physician A suggested to the committee for assessing consciousness

or, for that matter, any of the many lengthy proscriptions made by the Florida commission, outlined above. (TR 52-54) Of particular note are the Florida committee's recommendations for training its execution team about "foreseeable lethal injection contingencies" about which the Tennessee executioners remain ignorant. (TR 113) (Testimony of Warden Bell) ("We role play them, but we do not create problem scenarios.")

In fact, while retaining the three-drug protocol, the Tennessee Department of Corrections did not adopt any new safeguards that meaningfully reduce the plaintiff's risk of suffering pain. The new protocol does provide for greater documentation of the execution n19, and it does specify that the sodium thiopental should be dispersed into four different syringes. n20 However, it also eliminated a safeguard that, according to the testimony of Gayle Ray, existed under the old protocol. n21

FOOTNOTES

n19 Debbie Inglis testified that "I think the primary thing, the importance of what we ended up doing was actually reducing this to writing and providing documentation that could be, you know, reviewed later to insure that things were done appropriately." (TR 599)

n20 There was some testimony that, in the Coe execution, only one syringe was used. (TR 335) (Testimony of Executioner A) ("Yes. Yes. There were 5 grams of sodium pentothal in one 50 cc syringe. Yes.")

n21 Ms. Ray testified that, under the old protocol, the practice had been to inspect the syringes containing sodium thiopental "every 15 to 20 minutes" to insure that the solution "does not become cloudy, form any particles, and remains completely clear" but that this provision had been removed because the Committee "did not regard it as a protection anymore." (TR 563, 567) Julian Davis testified that medical doctors had informed the committee that sodium thiopental solution could become cloudy, and that this presented a problem because this drug can be mixed as much as three hours before the execution (TR 447-8); however, Ms. Ray testified that either Dr. Payne or Dr. Dershwitz had told the committee that this step was unnecessary. (TR 563)

The court finds that Commissioner Little[] reject[ed] the one-drug protocol, and the fail[ed] to provide for any of the safeguards considered by the Committee... . Commissioner Little was both aware of facts from which the inference could be drawn that a substantial risk of serious harm to the plaintiff existed, and he also drew the inference. Although Commissioner Little was not a member of the Committee, he testified that he "dropped by" Committee meetings (TR 35-36) and also that he was "updated periodically and kept in the loop as they made progress." (TR 29) In addition, Commissioner Little was presented with the

> Committee's draft report when it made its recommendation of the one-drug protocol, and the court concludes that Commissioner Little was aware of the reasoning for the Committee's recommendation. Although Commissioner Little did not gain the breadth of knowledge that the Committee gained by questioning medical experts and examining other jurisdictions' protocols, that does not work in his favor. In fact, Commissioner Little's rejection of the Committee's recommendation in complete disregard of the expertise the Committee members gained during this process weighs in favor of the court's determination.
>
> Moreover, Commissioner Little testified that he read the Florida Commission's report, including the statement of the physicians who participated in that report. (TR 59) That statement provides, "the inherent risks, and therefore the potential unreliability of lethal injection cannot be fully mitigated." (Docket No. 63, Ex. 18 at 11-12) In addition, the Commissioner testified that he was aware of the procedures recommended in the Florida report. (TR 58-59) Accordingly, Commissioner Little cannot at this time deny that he was aware of the risks posed by the three-drug protocol.
>
> According to information the Commissioner possessed when he made his decision, the three-drug protocol as implemented in Tennessee poses an unnecessary risk of pain. That risk could have been mitigated by either (1) switching to a one-drug protocol or (2) employing additional safeguards. The Committee recommended the first option. Commissioner Little, however, neither accepted their recommendation nor instructed them to incorporate the additional safeguards in their re-formulation of the three-drug protocol.

Harbison, 511 F. Supp. 2d at 895-898.

C. Known failures of persons carrying out Tennessee's lethal injection protocols.

Defendants themselves have experienced problems with collapsed veins, or a blowout, and clogged IV lines during practice sessions with Saline; a substance much less volatile than the three drugs used during actual exectuions. (*Harbison v. Little,* No.3:06-cv-1206, Docket No. 63-19, p.2 of 7, Bell Testimony (M.D.Tenn.)). Such problems result in a level of anesthesia insufficient to prevent the condemned from experiencing the terror of suffocation from the pancuronium bromide and excruciating pain from the potassium chloride.

The inability of those persons carrying out Mr. West's execution to properly prepare

and/or administer the lethal chemicals with only the amount of guidance and training provided under the Current Protocols, even absent the pressures attendant in actually taking a human life, was known to Defendants prior to the adoption of the Current Protocol, and has been revealed during practice sessions of the Protocol.

The fact that the failure to properly prepare and/or administer the lethal chemicals will result in the infliction of unnecessary pain and suffering on Mr. West was known to Defendants prior to the adoption of the Current Protocols.

D. A Pattern of Executions Demonstrating Cruel and Unusual Death

The use of an execution protocol that causes death by conscious suffocation violates the Eighth and Fourteenth Amendments and Article 1, §16 of the Tennessee Constitution. The evidence presented establishes a pattern showing that all inmates executed under Tennessee's three-drug lethal injection protocol for whom autopsies were performed were not adequately anesthetized during the execution. The evidence establishes a pattern showing that the cause of death under Tennessee's protocol is suffocation induced by pancuronium bromide. The facts show Defendants are aware that during West's execution he will very likely experience needless suffering.

Even if carried out according to the Protocol, Tennessee's lethal injection procedure inflicts unnecessary and wanton pain and suffering. Tennessee has conducted five executions by lethal injection. Of these, autopsies were not performed on Sedley Alley or Cecil Johnson. The autopsies of the other three, Robert Coe, Phillip Workman and Steve Henley, all show they were executed in a cruel and inhumane way. Autopsies and eye-witness observations from these executions show that the Protocol creates a demonstrated risk of severe pain. The only drug to reach undisputably lethal levels is pancuronium bromide, thus indicating that all three died as a

result of suffocation. None of the three inmates had a level of sodium thiopental that would ensure unconsciousness or a level anesthesia to nullify the pain of suffocation or the pain of the potassium chloride injection. This shows that Tennessee's protocols, even if properly administered, "create a demonstrated risk of severe pain." *See Baze v. Rees*, 553 U.S. at 61 .

The Supreme Court says this establishes a valid cause of action:

> Our cases recognize that subjecting individuals to a risk of future harm--not simply actually inflicting pain--can qualify as cruel and unusual punishment. To establish that such exposure violates the Eighth Amendment, however, the conditions presenting the risk must be "sure or very likely to cause serious illness and needless suffering," and give rise to "sufficiently imminent dangers." *Helling v. McKinney*, 509 U.S. 25, 33, 34-35, 113 S. Ct. 2475, 125 L. Ed. 2d 22 (1993) (emphasis added). We have explained that to prevail on such a claim there must be a "substantial risk of serious harm," an "objectively intolerable risk of harm" that prevents prison officials from pleading that they were "subjectively blameless for purposes of the Eighth Amendment." *Farmer v. Brennan*, 511 U.S. 825, 842, 846, and n. 9, 114 S. Ct. 1970, 128 L. Ed. 2d 811 (1994).
>
> 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. In *Louisiana ex rel. Francis v. Resweber*, 329 U.S. 459 (1947), a plurality of the Court upheld a second attempt at executing a prisoner by electrocution after a mechanical malfunction had interfered with the first attempt. The principal opinion noted that "[a]ccidents happen for which no man is to blame," *id.*, at 462, and concluded that such "an accident, with no suggestion of malevolence," *id.*, at 463, did not give rise to an Eighth Amendment violation, *id.*, at 463-464.
>
> As Justice Frankfurter noted in a separate opinion based on the Due Process Clause, however, "a hypothetical situation" involving "a series of abortive attempts at electrocution" would present a different case. *Id.*, at 471 (concurring opinion). In terms of our present Eighth Amendment analysis, such a situation-unlike an "innocent misadventure," *id.*, at 470, would demonstrate an "objectively intolerable risk of harm" that officials may not ignore. See *Farmer*, 511 U.S., at 846, and n. 9. In other words, 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." *Id.*, at 842.

Baze v. Rees, 553 U.S. 35, 49-50 (2008).

Mr. West's evidence does not present an "accident" or "innocent misadventure" resulting in conscious suffocation. Rather, it proves a pattern or "series" of cruel executions where all autopsied inmates were not sufficiently anesthetized; something state officials may not ignore.

