IN THE SUPREME COURT OF TENNESSEE AT NASHVILLE

ABU-ALI ABDUR'RAHMAN, et al,)
Plaintiffs-Appellants,)
Tiantinis Appenantis,)
V.)
TONY PARKER, et al,)
Defendants-Appellees))

No. M2018-01385-SC-RDO-CV

Davidson County Chancery Court Case No. 18-183-III

ON APPEAL FROM THE JUDGEMNT OF THE CHANCERY COURT

BRIEF OF PLAINTIFFS-APPELLANTS

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5.	a tim not h brom	reenblatt testified that the pharmacokinetics of Midazolam create e delay in the onset of its effects that make it certain that it will ave induced its peak sedative effect by the time vecuronium ide and potassium chloride are injected into an inmate under the col	

	6.	Because of the pH of Midazolam solution, the amount called for by the protocol would inflict severe damage to lung tissue and nearly certainly cause pulmonary edema
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	1.	Dr. Edgar reviewed the autopsies of twenty-seven inmates executed with Midazolam
	2.	Dr. Edgar was surprised by the weights of the lungs recorded in the state autopsies; the lungs were not consistent with instantaneous death
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		2. Mr. Baich discussed the legal accommodations made by Arizona in the wake of the Woods' execution: (1) lawyer-witnesses are now allowed the use of cellphones, and (2) Arizona has agreed to never again use Midazolam, benzodiazepines or paralytics in executions
		3. Julie Hall corroborated the testimony of Mr. Baich and shared additional details; she also testified about the difficulties in reaching a court during a botched two-hour long execution, when the attorneys are denied access to a telephone
		4. Robin Konrad, a law school professor, testified about the challenges in conveying information to a court when denied eye-witness access to the execution chamber

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	4.	docur their	and TDOC violated the Manual's requirements regarding nentation of training, forcing Plaintiffs and the public to just "take word for it" that the people carry out killings on behalf of the State been trained
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e.		-	rotocol contains the same kind of errors that caused Governor sen to halt executions and order a protocol review
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	5. Throughout modern history, courts have reached incorrect scie conclusions based on scientific opinions that were subsequently to be unreliable junk	y shown
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d.	Plaintiffs met their burden under <i>Glossip</i> to identify a known, fea and readily available alternative method of lethal injection in sp peculiarities of Tennessee law	ite of the
	1. The uncontroverted proof is that Pentobarbital was available to State of Tennessee at the time Commissioner Parker chose to a the three-drug Midazolam protocol; the uncontroverted proof is the Pentobarbital that was available for purchase in 2017 woul be good for use in executions in 2019 and into 2020; the uncont proof is that a single-drug Pentobarbital protocol was feasible a readily available and that the State of Tennessee chose not to u	adopt that d still croverted and atilize it.
	2. Having proven that there were at least ten willing and able sel Pentobarbital, the State was bound by their own proof	
	3. This honorable Court should infer that the "Drug Procurer's" to would have been adverse to the Defendants and would have established that there were multiple drug suppliers who would made Pentobarbital feasible and readily available	have

	4.	avai it; th Proc	ually, the record is clear: Pentobarbital was a feasible and readily lable alternative, and the State of Tennessee chose not to purchase he record is also clear, the "Drug Procurer" and <i>only</i> the "Drug urer," knows the identity of the roughly 80 willing drug bliers
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e.			nancery Court committed error by failing to consider Plaintiffs'
	ir p	n fact roduc	ed two-drug alternative, which would have substantially reduced— entirely removed—the risk of severe pain and mental anguish ed by vecuronium bromide, and which would have reduced the s's time of suffering by three minutes
	1.	drug subs	ntiffs, working under incredible time constraints, pled the two- g protocol as a feasible and readily available alternative that would tantially reduce a significant risk of severe pain and mental hish
	2.	suffi had	suant to Tennessee Rule of Civil Procedure 8.05, Plaintiffs ciently pled the two-drug alternative, such that (a) Defendants more than adequate notice of this claim, and (b) the Court should addressed this claim on its merits
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		ii. Any claim of prejudice was waived due to failure to lodge an appropriate objection
		 iii. The burden of proof was on Defendants to demonstrate prejudice, not on Plaintiffs to show entitlement to amend. 238
f.	courts indisti	dments to conform to the proof are regularly permitted by the of this state on circumstances that are materially nguishable from our own—except that in those cases the parties gnificantly more time to prepare for trial than did Plaintiffs 238
	alter Rule apply	Chancellor summarily denied Plaintiffs leave to plead a two-drug mative; her ruling did not involve any legal analysis under either 8.05 or Rule 15.02; the Chancellor abused her discretion by ying an incorrect legal standard and by reaching an illogical sion
	А.	The abuse of discretion standard, while deferential, is not supine
	В.	The Chancellor employed an incorrect legal standard that is contrary to the logic of <i>Zack Cheek</i> and is not based on any known authority
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5.	subst pain a bromi	ordrug protocol of Midazolam and potassium chloride would antially reduce (entirely eliminate) the significant risk of severe and mental anguish that will be produced by vecuronium ide, and it will substantially reduce the duration of severe pain mental anguish produced by the Midazolam
p]	hysical	ee's three-drug, Midazolam-based protocol will cause severe pain and extreme mental anguish for up to 18 excruciating ; it thus amounts to constitutionally forbidden torture
1.	inflict	lants pled that the Tennessee three-drug lethal injection protocol is torture upon the condemned; and they submitted that there to need to identify an alternative to torture
2.	the 8t	40 years the United States Supreme Court has maintained that th Amendment prohibits torture, barbarism and unnecessary cy
3.	agree forms every	ss than five current members of the United States Supreme Court that the Eighth Amendment categorically prohibits torture or of execution that are akin to torture—regardless of alternatives; current Justice agrees to the principles set-forth in <i>Wilkerson</i> <i>in re Kemmler</i>
	А.	The <i>Baze</i> standard of Roberts and Alito: inhuman and barbarous punishments are prohibited; the alternative requirement applies when considering a risk, not a certainty
	B.	Justice Thomas rejects <i>Baze</i> and <i>Glossip</i> alternatives; he believes the 8th Amendment categorically prohibits torture; either a punishment is cruel and unusual or it isn't
	C.	No less than four additional justices join with Justice Thomas, and agree that the 8th Amendment categorically prohibits torture
	D.	Ultimately, the majority, and possibly a unanimity, of the United States Supreme Court hold that there is no need to plead

f.

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	4.	The United States Supreme Court's definition of a punishment that is so inhuman and barbarous that the 8th Amendment prohibits it: for four justices our protocol has already been found to be barbarous; for the Chief Justice it would be an execution of a conscious inmate with a paralytic and potassium chloride
	5.	The forms of execution that have been found to be cruel and unusual: the gas chamber and electrocution inflict pain and suffering similar to that inflicted in Tennessee's protocol
required to prove a readily feasible alternative to burning at the stak that reasonable transactional efforts would provide a substitute to		nnessee Constitution prohibits punishments that involve "torture, gering death, wanton infliction of pain, or like methods;" this phibition does not contain any comparative analysis; an inmate is not quired to prove a readily feasible alternative to burning at the stake, or
	1.	Tennessee' definition of torture: the infliction of severe physical or mental pain upon [a human] while he or she remains alive and conscious
	2.	Alternatives apply to risk, not certainty; we never can tolerate the needless infliction of suffering
is embodied in the State of Tennessee's claim that death row inn deserve a torturous death as punishment for the actions of pharmaceutical companies who have declined to sell their healin		-
	1.	The First Amendment's free-exercise clause protects the religious liberty rights of individual citizens and corporations, so that they can choose, based on their own personal religious beliefs, not to participate in terminating human life
	2.	Corporations have protected First Amendment Rights pursuant to <i>Citizens United</i>
	3.	The Tennessee Constitution, Article I, § 3 protects the rights of conscience to a greater extent than the First Amendment, and the Tennessee Preservation of Religious Freedom Act provides statutory relief for unconstitutional government burdens on religious