E. Coe Execution

Robert Coe's autopsy report reveals that his execution occurred according to the Protocol and without mishaps. The intravenous catheters used for his execution remained properly placed in accordance with the Tennessee Protocol in the superficial blood vessels of the antecubital fossa of both of Mr. Coe's arms (Plaintiff's Exhibit 26 Bates p.05). Mr. Coe's autopsy did not describe any signs of infiltration at the injection site. *See also* Dr. Levy testimony, *Harbison v. Little, et al*, No. 3:06-cv-01206, Docket No. 142, TR725-26, Docket No. 143, TR903-04 (M.D. Tenn.).

1. Sodium thiopental level

Coe's toxicology report indicates a sodium thiopental level of 10.2 mg/L. (Plaintiff's Exhibit 26, Bates p.13). Assuming that Dr. Levy, who conducted the autopsy, correctly recalled that the blood sample was obtained from a peripheral location, *i.e.*, one of his femoral vessels, there is no substantial question but that the toxicology report accurately reflects his serum thiopental level at the time of death.

2. Pancuronium bromide level

The Coe autopsy report reveals a pancuronium bromide level of 4.7 mg/L. (Plaintiff's Exhibit 26, Coe Autopsy, Bates p.14). This level is far above that required to cause full paralysis and death by suffocation. (Plaintiff's Exhibit 32, 2010 Affidavit of Dr. Lubarsky, p.4-5).

3. Potassium chloride level

The Coe autopsy report shows his vitreous potassium was 9 mEq/L (9 mmol/L), far short

of the required minimum 16.4 mEq/l to cause electro mechanical arrest of the heart (Plaintiff's Exhibit 34, Affidavit of James Ramsey, p.8-9 ¶XXXI; *See* Ramsey testimony, *Harbison v. Little, et al*, No. 3:06-cv-1206, Docket No. 139, TR 262-63 (M.D. Tenn.)). Dr. Higgins testified in *Harbison*, that a potassium level of nine milliequivalents might not be fatal and a person like Mr. Coe could survive (*Harbison v. Little,* No. 3:06-cv-1206, at DE 143, TR950-51). Dr. Levy testified in *Harbison* that the only drug level in Mr. Coe's blood to completely reach a lethal level was the pancuronium bromide (*Id.*, at TR 920).

4. Cause of death

Mr. Coe died from suffocation caused by the pancuronium bromide and the resulting anoxic state, and not from cardiac arrest due to the administration of potassium chloride. Because he was likely inadequately anesthetized, he experienced the sensation and horror of suffocation from the pancuronium bromide, as well the excruciating pain associated with the introduction of potassium chloride. Mr. Coe was executed by suffocation while inadequately anesthetized.

F. Workman Execution

Philip Workman was executed on May 9, 2007, under the current Tennessee Protocol. The autopsy report was completed on October 24, 2007. (Plaintiff's Exhibit 27 Bates p.01). The autopsy report reveals that his execution occurred according to the Protocol and without mishaps. The report reveals that the intravenous catheters used for his execution remained properly placed in accordance with the Tennessee Protocol in the superficial blood vessels of the antecubital fossa of both of Mr. Workman's arms (Plaintiff's Exhibit 27 Bates p.05). Mr. Workman's autopsy report did not describe any signs of infiltration at the injection site. *See also* Dr. Levy testimony, *Harbison v. Little, et al*, No. 3:06-cv-1206, Docket No. 142, TR725-26,

Docket No. 143, TR903-04 (M.D. Tenn.).

1. Sodium thiopental

Mr. Workman's post-mortem thiopental level was 18.9 mg/L, (Plaintiff's Exhibit 27 Bates p.03, 07), which means he was not fully anesthetized during his execution (Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky, p.5).

Mr. Workman's autopsy was not performed, and blood was not drawn, until ten days after his execution (Plaintiff's Exhibit 27, Bates p.03). The blood sample used to determine Mr. Workman's level of thiopental was taken from his heart (*Id.* at p.7). Dr. Levy, who performed Mr. Workman's autopsy, testified that thiopental redistributes from the extremities back to the heart following death, making those levels higher than would be found at the time of death. *Harbison v. Little,* No. 3:06-cv-1206, Docket No. 142, TR733-34 (M.D.Tenn.); *see also* Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky, p.5. Due to the time lapse and post-mortem distribution, there is an even greater probability that the level of thiopental in Mr. Workman at the time of his death was less than 18.9 mg/L found in the heart blood drawn ten days after his death (Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky, p.5-6).

2. Pancuronium bromide level

The Workman autopsy reports a pancuronium bromide level of .630 mg/L. (Plaintiff's Exhibit 27, Workman Autopsy Bates p.03, 07). This is sufficient to cause full paralysis and death by suffocation. (Plaintiff's Exhibit 32, 2010 Affidavit of Dr. Lubarsky, p.6).

3. Potassium chloride level

The Workman autopsy report shows his vitreous potassium level was 9 mEq/l (9 mmol/l) (Plaintiff's Exhibit 27, Workman Autopsy, Bates p.12). This level is far short of the required minimum 16.4 mEq/L to cause electro mechanical arrest of the heart. (Plaintiff's Exhibit 34,

Ramsey Affidavit, p.7¶XXVII; *See* Ramsey testimony, *Harbison v. Little,* No. 3:06-cv-1206, Docket No.139, TR262-64 (M.D. Tenn.)).

4. Cause of death

The post-mortem drug level of thiopental measured in Mr. Workman would not be sufficient to produce unconsciousness or anesthesia. Mr. Workman died from suffocation caused by the pancuronium bromide and the resulting anoxic state, and not from cardiac arrest due to the administration of potassium chloride. This means that during the execution procedure, Mr. Workman was probably awake, suffocating in silence, and feeling the searing pain caused by the intravenous injection of potassium chloride (*Id.* p.6). Mr. Workman was executed by suffocation while inadequately anesthetized.

G. Henley Execution

Steve Henley was executed on February 4, 2009, under the current Tennessee Protocol. The autopsy report on Mr. Henley was finalized more than a year later on February 17, 2010, and released on March 10, 2010. (Plaintiff's Exhibit 29, Henley Autopsy, Bates p.01, 07). The autopsy report reveals that his execution occurred according to the Protocol and without mishaps. The autopsy report reveals that the intravenous catheters used for his execution remained properly placed in accordance with the Tennessee Protocol in the superficial blood vessels of the antecubital fossa of both of Mr. Henley's arms, (Plaintiff's Exhibit 29, Henley Autopsy, Bates p.04), and that all drugs had been fully dispensed in accordance with the Tennessee Protocol (*Id.*). Mr. Henley's autopsy report did not describe any signs of infiltration at the injection site. Witnesses observed Mr. Henley turn blue to purple in color during the execution process (Plaintiff's Exhibit 30, Affidavit of Stacy Rector & exhibits attached thereto).

1. Sodium thiopental

Mr. Henley's autopsy report reveals his sodium thiopental level was 8.31 mg/L; an amount inadequate to cause Mr. Henley to be unconscious during his execution (Plaintiff's Exhibit 29, Henley Autopsy, Bates p.02, 06, 09; Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky, p.6).

2. Pancuronium bromide level

Mr. Henley's pancuronium bromide level was 1.6 mg/L, far above the level required to cause full paralysis and death through suffocation (Plaintiff's Exhibit 29, Henley Autopsy, Bates p.02, 06; Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky, p.7).

3. Potassium chloride level

Mr. Henley's potassium level was 6 mEq/L, which is not elevated from normal and would have had no effect on his heart (Plaintiff's Exhibit 29, Henley Autopsy, Bates p.02, 06, 19; Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky p.6-7). The potassium level is far short of the required minimum 16.4 mEq/L to cause electromechanical arrest of the heart (Plaintiff's Exhibit 34, Ramsey Affidavit p.7¶XXVII; *See* Ramsey testimony, *Harbison v. Little,* No. 3:06-cv-1206, Docket No. 139, TR 262-64 (M.D.Tenn.)). This is consistent with the observations of witnesses to Mr. Henley's execution that his face began to turn blue to purple approximately seven minutes after the execution because a change of color occurs when non-oxygenated blood is pumped to the extremities by a beating heart (Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky, p.7).

4. Cause of death

Eyewitness accounts that Mr. Henley turned blue to purple during the execution are consistent with death by suffocation (Plaintiff's Exhibit 28, Affidavit of Dr. Lubarsky, p.7). Mr. Henley's death was caused by suffocation induced by pancuronium bromide at a time when

he was not adequately anesthetized (*Id.*).

Mr. Henley died from suffocation caused by the pancuronium bromide and the resulting anoxic state, and not from cardiac arrest due to the administration of potassium chloride. Because he was likely inadequately anesthetized, he experienced the sensation and horror of suffocation from the pancuronium bromide, as well the excruciating pain associated with the introduction of potassium chloride. Mr. Henley was executed by suffocation while inadequately anesthetized.