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	b. Plaintiffs' substantive due process claim is not barred by their method-of- execution claim
III.	The protocol violates plaintiffs' right to counsel and access to courts. (Count V)
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V.	The trial court erred in dismissing Counts 2 and 3
	a. Count II is legally sufficient
	b. Count III is legally sufficient
VI.	The trial court abused its discretion by imposing extreme restrictions on Plaintiffs' ability to conduct discovery essential to its claims
	a. May 7, 2018 order denying Plaintiffs' first motion to compel discovery
	b. May 24, 2018 order denying Commissioner Parker and Warden Mays'

	c.	June 12, 2018 order denying the question Plaintiffs certified during Commissioner Parker's deposition
	d.	June 13, 2018 order denying Plaintiffs' motion to compel the deposition of a TDOC staff member and an associate Riverbend warden and imposing extreme limitations on the scope of TDOC General Counsel/Assistant Commissioner Debbie Inglis' deposition testimony
	e.	These orders were an abuse of discretion
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		2. The court's order permitting Li to testify out of time prejudiced Plaintiffs
VIII.	tes th	ould this Honorable Court engage in any de novo factual review, the stimony of Dr. Roswell Lee Evans and Dr. Feng Li should be given no weight e Chancellor should have excluded their testimony pursuant to <i>McDaniel v</i> <i>SX</i> and Tennessee Rules of Evidence 702 and 703
a.	Τe	ennessee Rules of Evidence 702 and 703
b.	De	efendants' proffered experts were unqualified
	1.	Dr. Roswell Lee Evans qualifications; he was qualified to testify about compounding, but he had no relevant experience, professional expertise research interest, or basis of knowledge to testify about Midazolam, or to offer an opinion on its efficacy as an anesthetic
	2.	Dr. Feng Li's qualifications to provide an opinion on pain and suffering in living humans: he spent his career examining dead humans 338

3.	Neither defense experts' qualifications met the standard for admissibility				
	A. Pharmacists, like Dr. Evans, are regularly found not to be qualified to testify regarding pharmacology or medical matters				
4.	Accordingly, the testimony from Dr. Evans and Dr. Li should be given no weight, should there be a de novo review of the evidence				
c. Defen	dants' proffered experts are not reliable				
	fendants' proffered experts' opinions were based on speculation, not ence				
=	<i>se dixit</i> expert opinions are not reliable, not admissible, and have been wned on since the time of Pythagoras and Cicero				
	fendants' proffered experts relied on warnings on package inserts, which e of no significance				
prior t	nnot "wantonly and freakishly" impose a method of execution on inmates to deliberative appellate review of a fulsome trial record; to do so violates Process, the Law of the Land and the promise of <i>Gregg v. Georgia</i> 352				
vir apj	e record is over 15,000 pages in length; this Honorable Court has tually no time available to review it, while counsel for appellants (and pellees) have too-little time to prepare helpful and thoughtful thefings				
hov pro	<i>regg v. Georgia</i> ended the ban on executions mandated by Furman, wever, Gregg relied on the promise that appropriate due process otections would ensure that "death sentences are not imposedin a makish manner."				
c. Me	eaningful appellate review is constitutionally required				
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ATTACHMENTS					

"By protecting even those convicted of heinous crimes, the Eighth Amendment reaffirms the duty of the government to respect the dignity of all persons."

> Justice Anthony Kennedy Roper v. Simmons, 543 U.S. 551, 560 (2005)

This Court is in an unprecedented position. It has a record of science and testimony that no other court, including our nation's highest court, has ever seen. The science that this brief contains mirrors a graduate school thesis. The witnessto-execution testimony is vaster than what any court has heard previously—eleven witnesses, representing every state where midazolam has been used in an execution. It has been the privilege, and challenge, of counsel to try to distill this vast and comprehensive record into a document that will assist this Honorable Court.

This case is not about whether the death penalty is constitutional. It is about whether Tennessee, in the name of its citizens and its governor, and with knowledge and approval of its courts, will carry out executions aware that the condemned will suffer severe pain and anguish. This case is about whether it is constitutional to inject a human with a small bottle of acid—which will destroy the lining of their lungs and cause them to drown in blood—and then to inject them with a paralytic that will leave them conscious but expressionless—unable to speak or scream—feeling as if they are buried alive, and finally to stop their heart with an injection that will, in their last minute of life, cause them to chemically burn alive. This is not hyperbole. The science and the facts establish that inmates have died, and if this continues, will die in this hideous manner.

The lower court accepted the scientific proof, and acknowledged that eyewitnesses to execution observed pain and suffering. However, the lower court determined that such executions were constitutionally permissible because, one, other courts (on lesser records, while addressing temporary injunctions, and based on meager science) have permitted such, and, two, because the torture will likely last no more than eighteen (18) minutes. The lower courts abdication of its factfinding responsibility to other courts was legally wrong. The lower courts acceptance of up to eighteen (18) minutes of human suffering was tragically misguided. The lower courts failure to follow the precedents of this Honorable Court and the United States Supreme Court require reversal.

The torture that occurs is no secret. The Tennessee Department of Corrections has known of the torture from the second and third chemicals in the protocol since at least 2007 when they consulted medical professionals on the pharmacology of lethal injection. That is one reason TDOC has fought relentlessly to hide facts from Plaintiffs, the press, and the public. At trial in the court below, the Defendants' own experts, whom they relied upon to defend the protocol, agreed with the science presented in Plaintiffs' case. Indeed, they relied on the articles and treatises written by Plaintiff's experts.

Knowing the unavoidable probability of inmates being tortured, Defendants continued to adjust their protocol, even in the very last minutes before they

executed Billy Ray Irick. Thus, Mr. Irick died bound with sufficient straps to restrain a mountain gorilla, with his hands so tightly taped that his fingers would not be seen to move, and with the public protected from the horror of knowing the pain that he experienced in his last minutes on earth. He died, hidden under physical restraint and the chemical veil of a paralytic that ensured that his screams could not leave his mouth. An illusion of peace masked a grim reality.

There is no legal, equitable, factual or moral reason for this Honorable Court to repeat the errors committed by the lower court. There is no reason for this Court to defer to rulings from preliminary injunction hearings held on paltry records. The law that will be set-forth in this brief is clear and unambiguous; this Court and the Supreme Court of this nation have both maintained that torture is constitutionally unacceptable, that executions of conscious inmates with excruciatingly painful poison is not allowed, that the 8th Amendment protects the dignity of man and is not merely a procedural pleading requirement.

This case has progressed at breathtaking speed. It is emotionally charged and politically volatile. It is "dreadful and grim." But it is also about the government undertaking one of its most daunting responsibilities: that of extinguishing life in a manner that does not denigrate the individual, or demean us as a people. Plaintiffs have every right to protest when the plans to execute them involve a substantial likelihood, indeed a certainty, that they will drown in their own fluids, suffocate as if buried alive, and then be burned by chemical fire for a

period that will last anywhere from 10 to 18 minutes. Plaintiffs' interest is constitutionally compelling. The people's interest is compelling as well.

Defendants' repeated mantra, barely acceptable from a teenager, is that — "all the other states are doing it, so it must be ok." This philosophy has been the history of lethal injection in this state. As Chancellor Lyle wrote in 2003, the Department's lethal injection protocol was "copy-catted" from other states. In 2007, Governor Bredesen revoked the protocol as a "cut and paste job." Later in 2007, the TDOC Commissioner rejected the much safer single-drug protocol recommendation of his own committee because other jurisdictions were still using three-drug protocols. Even then, TDOC became intransigent and failed to adopt other recommendations of the committee. That resistance to following the advice of experts, resulted in two separate judgments that the Department's Lethal Injection Protocol was unconstitutional. It was only after the second judgment that the Department agreed to modify its protocol. Had the Department simply adopted the recommendation of the committee in 2007, the litigation that followed would have been unnecessary.

Now in 2018, the Department has adopted a radically different protocol with full knowledge that the first drug—midazolam—is scientifically incapable of protecting against the painful effects of the second and third drugs. Indeed, their drug supplier specifically told them that midazolam would not work, before the Department choose to use it anyway. Now that Defendants have heard the proof at

trial, they also know that the large bolus of acidic midazolam will cause suffering, all on its own.