VII. PANCURONIUM BROMIDE, WHEN ADMINISTERED AS INTENDED, IS THE FATAL AGENT UNDER THE TENNESSEE PROTOCOL AND CONSTITUTES CRUEL AND UNUSUAL PUNISHMENT.

Pancuronium bromide is a neuromuscular blocking agent which causes paralysis of the skeletal muscles of an individual. While pancuronium bromide paralyzes the diaphragm to prevent breathing, it does not affect the heart muscle. Pancuronium bromide does not affect the brain or nervous system, nor does it block the actual reception of nerve impulses in the brain or the passage of such impulses within the brain. Pancuronium bromide does not affect consciousness or the sensation of pain or suffering. An individual under the influence of pancuronium bromide, though paralyzed, still has the ability to think, to be oriented to where he is, to experience fear or terror, to feel pain, and to hear. (*See Harbison v. Little,* No. 3:06-cv-01206, Docket No. 138, TR 50; Levy testimony, Docket No. 142, TR 718; Higgins testimony, Docket No. 143. TR 953 (M.D.Tenn.)). *See also, Harbison*, 511 F.Supp.2d at 883-84.

Because pancuronium bromide paralyzes all skeletal muscles including facial muscles and those used to speak or communicate through noises, an observer cannot detect, from outward appearance, any expression of pain, horror, or suffering experienced because of the use of pancuronium bromide or suffering from any other source, such as potassium chloride which will

activate the nerves of the venous system causing an extreme burning pain.

A lethal level of pancuronium is 0.16 mg/L (Plaintiff's Exhibit 33, Winek, *Drug & Chemical Blood-Level Data 2001,* p.12). Pancuronium bromide in the levels produced by Tennessee's execution protocol will ultimately cause someone to asphyxiate or suffocate to death while still conscious.

If an individual is not properly anesthetized when injected with pancuronium bromide, he will consciously experience extreme pain and terror while being completely paralyzed. In this state, the person will undergo the terrorizing and excruciating experience of suffocation without the ability to move or to express the pain and suffering which he is experiencing as he is being suffocated. *Baze*, 553 U.S. at 54; *Harbison*, 511 F.Supp.2d at 883-84.

Pancuronium bromide, administered by itself as a "lethal dose," would not result in a quick death; instead, it would ultimately cause someone to asphyxiate or suffocate to death while still conscious.

Death by asphyxiation or suffocation constitutes cruel or unusual punishment.

A. Pancuronium Bromide Is the Only Drug in Tennessee's Three-Drug Protocol that Reaches Lethal Levels

The Protocol uses two syringes containing a total of 100mg/100mL of pancuronium bromide as a "muscle paralytic" that will "assist in the suppression of breathing and insure death" (Plaintiff's Exhibit 4 p. 35). The Tennessee Protocol, when administered as designed, will inject an amount of pancuronium bromide that will paralyze and suffocate Mr. West, causing his death. The use of pancuronium bromide to paralyze Plaintiff greatly increases the risk that he will be subjected to a painful and protracted death.

The Current Protocol fails to insure the proper storage and effectiveness of pancuronium

bromide before its use (assuming it is to effect a quicker death). The Current Protocol acknowledges that pancuronium bromide "must be refrigerated at approximately 40 degrees" (Plaintiff's Exhibit 4 p.36). The Committee Report acknowledges that use of a one-drug protocol would entail less risk because it would "not require refrigeration" (Plaintiff's Exhibit 4 p.8). However, the Current Protocol directs that three hours before the scheduled execution, the pancuronium bromide, and other Lethal Injection Chemicals, will be moved to the Lethal Injection Room (Plaintiff's Exhibit 4 p.38). The pancuronium bromide could remain in the Lethal Injection Room, at room temperature or higher, for up to 25 hours and 59 minutes before being used. This procedure and handling of pancuronium bromide demonstrates deliberate indifference to the unnecessary risk of pain and suffering by failing to insure the effectiveness of the drug before its use (assuming it is to effect a quicker death).

B. There Is No Legitimate Purpose for Using Pancuronium Bromide in Executions

The pancuronium bromide levels in Mr. Coe (4.7 mg/L), Mr. Workman (.630 mg/L), and Mr. Henley (1.6 mg/L), were above 0.16 mg/L, and were sufficient to cause paralysis and death by suffocation (Plaintiff's Exhibit 26, Coe Autopsy, Bates p.14; Plaintiff's Exhibit 27, Workman Autopsy, Bates p.03, 07; Plaintiff's Exhibit 29, Henley Autopsy, Bates p.02; Plaintiff's Exhibit 32, 2010 Affidavit of Dr. Lubarsky, p.4-5, 6, 7). In each of these executions, it was the only drug to reach lethal levels. This means death under Tennessee's protocol is achieved through asphyxiation, an unquestionably cruel and unusual punishment.

There is no legitimate penological purpose and no legitimate state interest for the use of pancuronium bromide articulated in the Protocol, or otherwise. The use of pancuronium bromide, also known as Pavulon, is not narrowly tailored to any compelling state interest

articulated in the Protocol, or otherwise. *See* Plaintiff's Exhibit 4, p.35; Plaintiff's Exhibit 5, p.7-8. Chancellor Ellen Hobbs Lyle has explained that pancuronium bromide as used in the Tennessee Protocol is unconstitutional: "[T]he use of Pavulon is . . . unnecessary. . . [T]he State [has] failed to demonstrate any reason for its use. The record is devoid of proof that the Pavulon is needed. Thus, the Court concludes that . . . the State's use of Pavulon is . . . in legal terms 'arbitrary.'" *Abdur'Rahman v. Sundquist*, No. 02-2236-III, opinion p. 13 (Tenn. Ch. 20th Jud. Dist. June 2, 2003).

The creator of the original three-drug protocol believes pancuronium bromide should be eliminated from the protocol and, if he were to create a protocol today, he would eliminate it. (Plaintiff's Exhibit 36, Cohen, Elizabeth, *Lethal Injection Creator: Maybe It's Time to Change Formula*, www.CNN.com/2007/HEALTH/05/07/lethal.injection/index.html).

The Committee which adopted the three-drug protocol set forth no compelling state interest for the use of pancuronium bromide. It does not speed or contribute to the death process. *See* Plaintiff's Exhibit 5, p.7. The Committee acknowledges that without the use of pancuronium bromide, the condemned would be able to move and communicate if not properly anesthetized. *Id.* at p.7-8. This would allow the condemned to communicate if the sodium thiopental did not properly anesthetize the person. The Committee, instead, arbitrarily attributes any such movement as "involuntary movement which might be misinterpreted as a seizure or an indication of consciousness." *Id.* at p.8. This is especially egregious since the Tennessee Protocol does not provide for any check for consciousness following administration of the sodium thiopental. Thus the Committee has displayed deliberate indifference to assuring that the condemned is properly anesthetized or to account for any contingency planning in the improper mixing and/or administration of the sodium thiopental thus creating an unnecessary risk of pain and suffering.

The Committee noted pancuronium bromide, when properly administered, "prevents involuntary muscular movement" (Plaintiff's Exhibit 5, p.7). However, using pancuronium bromide to prevent such movement "that *may* interfere with the proper functioning of the IV equipment," *id.*, is not necessary nor narrowly tailored to meet the stated objective. Under the Current Protocol, the prisoner's arms are securely restrained to the gurney (Plaintiff's Exhibit 4, p.64); the catheters are covered with dressing (Plaintiff's Exhibit 4, p.42); the IV lines are taped in place near the catheter, *id.*; and the prisoner's hands are taped in place (Plaintiff's Exhibit 4, p.43). There is a final inspection of the restraint devices to insure the condemned is secure on the gurney (Plaintiff's Exhibit 4, p.14). These restraining devices are designed to keep the body parts containing catheters and IV lines still; there is no need to also paralyze the prisoner. Moreover, movements observed during actual executions are not caused by proper administration of the first drug, sodium thiopental, which is supposed to place the prisoner under a surgical plane of anesthesia. Movements observed during actual executions are caused when the second drug, pancuronium bromide, suffocates the person and his chest heaves as he gasps for air. Thus, the very drug purportedly used to prevent movements of the body actually induces such movements.

The use of pancuronium bromide in the Current Protocol is arbitrary, unreasonable, degrading to human dignity, shocks the conscience and serves no legitimate interest. Because pancuronium bromide causes paralysis, suffocation, and the suffering attendant to such paralysis and suffocation, in 2001, Tennessee declared in the "Nonlivestock Humane Death Act" (TENN. CODE ANN. § 44-17-301, *et seq.*) that pancuronium bromide cannot be used to euthanize animals, because its use is not humane. Where the use of pancuronium bromide is not "humane" to use on non-humans, it is arbitrary and shocks the conscience to claim that its use is "humane" on

humans. Its use on humans to cause death violates basic precepts of human dignity.