They Department amended the protocol once, four days before trial, removing a much more humane single-drug pentobarbital option, and committing exclusively to the three-drug method that guarantees severe pain and needless suffering. Then after adopting this protocol on July 5, 2018, they radically deviated from it in the execution of Billy Ray Irick.

Progress in the law is made by continuing to challenge that which litigators know to be wrong, even if the law has not caught up. That is the story of Thurgood Marshall, a hero that all litigators seek to emulate. In the area of the death penalty, the work of litigators who claimed that the Eighth Amendment stood for something more has repeatedly led to Supreme Court rulings that changed the law.

In the modern era, from 1976-2002, this country executed the intellectually disabled, and then recognized that this was wrong. *Compare Penry v. Lynaugh*, 492 U.S. 302 (1989) (Eighth Amendment does not exempt the mentally retarded from capital punishment); *with Atkins v. Virginia*, 536 U.S. 304 (2002) (Eighth Amendment exempts the intellectually disabled from execution).¹ From 1976-2002, death row defendants did not have a constitutional right to jury sentencing, now they do. *Compare Walton v. Arizona*, 536 U.S. (1990) (no right to jury sentencing in

¹ According to Dr. Denis Keyes, who has published several articles regarding disability issues, at least 46 known "mentally retarded" persons have been executed since 1976. <u>https://capitalpunishmentincontext.org/node/77467</u> (last visited September 6, 2018).

a capital case); *with Ring v. Arizona*, 536 U.S. 584 (2002) (recognizing Sixth Amendment right to jury sentencing in a capital case, overruling *Walton*).² From 1976-2005, it was constitutional to execute 16 and 17 year old juveniles, blessedly no more. *Compare Stanford v. Kentucky*, 492 U.S. 361 (1989) (upholding the death penalty for 16 and 17 year olds and noting that at the time of the adoption of the Bill of Rights capital punishment could theoretically be imposed on anyone over the age of 7); *with Roper v. Simmons*, 543 U.S. 551 (2005) (Justice Kennedy, who joined the majority in *Stanford*, overturned *Stanford*.)³

Thus, the Supreme Court's finding that a district court in Oklahoma did not commit clear error in denying a motion for a preliminary injunction in *Glossip v. Gross*, 135 S.Ct. 2726 (2015), does not immutably establish that midazolam can be used to constitutionally kill other humans. The fact that courts in other jurisdictions, examining meager factual presentations in other preliminary injunction proceedings, followed *Glossip* is not of any precedential value. What is of value are the facts and scientific truths that are in this record, and the law that is in this brief—law that comes from this Honorable Court and from still-vibrant United States Supreme Court precedent.

The record in this case, causes the factual foundation of *Glossip* to crumble. Every "fact" relied upon by the Oklahoma district court during that injunction

² Twenty-two inmates were executed in Arizona prior to *Ring*. <u>https://deathpenaltyinfo.org/views-executions</u> (last checked September 6, 2018).

³ As a result of Roper, 72 inmates were re-sentenced. Prior to Roper 22 juveniles were executed. <u>https://capitalpunishmentincontext.org/issues/juveniles</u> (last checked September 6, 2018).

proceeding has been repudiated and scientifically defeated. The expert, essential to that holding, a now-retired pharmacy administrator, has retreated from his opinions, and now acknowledges the validity of Plaintiffs' science.

Moreover, the proof in this case was unequivocal, there is a feasible, readily available alternative to the three-drug protocol that substantial reduces (eliminates) a significant risk of severe pain and needless suffering. Tennessee could remove the paralytic vecuronium and use a two-drug protocol. While, there would still be suffering, this suffering would be reduced by three-minutes of duration, and the horror of suffocation, paralysis and being "buried alive" would be entirely removed.

Beyond that alternative, plaintiffs also proved that the only reason Tennessee does not presently have pentobarbital, which would be an ideal alternative, is due to the complete failure of the "Drug Procurer" to purchase pentobarbital from ten or more willing and able sellers in 2017. This person, two (or more) tiers of responsibility below the Commissioner of Corrections, was given sole control over the procurement of lethal injection drugs, a responsibility this individual failed to handle responsibly, competently or with any effort to succeed.