Death caused by the use of pancuronium bromide is gruesome, horrible, and painful. Pancuronium bromide could not lawfully be used alone as the fatal agent because causing death by suffocation violates the Eighth Amendment's and Tennessee Constitution Article 1, § 16's prohibition against cruel and unusual punishment.

VIII. POTASSIUM CHLORIDE, WHEN ADMINISTERED AS INTENDED, UNDER THE TENNESSEE PROTOCOL DOES NOT INDUCE CARDIAC ARREST AND CONSTITUTES CRUEL AND UNUSUAL PUNISHMENT.

The Tennessee Protocol lacks any provision for ascertaining the level of the prisoner's anesthetic depth before introduction of the potassium chloride. The administration of potassium chloride activates all the nerve fibers inside the venous system. Because veins are replete with nerve fibers, the administration of potassium chloride into the veins creates extreme pain.

In the Tennessee Protocol, potassium chloride is the stated means for "cardiac arrest and rapid death" (Plaintiff's Exhibit 4, Tennessee Protocol, p.35). Under the Protocol, 100 mL of 2 mEq/mL, or 100 mg/mL of 2mEq/mL, of potassium chloride is introduced *via* two syringes into the body through a vein, usually in the arm. This method of administering this amount of potassium chloride is inadequate to stop the heart. It is a pathophysiological impossibility for the heart to succumb to electro mechanical arrest due to the potassium component of the Current Protocol (Ramsey Affidavit, Plaintiff's Exhibit 34, p.9 ¶xxxii).

It takes a serum concentration of more than 16 mEq/l (16mmol/l) of potassium to arrest the heart (Plaintiff's Exhibit 34, Affidavit of James Ramsey p.6-7 ¶¶XXV & XXVII; *See* Ramsey testimony, *Harbison v. Little,* No. 3:06-cv-1206, Docket No. 139, TR 262-64; TR 272-78 (M.D. Tenn.)).

The autopsy report of Robert Coe demonstrates that his vitreous potassium was 9 mEq/L

(9 mmol/L), far short of the required minimum 16.4 mEq/l to cause electro mechanical arrest of the heart (Plaintiff's Exhibit 34, Affidavit of James Ramsey, p.8-9 ¶XXXI; *See* Ramsey testimony, *Harbison v. Little, id.* at Docket No. 139, TR 262-63). Dr. Higgins testified that a potassium level of nine milliequivalents might not be fatal and a person like Mr. Coe could survive (*Harbison v. Little, id.* at Docket No. 143, TR 950-51). Dr. Levy testified that the only drug level in Mr. Coe's blood to completely reach a lethal level was the pancuronium bromide (*Id.*, TR 920).

The autopsy report of Philip Workman indicates his vitreous potassium level was 9 mEq/l (9 mmol/l) (Plaintiff's Exhibit 27, Workman Autopsy, Bates p.12). This level is far short of the required minimum 16.4 mEq/L to cause electro mechanical arrest of the heart.

The autopsy report of Steve Henley demonstrates that his vitreous potassium was 6 mEq/L (6mmol/L) (Plaintiff's Exhibit 29, Henley Autopsy, Bates p.19). The vitreous potassium level was normal, not elevated, and far short of the required minimum 16.4 mEq/L to cause electromechanical arrest of the heart (Plaintiff's Exhibit 34, Ramsey Affidavit, p.7 ¶XXVII; *See* Ramsey testimony, *Harbison v. Little, id.* at Docket No. 139, TR262-64). Witnesses to the Henley execution observed his skin color turn blue to purple during his execution (Plaintiff's Exhibit 30, Affidavit of Stacy Rector & exhibits attached thereto). Mr. Henley's change in skin color is consistent with death by suffocation while his heart continued to beat (Plaintiff's Exhibit 32, 2010 Affidavit of Dr. Lubarsky, p.7).

One of the main contributing factors to low potassium concentration solutions reaching the heart would be that, given an intravenous injection, the solution would necessarily have to pass through the lungs (which have the surface area of approximately that of a tennis court) during which the potassium concentrations would fall dramatically (Plaintiff's Exhibit 34,

Affidavit of James Ramsey p.8 ¶XXX; *See* Ramsey testimony, *Harbison v. Little, id.* at Docket No. 139, TR 257-58).

If potassium chloride contributes to death then cardiac activity ought to cease more quickly when potassium is used in a lethal injection protocol than when it is not. Data from North Carolina executions, however, shows that the use of potassium chloride did not hasten death over a protocol that used a thiopental and pancuronium alone. Teresa A. Zimmers, et al, *Lethal Injection for Execution: Chemical Asphyxiation?* 4 PLOS Medicine 0004 (April 2007).

In California executions, ECG flatlining was noted from 2 to 9 minutes after potassium chloride administration. *Id.* at p.0005. This observation contrasts administration of potassium chloride in which patients experienced complete cardiopulmonary arrest almost immediately upon injection. *Id.* Additional doses of potassium chloride were administered in three California executions before the inmate died. PLOS, p.0003. This data coupled with the North Carolina data, the data from Tennessee executions that potassium chloride did not reach lethal levels, and the observations that Steve Henley's skin color turned to blue and purple indicates that potassium chloride cannot reliably be the agent of death in Tennessee three-drug protocol.

Using an amount of, and a method of administering, potassium chloride which does not arrest the heart is meaningless and arbitrary and without a legitimate or compelling purpose. It will not hasten or effect death. It will only inflict excruciating pain if the condemned is not properly anesthetized. Instead, the killing agent will be the pancuronium bromide meaning death by suffocation or asphyxiation.

The Tennessee Protocol, when administered as designed, will inject an amount of potassium chloride that will not cause Mr. West's death but will cause excruciating pain. If Mr. West remains conscious during the administration of the potassium chloride, he will suffer

excruciating pain. Due to the paralysis induced by the pancuronium bromide, he will have no alternative reasonable and effective means to communicate the fact that he was not properly anesthetized. He will suffer a terrifying and painful death by suffocation. This constitutes cruel and unusual punishment and Defendants cannot ignore the substantial risk of such severe pain resulting from the Tennessee protocol.

IX. TENNESSEE'S LETHAL INJECTION PROTOCOL IS NOT SUBSTANTIALLY SIMILAR TO THE KENTUCKY PROTOCOL APPROVED BY THE SUPREME COURT IN *BAZE V. REES*, 553 U.S. 35 (2008).

Tennessee's protocol is substantially different from Kentucky's protocol approved by the Supreme Court in *Baze v. Rees*, 553 U.S. 35 (2008). The three-drug protocol as implemented in Tennessee contains substantial risk that is compounded by deficiencies and a lack of safeguards not seen in Kentucky.

Tennessee's protocol does not include important safeguards recommended by the Committee and adopted by other states. *Harbison*, 511 F.Supp.2d at 895. "[T]he most glaring omission" is a check for consciousness before the pancuronium bromide is administered. *Id.* at 884.

"Kentucky's protocol specifically requires the warden to redirect the flow of chemicals to the backup IV site if the prisoner does not lose consciousness within 60 seconds" and to watch for signs of infiltration. *Baze*, 553 U.S. at 56. The Tennessee Protocol does not.

The Tennessee Protocol's failure to provide a check for consciousness or monitoring for signs of infiltration "greatly increased the risk of pain because the pancuronium bromide would make it impossible for Warden Bell to determine if [the inmate] is suffering." *Harbison*, 511 F.Supp.2d at 884. Additionally, Warden Bell does not know what signs to look for should infiltration occur. *See Harbison*, 571 F.3d at 540 n1 (Clay, J., dissenting). These are significant

differences from the Kentucky protocol.

Tennessee officials recognized and a district court has found, "the failure to check for consciousness greatly enhances the risk that the inmate will suffer unnecessary pain." *Harbison*, 511 F.Supp.2d at 884. The Kentucky court did not so find.

One of the primary reasons that the *Baze* Court concluded Kentucky's protocol did not present a "subtantial" risk of harm from an improper administration of sodium thiopental was this check for consciousness. *Baze*, 553 U.S. at 56 ("it was the explicit measures Kentucky took to ensure the proper administration of sodium thiopental that made the protocol in Baze constitutional."). Again, this critical step of checking for consciousness is lacking from the Tennessee Protocol.

Other shortcomings in Tennessee's Protocol create substantial risks not present in the Kentucky protocol. "The risk created by Tennessee's decision not to check for consciousness is compounded by Tennessee's choice of individuals to mix and inject the drugs and monitor the IV lines during executions." *Harbison*, 511 F.Supp.2d at 886. Similar shortcomings were not found in Kentucky's protocol or in Kentucky's personnel.

Ralph Baze conceded, and the Kentucky courts found, that "'if performed properly,' an execution carried out under Kentucky's procedures would be 'humane and constitutional.'" *Baze,* 553 U.S. at 49. West does not so concede. A federal district court found that Tennessee's Protocol contains inherent, significant risks of error, even when properly followed. *Harbison*, 511 F.Supp.2d at 891 ("This is not a mere 'risk of negligence' but a guarantee of accident, written directly into the protocol itself."); *see also id.* at 880-82.

There is an inherent risk that even an initially properly inserted catheter will slip from the vein during the injections of the lethal drugs. There is also a risk that "a person inserting an IV

might get 'false positives' showing that an IV was inserted properly when, in fact, it was not." Expert testimony in *Harbison* showed that IV catheters do move "with a fairly high frequency," from veins into outer tissue even in a clinical setting. *Id.* at 889. Dr. Dershwitz, an expert witness for the State of Tennessee in *Harbison*, stated that '[s]ometimes intravenous catheters fail' and that if the only individuals who are trained in monitoring IV lines leave the room following insertion of the catheters--which is what the new protocol dictates--he 'think[s] it is logical to assume that there's an increased risk.'" *Id.* at 888. The Kentucky court did not make similar findings.

A district court has found IV disruption is much more likely to occur under Tennessee's Protocol where untrained executioners administer large amounts of bolus injections, from far away, through long IV lines, "'without direct visual contact and without tactile contact,' all of which [are] 'set-ups for failure and mistakes.'" *Id.* at 889. The Kentucky court did not make similar findings. Accordingly these facts were not present in the Supreme Court's analysis of the Kentucky protocol.

Under Tennessee's Current Protocol swelling might not occur in surrounding tissue, and other signs of 'infiltration' might not be present," thus, making detection by untrained executioners unlikely. *Id.* at 890. Under the Current Protocol, such errors could not be detected by remote visual observation of the injection site, especially at the antecubital fossa, and that the IV Team members and the Executioners were "largely ignorant" about reliable ways to detect infiltration. *Id.* This is another significant difference from the Kentucky court's finding that errors in administration of the anesthetic under Kentucky's protocol could easily be detected by a lay person looking for swelling at the injection site. *Baze*, 553 U.S. at 56.

A further important distinction is that, under Kentucky's protocol, the training level of

personnel performing executions was found not to pose a substantial risk of pain to Baze, in light of safeguards included in the protocol. *Id.* In contrast, the Executioners selected under Tennessee's Protocol "received only very limited instruction, and that instruction relates to the tasks of the IV Team Members, not the actions they are actually charged with performing." *Harbison*, 511 F.Supp.2d at 891. During practice sessions, the Executioners "do not receive any instruction . . . from the paramedics or any other medically qualified individuals. They do not troubleshoot potential problems that might occur, such as catheter infiltration, but simply practice performing their functions with saline solution." *Id.* at 887.

A further factor in this analysis is the fact that "the decision to remove the paramedics from the execution chamber before the administration of the drugs would 'certainly increase the risk' of pain." *Id.* at 889. The *Harbison* Court found "[t]he conclusion that somehow the 'participation of the certified IV team' in inserting the catheters and the 'presence of a doctor,' who is standing in a garage, somehow makes up for the failure to monitor the inmate for consciousness before the injection of the two drugs likely to cause pain is entirely unwarranted by the evidence . . ." *Id.* at 900. Thus, "the failure to utilize adequately trained executioners increases the plaintiff's [Harbison's] risk of unnecessary pain." *Id.* at 891. Similar findings were not made about the Kentucky protocol.

Experts told Tennessee officials that "with regard to mixing the sodium thiopental (the first drug), '[y]ou need someone who knows how to show them how to mix--a pharmacist, a nurse, or an anaesthesiologist.'" *Harbison*, 511 F.Supp.2d at 876; *See* Lubarsky testimony, *Harbison v. Little, et al*, M.D. Tenn., No. 3:06-cv-1206, Docket No. 142, TR 657; *see* Physician A testimony, *Harbison v. Little, et al*, M.D. Tenn., No. 3:06-cv-1206, Docket No. 142, TR 497, 503-04. Tennessee, instead, selected a person without training in mixing sodium thiopental but

who had once watched a Texas executioner perform the same task. *Harbison*, 511 F.Supp.2d at 886-87, 897. The *Harbison* Court found this compounded the risk of harm in the three-drug protocol as implemented in Tennessee. *Id.* Similar findings were not made about Kentucky's implementation of its protocol.

Another factor further distinguishes Tennessee's protocol from Kentucky's. The new Tennessee Protocol eliminated a safeguard that existed under the old protocol. *Id.* at 898.

The Tennessee Protocol, when performed as written, does not sufficiently anesthetize the condemned prisoner. Evidence from past Tennessee executions proves this. *See* Workman, Coe and Henley autopsies, Plaintiff's Exhibits 27, 26 and 29, respectively. Kentucky's protocol does.

The only drug to reach lethal levels in the inmates executed under Tennessee's protocol is pancuronium bromide. This fact was not found under the Kentucky protocol.

Finally, in stark contrast to the *Baze* case, Tennessee officials failed to adopt an alternative one-drug protocol which they knew was feasible, was recommended by the Protocol Committee and all of the consulting experts, and which would eliminate the risks of pain inherent in Tennessee's three-drug protocol. The *Harbison* Court found "that Commissioner Little's rejection of the one-drug protocol, and the failure to provide for any of the safeguards considered by the Committee, constitutes deliberate indifference[ ]" to "a substantial risk of serious harm . . . ." *Id.* at 898. Kentucky officials did not adopt a protocol with deliberate indifference to a substantial risk of serious harm.

Tennessee's Protocol differs in substantial aspects to the Kentucky protocol. Accordingly, the outcome in neither *Baze* nor *Harbison*, 571 F.3d 531 (6th Cir. 2009), controls the disposition of Mr. West's case.

PRAYER FOR RELIEF

WHEREFORE, Mr. West respectfully requests:

Declaratory judgment declaring that execution by means of lethal injection in the manner prescribed by Tennessee's Current Execution Protocol, Plaintiff's Exhibit 4, violates the Eighth and Fourteenth Amendments and Tennessee Constitution Article 1, § 16.

Declaratory judgment declaring that Defendants must comply with those provisions on Pages 12 and 88 of the Current Protocol prior to carrying out his execution.

Temporary, preliminary and permanent injunctive relief directing the Defendants, their officers, agents, servants, employees, and all persons acting in concert with them to carry out Mr. West's November 30, 2010, execution in a manner which does not violate Eighth and Fourteenth Amendments and Tennessee Constitution Article 1, § 16, as does execution by means of lethal injection in the manner prescribed by Tennessee's Current Execution Protocol, Plaintiff's Exhibit

4.

Temporary, preliminary and permanent injunctive relief directing the Defendants, their officers, agents, servants, employees, and all persons acting in concert with them to comply with the provisions of Pages 12 and 88 described in Count VIII hereof prior to carrying out Mr. West's November 9, 2010, execution in a manner which does not violates Eighth and Fourteenth Amendments and Tennessee Constitution Article 1, § 16 as does execution by means of lethal injection in the manner prescribed by Tennessee's Current Execution Protocol, Plaintiff's Exhibit 4.

Temporary, preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from executing

Mr. West by lethal injection using the Tennessee three-drug lethal injection protocol.

In the event that the Tennessee Protocol is not enjoined in its entirety as violating the Eighth and Fourteenth Amendments and Tennessee Constitution Article 1, § 16, temporary, preliminary, and permanent injunctive relief to enjoin Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from administering the short acting barbiturate, sodium thiopental, in the manner prescribed by the Tennessee Protocol, which does not render the inmate unconscious, and thereafter subjects him to a horrifying and excruciatingly painful death through the use of pancuronium bromide and potassium chloride.

In the event that the Tennessee Protocol is not enjoined in its entirety as violating the Eighth and Fourteenth Amendments and Tennessee Constitution Article 1, § 16, temporary, preliminary, and permanent injunctive relief to enjoin Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from administering pancuronium bromide during the execution process which serves no legitimate purpose but paralyzes the prisoner and causes suffocation or asphyxiation.

In the event that the Protocol is not enjoined in its entirety as violating the Eighth and Fourteenth Amendments and Tennessee Constitution Article 1, § 16, temporary, preliminary, and permanent injunctive relief to enjoin Defendants, their officers, agents, servants, employees, and all persons acting in concert with them from administering potassium chloride during the execution process which serves no legitimate purpose, does not arrest the heart, but causes excruciating internal burning.