The speed at which this litigation has and is progressing is punishing. The record is massive—19 volumes of Technical Record, 32 volumes of transcript, 150 exhibits plus dozens of items under seal. Plaintiffs acknowledge that this brief could be much better. It could be more concise. It will in places be repetitive. One writer

may repeat what another wrote elsewhere. In places there may be holes because something was forgotten. There will be typos and citation errors. We apologize.

We also, respectfully, urge this Court to take pause, reflect, and set a new schedule. Allow for new briefing. Studied, thoughtful review does not require years. But it cannot humanly be done under the current schedule. "The principles of constitutional adjudication and procedural fairness require that decisions regarding constitutional challenges to acts of the Executive and Legislative Branches be considered in the light of a fully developed record addressing the specific merits of the challenge." *West v. Schofield*, No. M1997-000130-SC-DPE-DD, at *3 (Tenn. 2010).

This Court has found that it is constitutionally intolerable to execute an inmate using a paralytic and potassium chloride unless the inmate is rendered unable to experience the effects of those drugs through the use of an effective anesthetizing drug. *Abdur'Rahman v. Bredesen*, 181 S.W.3d 292 (2005). The United States Supreme Court agrees. *Baze v. Rees*, 563 U.S. 35 (2008). Midazolam is not sodium thiopental, it is not a barbiturate, and it cannot replace those more potent drugs. Due to its different and lesser single mechanism of action it will not and cannot protect the inmates from the second and third drugs.

That is not all. The record in this case reveals a truth, previously unknown. Midazolam must be dissolved in a strong acid to be injected. With normal, significantly smaller, doses that are administered over minutes this acid is of no consequence. However, when 500 mg are injected in less than two-minutes, in a

near-half-pint bolus of acid, this has its own torturous side effects. The acid causes pulmonary edema; blood and fluid leak into the lungs, through the damaged lung walls. This causes choking, gasping, drowning, heaving, in one case, witnesses watched as the condemned barked like a seal, in another he heaved against his restraints, others have looked like a fish, dying out of water. This is not dignified, nor is it respectful of life.

The proof in this record is unlike the proof in any other case. It is highly scientific. It deserves to be read carefully, studied, and digested. The proof from four eminent experts should be examined without haste. The testimony of eleven eye-witnesses to executions is worthy of consideration. Justice and human dignity require no less.

JURISDICTION

Chancery courts have subject matter jurisdiction over claims brought under the Declaratory Judgment Act, Tenn. Code Ann. § 29-14-101-113. *Id.* at § 29-14-102; *Colonial Pipeline Co. v. Morgan*, 263 S.W.3d 827, 836 (Tenn. 2008) ("In its present form, the Tennessee Declaratory Judgment Act grants courts of record the power to declare rights, status, and other legal relations.") (citing Tenn. Code Ann. § 29-14-102).

After a ten-day bench trial, on July 26, 2018, the Chancery Court for Davidson County, Lyle, J., entered judgment against Plaintiffs on claims I, IV, V, and VIII in their Second Amended Complaint.⁴ This was a final order that disposed of all parties' claims. The Chancery Court had earlier dismissed Counts II and III of the (first) Amended Complaint.

On July 30, 2018, Plaintiffs timely filed their notice of appeal.

On August 13, 2018, this Court assumed jurisdiction over this appeal, bypassing review in the Tennessee Court of Appeals.

STATEMENT OF THE ISSUES

This is an appeal from the Chancery Court of Davidson County, Tennessee dismissing Plaintiffs' Second Amended Complaint for Declaratory Judgment. Plaintiffs also appeal the decisions of the Chancery Court denying discovery and denying rule 15.01 motions to amend pre-trial and at the close of Plaintiff's proof. Each issue presented for review starts from the foundation that it is settled law that if the first drug in a three-drug protocol fails to render an inmate insensate, "there is a substantial, constitutionally unacceptable risk of suffocation from the administration of [the paralytic] and pain from the injection of potassium chloride." *Baze v. Rees*, 553 U.S. 35, 53 (2008). The issues presented for review include:

1. Where the scientific and expert proof establishes, and the Chancellor finds, Midazolam fails to protect condemned inmates from the effects of the second and third drugs, does the Tennessee Lethal Injection Protocol violate the 8th

⁴ The record of the proceedings below was entered as series of consecutively numbered volumes. Citations to the record herein indicate the volume of the record (I-XL); whether it is the technical record ("TR") or the transcript of the proceedings ("Tr."); the page number; and, as appropriate, an explanatory parenthetical.