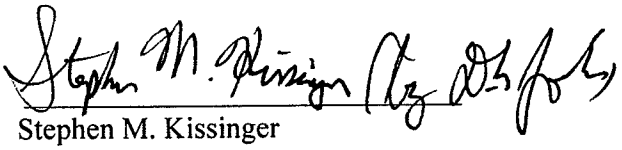
In the event that the Protocol is not enjoined in its entirety as violating the Eighth and Fourteenth Amendments and Tennessee Constitution Article 1, § 16, temporary, preliminary, and permanent injunctive relief to enjoin Defendants, their officers, agents, servants, employees,

and all persons acting in concert with them from allowing personnel who lack sufficient training, credentials, certification, experience, or proficiency to conduct a lethal injection procedure which is materially different from the Kentucky protocol addressed in *Baze* and which thereby needlessly poses a substantial risk of a conscious prisoner experiencing a horrifying and excruciatingly painful death.

Any further relief that this Court finds necessary and just.

Respectfully submitted,

FEDERAL DEFENDER SERVICES
OF EASTERN TENNESSEE, INC.

BY: 

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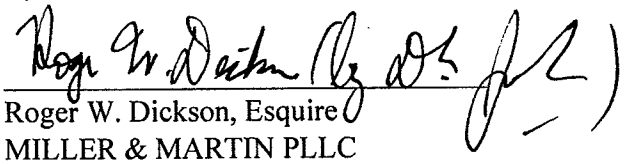

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CERTIFICATE OF SERVICE

I, Stephen M. Kissinger, hereby certify that a true and correct copy of the foregoing

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this the 16th day of November, 2010.

Stephen M. Kissinger

ATTACHMENT A

TO

PLAINTIFF'S TRIAL BRIEF

WEST V. RAY, ET AL
CHANCERY COURT NO. 10-1675-I

Hospira, Inc. 2005
Pentothal Information

PENTOTHAL®

Thiopental Sodium for Injection, USP Ⓒ III

℞ only

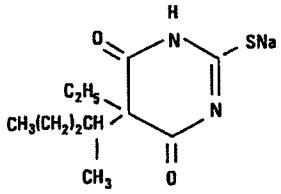
WARNING: MAY BE HABIT FORMING.

DESCRIPTION

Pentothal (Thiopental Sodium for Injection, USP) is a thiobarbiturate, the sulfur analogue of sodium pentobarbital.

The drug is prepared as a sterile powder and after reconstitution with an appropriate diluent is administered by the intravenous route.

Pentothal is chemically designated sodium 5-ethyl-5-(1-methylbutyl)-2-thiobarbiturate and has the following structural formula:



The drug is a yellowish, hygroscopic powder, stabilized with anhydrous sodium carbonate as a buffer (60 mg/g of thiopental sodium).

CLINICAL PHARMACOLOGY

Pentothal (Thiopental Sodium for Injection, USP) is an ultrashort-acting depressant of the central nervous system which induces hypnosis and anesthesia, but not analgesia. It produces hypnosis within 30 to 40 seconds of intravenous injection. Recovery after a small dose is rapid, with some somnolence and retrograde amnesia. Repeated intravenous doses lead to prolonged anesthesia because fatty tissues act as a reservoir; they accumulate Pentothal in concentrations 6 to 12 times greater than the plasma concentration, and then release the drug slowly to cause prolonged anesthesia.

The half-life of the elimination phase after a single intravenous dose is three to eight hours.

The distribution and fate of Pentothal (as with other barbiturates) is influenced chiefly by its lipid solubility (partition coefficient), protein binding and extent of ionization. Pentothal has a partition coefficient of 580.

Approximately 80% of the drug in the blood is bound to plasma protein. Pentothal is largely degraded in the liver and to a smaller extent in other tissues, especially the kidney and brain. It has a pKa of 7.4.

Concentration in spinal fluid is slightly less than in the plasma.

Biotransformation products of thiopental are pharmacologically inactive and mostly excreted in the urine.

INDICATIONS AND USAGE

Pentothal (Thiopental Sodium for Injection, USP) is indicated (1) as the sole anesthetic agent for brief (15 minute) procedures, (2) for induction of anesthesia prior to administration of other anesthetic agents, (3) to supplement regional anesthesia, (4) to provide hypnosis during balanced anesthesia with other agents for analgesia or muscle relaxation, (5) for the control of convulsive states during or

following inhalation anesthesia, local anesthesia, or other causes, (6) in neurosurgical patients with increased intracranial pressure, if adequate ventilation is provided, and (7) for narcoanalysis and narcosynthesis in psychiatric disorders.

CONTRAINDICATIONS

Absolute Contraindications:

(1) Absence of suitable veins for intravenous administration, (2) hypersensitivity (allergy) to barbiturates and (3) variegate porphyria (South African) or acute intermittent porphyria.

Relative Contraindications:

(1) Severe cardiovascular disease, (2) hypotension or shock, (3) conditions in which the hypnotic effect may be prolonged or potentiated — excessive premedication, Addison's disease, hepatic or renal dysfunction, myxedema, increased blood urea, severe anemia, asthma, myasthenia gravis, and (4) status asthmaticus.

WARNINGS

KEEP RESUSCITATIVE AND ENDOTRACHEAL INTUBATION EQUIPMENT AND OXYGEN READILY AVAILABLE. MAINTAIN PATENCY OF THE AIRWAY AT ALL TIMES.

This drug should be administered only by persons qualified in the use of intravenous anesthetics.

Avoid extravasation or intra-arterial injection.

WARNING: MAY BE HABIT FORMING.

PRECAUTIONS

Observe aseptic precautions at all times in preparation and handling of Pentothal (Thiopental Sodium for Injection, USP) solutions.

If used in conditions involving relative contraindications, reduce dosage and administer slowly.

Care should be taken in administering the drug to patients with advanced cardiac disease, increased intracranial pressure, ophthalmoplegia plus, asthma, myasthenia gravis and endocrine insufficiency (pituitary, thyroid, adrenal, pancreas).

Drug interactions: The following drug interactions have been reported with thiopental.

Drug	Effect
Probenecid	Prolonged action of thiopental
Diazoxide	Hypotension
Zimelidine	Thiopental antagonism
Opioid analgesics	Decreased antinociceptive action
Aminophylline	Thiopental antagonism
Midazolam	Synergism

Nursing Mothers: Thiopental sodium readily crosses the placental barrier and small amounts may appear in the milk of nursing mothers following administration of large doses.

Pregnancy Category C. Animal reproduction studies have not been conducted with Pentothal. It is also not known whether Pentothal can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Pentothal should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Adverse reactions include respiratory depression, myocardial depression, cardiac arrhythmias, prolonged somnolence and recovery, sneezing, coughing, bronchospasm, laryngospasm and shivering. Anaphylactic and anaphylactoid reactions to Pentothal (Thiopental Sodium for Injection, USP) have been reported. Symptoms, e.g., urticaria, bronchospasm, vasodilation and edema should be managed by conventional means.

Rarely, immune hemolytic anemia with renal failure and radial nerve palsy have been reported.

DRUG ABUSE AND DEPENDENCE

WARNING: MAY BE HABIT FORMING.

Thiopental sodium is classified as a Schedule III controlled substance.

OVERDOSAGE

Overdosage may occur from too rapid or repeated injections. Too rapid injection may be followed by an alarming fall in blood pressure even to shock levels. Apnea, occasional laryngospasm, coughing and other respiratory difficulties with excessive or too rapid injections may occur. In the event of suspected or apparent overdosage, the drug should be discontinued, a patent airway established (intubate if necessary) or maintained, and oxygen should be administered, with assisted ventilation if necessary. The lethal dose of barbiturates varies and cannot be stated with certainty. Lethal blood levels may be as low as 1 mg/100 mL for short-acting barbiturates; less if other depressant drugs or alcohol are also present.

MANAGEMENT OF OVERDOSAGE

It is generally agreed that respiratory depression or arrest due to unusual sensitivity to thiopental sodium or overdosage is easily managed if there is no concomitant respiratory obstruction. If the airway is patent, any method of ventilating the lungs (that prevents hypoxia) should be successful in maintaining other vital functions. Since depression of respiratory activity is one of the characteristic actions of the drug, it is important to observe respiration closely.

Should laryngeal spasm occur, it may be relieved by one of the usual methods, such as the use of a relaxant drug or positive pressure oxygen. Endotracheal intubation may be indicated in difficult cases.

DOSAGE AND ADMINISTRATION

Pentothal is administered by the intravenous route only. Individual response to the drug is so varied that there can be no fixed dosage. The drug should be titrated against patient requirements as governed by age, sex and body weight. Younger patients require relatively larger doses than middle-aged and elderly persons; the latter metabolize the drug more slowly. Pre-puberty requirements are the same for both sexes, but adult females require less than adult males. Dose is usually proportional to body weight and obese patients require a larger dose than relatively lean persons of the same weight.

Premedication

Premedication usually consists of atropine or scopolamine to suppress vagal reflexes and inhibit secretions. In addition, a barbiturate or an opiate is often given. Sodium pentobarbital injection (Nembutal®) is suggested because it provides a preliminary indication of how the patient will react to barbiturate anesthesia. Ideally, the peak effect of these medications should be reached shortly before the time of induction.

Test Dose

It is advisable to inject a small "test" dose of 25 to 75 mg (1 to 3 mL of a 2.5% solution) of Pentothal (Thiopental Sodium for Injection, USP) to assess tolerance or unusual sensitivity to Pentothal, and pausing to observe patient reaction for at least 60 seconds. If unexpectedly deep anesthesia develops or if respiratory depression occurs, consider these possibilities: (1) the patient may be unusually sensitive to Pentothal, (2) the solution may be more concentrated than had been assumed, or (3) the patient may have received too much premedication.

Use in Anesthesia

Moderately slow induction can usually be accomplished in the "average" adult by injection of 50 to 75 mg (2 to 3 mL of a 2.5% solution) at intervals of 20 to 40 seconds, depending on the reaction of the patient. Once anesthesia is established, additional injections of 25 to 50 mg can be given whenever the patient moves.

Slow injection is recommended to minimize respiratory depression and the possibility of overdosage. The smallest dose consistent with attaining the surgical objective is the desired goal. Momentary apnea following each injection is typical, and progressive decrease in the amplitude of respiration appears with increasing dosage. Pulse remains normal or increases slightly and returns to normal. Blood pressure usually falls slightly but returns toward normal. Muscles usually relax about 30 seconds after unconsciousness is attained, but this may be masked if a skeletal muscle relaxant is used. The tone of jaw muscles is a fairly reliable index. The pupils may dilate but later contract; sensitivity to light is not usually lost until a level of anesthesia deep enough to permit surgery is attained. Nystagmus and divergent strabismus are characteristic during early stages, but at the level of surgical anesthesia, the eyes are central and fixed. Corneal and conjunctival reflexes disappear during surgical anesthesia.

When Pentothal (Thiopental Sodium for Injection, USP) is used for induction in balanced anesthesia with a skeletal muscle relaxant and an inhalation agent, the total dose of Pentothal can be estimated and then injected in two to four fractional doses. With this technique, brief periods of apnea may occur which may require assisted or controlled pulmonary ventilation. As an initial dose, 210 to 280 mg (3 to 4 mg/kg) of Pentothal is usually required for rapid induction in the average adult (70 kg).

When Pentothal (Thiopental Sodium for Injection, USP) is used as the sole anesthetic agent, the desired level of anesthesia can be maintained by injection of small repeated doses as needed or by using a continuous intravenous drip in a 0.2% or 0.4% concentration. (Sterile water should not be used as the diluent in these concentrations, since hemolysis will occur.) With continuous drip, the depth of anesthesia is controlled by adjusting the rate of infusion.

Use in Convulsive States

For the control of convulsive states following anesthesia (inhalation or local) or other causes, 75 to 125 mg (3 to 5 mL of a 2.5% solution) should be given as soon as possible after the convulsion begins. Convulsions following the use of a local anesthetic may require 125 to 250 mg of Pentothal given over a ten minute period. If the convulsion is caused by a local anesthetic, the required dose of Pentothal will depend upon the amount of local anesthetic given and its convulsant properties.

Use in Neurosurgical Patients with Increased Intracranial Pressure

In neurosurgical patients, intermittent bolus injections of 1.5 to 3.5 mg/kg of body weight may be given to reduce intraoperative elevations of intracranial pressure, if adequate ventilation is provided.

Use in Psychiatric Disorders

For narcoanalysis and narcosynthesis in psychiatric disorders, premedication with an anticholinergic agent may precede administration of Pentothal. After a test dose, Pentothal (Thiopental Sodium for Injection, USP) is injected at a slow rate of 100 mg/min (4 mL/min of a 2.5% solution) with the patient counting backwards from 100. Shortly after counting becomes confused but before actual sleep is produced, the injection is discontinued. Allow the patient to return to a semidrowsy state where conversation is coherent. Alternatively, Pentothal may be administered by rapid I.V. drip using a 0.2% concentration in 5% dextrose and water. At this concentration, the rate of administration should not exceed 50 mL/min.

MANAGEMENT OF SOME COMPLICATIONS

Respiratory depression (hypoventilation, apnea), which may result from either unusual responsiveness to Pentothal or overdosage, is managed as stated above. Pentothal should be considered to have the same potential for producing respiratory depression as an inhalation agent, and patency of the airway must be protected at all times.

Laryngospasm may occur with light Pentothal narcosis at intubation, or in the absence of intubation if foreign matter or secretions in the respiratory tract create irritation. Laryngeal and bronchial vagal reflexes can be suppressed, and secretions minimized by giving atropine or scopolamine premedication and a barbiturate or opiate. Use of a skeletal muscle relaxant or positive pressure oxygen will usually relieve laryngospasm. Tracheostomy may be indicated in difficult cases.

Myocardial depression, proportional to the amount of drug in direct contact with the heart, can occur and may cause hypotension, particularly in patients with an unhealthy myocardium. Arrhythmias may appear if PCO2 is elevated, but they are uncommon with adequate ventilation. Management of myocardial depression is the same as for overdosage. Pentothal (Thiopental Sodium for Injection, USP) does not sensitize the heart to epinephrine or other sympathomimetic amines.

Extravascular infiltration should be avoided. Care should be taken to insure that the needle is within the lumen of the vein before injection of Pentothal. Extravascular injection may cause chemical irritation of the tissues varying from slight tenderness to venospasm, extensive necrosis and sloughing. This is due primarily to the high alkaline pH (10 to 11) of clinical concentrations of the drug. If extravasation occurs, the local irritant effects can be reduced by injection of 1% procaine locally to relieve pain and enhance vasodilatation. Local application of heat also may help to increase local circulation and removal of the infiltrate.

Intra-arterial injection can occur inadvertently, especially if an aberrant superficial artery is present at the medial aspect of the antecubital fossa. The area selected for intravenous injection of the drug should be palpated for detection of an underlying pulsating vessel. Accidental intra-arterial injection can cause arteriospasm and severe pain along the course of the artery with blanching of the arm and fingers. Appropriate corrective measures should be instituted promptly to avoid possible development of gangrene. Any patient complaint of pain warrants stopping the injection. Methods suggested for dealing with this complication vary with the severity of symptoms. The following have been suggested:

1. Dilute the injected Pentothal (Thiopental Sodium for Injection, USP) by removing the tourniquet and any restrictive garments.
2. Leave the needle in place, if possible.
3. Inject the artery with a dilute solution of papaverine, 40 to 80 mg, or 10 mL of 1% procaine, to inhibit smooth muscle spasm.

4. If necessary, perform sympathetic block of the brachial plexus and/or stellate ganglion to relieve pain and assist in opening collateral circulation. Papaverine can be injected into the subclavian artery, if desired.
5. Unless otherwise contraindicated, institute immediate heparinization to prevent thrombus formation.
6. Consider local infiltration of an alpha-adrenergic blocking agent such as phentolamine into the vasospastic area.
7. Provide additional symptomatic treatment as required.

Shivering after Pentothal anesthesia, manifested by twitching face muscles and occasional progression to tremors of the arms, head, shoulder and body, is a thermal reaction due to increased sensitivity to cold. Shivering appears if the room environment is cold and if a large ventilatory heat loss has been sustained with balanced inhalation anesthesia employing nitrous oxide. Treatment consists of warming the patient with blankets, maintaining room temperature near 22° C (72° F), and administration of chlorpromazine or methylphenidate.

PREPARATION OF SOLUTIONS

Pentothal (Thiopental Sodium for Injection, USP) is supplied as a yellowish, hygroscopic powder in a variety of different containers. Solutions should be prepared aseptically with one of the three following diluents: Sterile Water for Injection, USP, 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Clinical concentrations used for intermittent intravenous administration vary between 2.0% and 5.0%. A 2.0% or 2.5% solution is most commonly used. A 3.4% concentration in sterile water for injection is isotonic; concentrations less than 2.0% in this diluent are not used because they cause hemolysis. For continuous intravenous drip administration, concentrations of 0.2% or 0.4% are used. Solutions may be prepared by adding Pentothal to 5% Dextrose Injection, USP, 0.9% Sodium Chloride Injection, USP or Normosol®-R pH 7.4.

Since Pentothal contains no added bacteriostatic agent, extreme care in preparation and handling should be exercised at all times to prevent the introduction of microbial contaminants. Solutions should be freshly prepared and used promptly; when reconstituted for administration to several patients, unused portions should be discarded after 24 hours. Sterilization by heating should not be attempted.