Amendment to the United States Constitution and/or Article 1 § 16 of the Tennessee Constitution (Count I of the Second Amended Complaint)?

2. Did the Chancery Court err in finding that Plaintiffs failed to show that a single-drug Pentobarbital lethal injection protocol was known, feasible, and readily available alternative?

3. Did the Chancery Court err in refusing to consider Plaintiffs' second alternative lethal injection protocol: a two-drug protocol which eliminates the paralytic, where the proof clearly supported the feasibility and availability of the protocol—including admissions by Defendants?

4. Did Defendants waive the pleading requirement of a known, feasible, and readily available alternative by refusing to produce the only source of information regarding Defendants' efforts to obtain Pentobarbital?

5. Did the Chancery Court err in denying discovery requests which were designed to discover evidence of the availability of Pentobarbital to the State of Tennessee where it is known that the states of Texas and Georgia continue to use Pentobarbital in executions based on an erroneous interpretation of state secrecy laws related to executions?

6. Does Tennessee's secrecy statute excuse Plaintiffs from the burden to establish the availability of an alternative lethal injection protocol?

7. Where Plaintiffs presented unrebutted proof that the denial of a telephone, visual access, and a second attorney in the observation room during an execution will prevent them from accessing the court and where the TDOC's general

counsel admits that the reason for the denial of telephone access is to prevent the inmates from calling the courts because the court might interrupt the execution, did the Chancery Court err in dismissing Count V of the Second Amended Complaint?

8. Given Defendants' knowledge of the effects of the second and third drugs and actual knowledge of the ineffectiveness of Midazolam, does their conduct in choosing and using this protocol violate substantive due process under Article 1, § 8 of the Tennessee Constitution and the Fourteenth Amendment to the United States Constitution (Count VIII of the Second Amended Complaint)?

9. Did the chancery court err in dismissing Plaintiffs' claim that the Protocol violates their right to dignity because it does not reflect evolving standards of decency as required by Article 1, § 16 of the Tennessee Constitution and the Eighth Amendment of the United States Constitution (Count II of the (first) Amended Complaint)

10. Did the chancery court err in dismissing Plaintiffs' claim that the Protocol violates the dignity of man by using lethal injection chemicals that are prohibited by state statutes for use in non-livestock animal euthanasia in violation of Article 1, § 16 of the Tennessee Constitution and the Eighth Amendment of the United States Constitution (Count III of the (first) Amended Complaint)?

11. Did the Chancery Court err in denying Plaintiffs' pre-trial motion to amend their complaint to add an as-applied challenge to the use of the secret Drug Supplier who was uncredentialed and unqualified to compound Midazolam let alone provide instruction on how to prepare and store compounded Midazolam?

12. Did the Chancery Court err in reconsidering her order excluding the testimony of Dr. Feng Li who Defendants engaged knowing that he would be out of town during the trial and whose late testimony delayed the adjudication of the trial where Defendants had been on notice for months that the protocol would be challenged and in fact knew three months before Plaintiffs that they were going to use this highly problematic protocol?

13. Did the Chancery Court err in failing to exclude Defendants' witnesses under *McDaniel v. CSX Transportation Inc.*, 955 S.W.2d 257 (Tenn. 1997)?

14. Does the appellate schedule in this case deny Plaintiffs' appellate due process?

STATEMENT OF THE CASE

On February 20, 2018, Plaintiffs challenged the January 8, 2018 protocol in Davidson County Chance Court under the Declaratory Judgment Act. I 1-94 (Complaint); I 95-II 201 (Attach. A, 1/8/18 Protocol); II 202-03 (Attach. B, email from State's drug supplier warning of ineffectiveness of Midazolam).