WARNING: The 2.5 g and larger sizes contain adequate medication for several patients.

COMPATIBILITY

Any solution of Pentothal (Thiopental Sodium for Injection, USP) with a visible precipitate should not be administered. The stability of Pentothal solutions depends upon several factors, including the diluent, temperature of storage and the amount of carbon dioxide from room air that gains access to the solution. Any factor or condition which tends to lower pH (increase acidity) of Pentothal solutions will increase the likelihood of precipitation of thiopental acid. Such factors include the use of diluents which are too acidic and the absorption of carbon dioxide which can combine with water to form carbonic acid.

Solutions of succinylcholine, tubocurarine or other drugs which have an acid pH should not be mixed with Pentothal solutions. The most stable solutions are those reconstituted in water or isotonic saline, kept under refrigeration and tightly stoppered. The presence or absence of a visible precipitate offers a practical guide to the physical compatibility of prepared solutions of Pentothal.

CALCULATIONS FOR VARIOUS CONCENTRATIONS

Concentration Desired		Amounts to Use	
		Pentothal	Diluent
Percent	mg/mL	g	mL
0.2	2	1	500
0.4	4	1	250
		2	500
2.0	20	5	250
		10	500
2.5	25	1	40
		5	200
5	50	1	20
		5	100

Reconstituted solutions of Pentothal (Thiopental Sodium for Injection, USP) should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

HOW SUPPLIED

Pentothal is available in a variety of sizes and containers shown at the end of this insert.

Diluents in
Pentothal® Kits
READY-TO-MIX SYRINGES AND VIALS
(For preparing solutions of Thiopental Sodium for Injection, USP)

DESCRIPTION

The following diluents in various container, syringe and vial sizes are provided in Pentothal Kits, Pentothal Ready-to-Mix Syringes and Vials for preparing solutions of Pentothal (Thiopental Sodium for Injection, USP) for clinical use:

Sterile Water for Injection, USP is a sterile, nonpyrogenic preparation of water for injection which contains no bacteriostat, antimicrobial agents or added buffers. The pH is 5.7 (5.0 to 7.0).

Sterile Water for Injection, USP is a pharmaceutic aid (solvent) for intravenous administration only after addition of a solute.

Water is chemically designated H_2O.

0.9% Sodium Chloride Injection, USP is a sterile, nonpyrogenic, isotonic solution of sodium chloride and water for injection. Each mL contains sodium chloride 9 mg (308 mOsmol/liter calc). It contains no bacteriostat, antimicrobial agents or added buffers except for pH adjustment. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH is 5.7 (4.5 to 7.0).

0.9% Sodium Chloride Injection, USP is an isotonic vehicle for intravenous administration of another solute.

Sodium chloride is chemically designated NaCl, a white crystalline compound freely soluble in water.

The semi-rigid vial contained in List Nos. 3329, and 6435 is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper labeled volume.

CLINICAL PHARMACOLOGY

Sterile Water for Injection, USP serves only as a pharmaceutic aid for diluting or dissolving drugs prior to administration.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine excretion).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of dissociated electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining a physiologic equilibrium between fluid intake and output.

0.9% Sodium Chloride Injection, USP serves only as an isotonic vehicle for drugs prior to administration.

Sodium chloride in water is an electrolyte solution of sodium (Na^+) and chloride (Cl^-) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output of these ions.

The small volumes of fluid and amounts of sodium chloride provided by 0.9% Sodium Chloride Injection in Ready-to-Mix Syringes are unlikely to produce a significant effect on fluid or electrolyte balance.

INDICATIONS AND USAGE

These products are indicated only for preparing Pentothal (Thiopental Sodium for Injection, USP) solutions for clinical use.

CONTRAINDICATIONS

Do not use unless the diluent is clear and the bottle or vial seal or syringe package is undamaged.

Diluents in Pentothal Kits, Ready-to-Mix Syringes or Vials should not be used for fluid or sodium chloride replacement.

WARNINGS

Intravenous administration of Sterile Water for Injection, USP without a solute may result in hemolysis.

Use aseptic technique for preparing Pentothal solutions when using Pentothal Kits, Syringes or Vials and during withdrawal from reconstituted single or multiple-use containers.

Administer only clear reconstituted solutions.

Use within 24 hours after reconstitution. Discard unused portions.

PRECAUTIONS

Do not use unless solution is clear and container is undamaged.

Inspect reconstituted (mixed) solutions of Pentothal (Thiopental Sodium for Injection, USP) for clarity and freedom from precipitation or discoloration prior to administration. Use reconstituted solution only if it is clear, free from precipitate and not discolored.

Use Transfer Label in each Pentothal Kit and affix to container of reconstituted solution to show concentration and time of preparation.

Pregnancy Category C. Animal reproduction studies have not been conducted with sterile water for injection or sodium chloride injection. It is also not known whether sterile water or sodium chloride injection containing additives can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sterile water for injection or sodium chloride injection with additives should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Reactions which may occur because of the diluents, technique of preparation or mixing, or administration of reconstituted solutions of Pentothal include febrile response or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the injection, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of unused solution (or the used container or syringe) for examination if deemed necessary.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

Used as diluents for preparing solutions of Pentothal (Thiopental Sodium for Injection, USP) the small volumes of administered fluid (from Sterile Water for Injection in bottles and vials) and amounts of sodium chloride (from 0.9% Sodium Chloride Injection in Ready-to-Mix Syringes) are unlikely to pose a threat of fluid or sodium chloride overload.

DOSAGE AND ADMINISTRATION

Pentothal solutions should be administered only by intravenous injection and by individuals experienced in the conduct of intravenous anesthesia.

The volume and choice of diluent for preparing Pentothal (Thiopental Sodium for Injection, USP) solutions for clinical use depends on the concentration and vehicle desired. Pentothal Kits provide only Sterile Water for Injection as the diluent for individual or multi-patient use; Pentothal Ready-to-Mix Syringes provide only 0.9% Sodium Chloride Injection, USP as the diluent for individual patient use; vials provide only Sterile Water for Injection, USP as the diluent for individual patient use.

Parenteral drug products should be inspected visually for

particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

HOW SUPPLIED

The diluent in Pentothal Kits is supplied in various size containers with various dosage sizes of Pentothal (Thiopental Sodium for Injection, USP). Kits include all items needed for aseptic transfer of Pentothal powder from a squeeze bottle into the diluent container.

The diluent in Pentothal Ready-to-Mix Syringes is supplied in a separate container to permit mixing

with the Pentothal in a powder vial to permit immediate intravenous injection of reconstituted solution into a vein or attachment to a standard stopcock assembly.

Vials are supplied in cartons with different dosage sizes of Pentothal for preparing 2.0% or 2.5% concentrations by using a separate syringe (not supplied) for mixing.

See table for list of sizes available.

Store at 20 to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Keep reconstituted solution in a cool place.

Table: Pentothal® (Thiopental Sodium for Injection, USP) and Diluent in Kits, Ready-to-Mix Syringes and Ready-to-Mix LifeShield® Syringes

List No.	Pentothal	Pentothal Container	Diluent (mL)*	Diluent Container	Theoretical Reconstituted Conc.
6108 (Kit)	5 g	Squeeze Bottle	W (250)	PF Bottle	2% (20 mg/mL)
6244 (Kit)	1 g	Squeeze Bottle	W (40)	PF Bottle	2.5% (25 mg/mL)
6435 (Kit)	1 g	Vial	W (50)	Plastic Vial	2% (20 mg/mL)
3329 (Kit)	500 mg	Vial	W (20)	Plastic Vial	2.5% (25 mg/mL)
9087 (Kit)	1 g	Vial	W (50)	Plastic Vial	2% (20 mg/mL)
6246 (Ready-to-Mix Syringe)	400 mg	Syringe	S (20)	Syringe	2% (20 mg/mL)
6241 (Ready-to-Mix Syringe)	250 mg	Syringe	S (10)	Syringe	2.5% (25 mg/mL)
6243 (Ready-to-Mix Syringe)	500 mg	Syringe	S (20)	Syringe	2.5% (25 mg/mL)
3351 (Ready-to-Mix LifeShield Syringe)	250 mg	Syringe	S (10)	Plastic Vial	2.5% (25 mg/mL)
3352 (Ready-to-Mix LifeShield Syringe)	400 mg	Syringe	S (20)	Plastic Vial	2% (20 mg/mL)
3353 (Ready-to-Mix LifeShield Syringe)	500 mg	Syringe	S (20)	Plastic Vial	2.5% (25 mg/mL)

PF — denotes Partial-Fill

W — denotes Sterile Water for Injection, USP

S — denotes 0.9% Sodium Chloride Injection, USP

* Diluent containers are slightly overfilled to assure compliance with USP minimum fill volume requirements.

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Hospira