On February 21, 2018, the trial court granted Plaintiffs' motion to proceed in forma pauperis. II 204-05.

On March 29, 2018, Defendants filed a motion to dismiss pursuant to Rule 12.02(6) of the Tennessee Rules of Civil Procedure. II 209-43.

On April 9, 2018, Plaintiffs' filed an expedited motion to compel discovery requesting that the trial court compel Defendants to respond to two interrogatories

served on them and to provide all documents responsive to Plaintiffs' request for production of documents. II 244-84.

On April 11, 2018, the trial court conducted a Rule 16 Conference and entered a scheduling order, which included a deadline for Plaintiffs to amend their complaint to provide more specificity on issues raised in Defendants' motion to dismiss. II 285-92 (order); XX (hearing transcript).

On April 13, 2018, Plaintiffs filed an Amended Complaint asserting sixteen causes of action. III 293-389.

On April 20, 2018, Defendants filed a response to Plaintiffs' motion to compel discovery. III 390-405.

On April 25, 2018, Plaintiffs filed a motion to voluntarily dismiss Counts X and XI of the Amended Complaint. III 406-08.

On April 25, 2018, Plaintiffs filed a response in opposition to Defendants' motion to dismiss. III 409-54.

On April 27, 2018, Plaintiffs filed a reply in support of their motion to compel discovery. IV 455-84.

On April 30, 2018, Plaintiffs filed a notice of supplemental authority regarding the United States Supreme Court's granting certiorari in the case of *Bucklew v. Precythe*, Case No. 17-8151. IV 485-540.

On April 30, 2018, Plaintiffs filed supplemental facts in support of their motion to compel discovery noting that Defendants' discovery requests served on April 27, 2018, sought discovery of information similar to that requested by

Plaintiffs to which Defendants had objected, thus necessitating Plaintiffs' filing of a motion to compel. IV 541-64.

On April 30, 2018, Defendants filed a reply in support of their motion to dismiss. IV 565-73.

On May 2, 2018, the trial court conducted oral argument on Defendants' motion to dismiss and Plaintiff's motion to compel discovery and took the matters under advisement. XXI 1-140.

On May 2, 2018, the court also granted Defendants' April 25, 2018 motion to voluntarily dismiss counts X and XI. XXI 6.

On May 4, 2018, the trial court entered an order granting in part and denying in part Defendants' motion to dismiss. IV 574-V 616. The court denied the motion to dismiss as to Counts IV (procedural due process), V (right to counsel and access to courts), and VIII (substantive due process. Defendants had withdrawn their motion to dismiss as to Count I (cruel and unusual punishment) after Plaintiffs filed the Amended Complaint. IV 581. The court granted the motion to dismiss as to the remaining ten claims. *Id.* Plaintiffs appeal the ruling on the motion to dismiss as to Counts II and III of the Amended Complaint.

On May 7, 2018, the trial court entered an order granting in part and denying in part Plaintiffs' motion to compel. V 617-32. Plaintiffs appeal this order to the extent that it denied Plaintiffs' motion to compel. As discussed below, the trial court erred in restricting Plaintiffs' ability to conduct discovery relevant to their claims.

On May 8, 2018, Defendants filed an answer to Plaintiffs' Amended Complaint. V 633-60.

On May 21, 2018, Defendants Commissioner Parker and Warden Mays filed a motion for protective order seeking to quash the subpoenas issued for their depositions. V 661-71. That day, the court issued an order staying the scheduled depositions under it could rule on the motion for protective order. V 672-74.

On May 21, 2018, the court conducted a hearing during which it addressed, among other things, the motion for protective order filed by Commissioner Parker and Warden Mays earlier that day; Parker's affidavit filed with that motion that stated pentobarbital was not available to the State; and the issues related to Dr. Li's unavailability during the trial. XXII 1-63. Plaintiffs explained the necessity of deposing Commissioner Parker to find out what efforts the Department made to find pentobarbital; what he knew about and did in response to an email from the Direct Source informing someone at the Department that Midazolam was not effective in this context; what he knew about other executions in which Midazolam failed to render inmates insensate. XXII 7-13, 42-45.

On May 24, 2018, the trial court denied the motion to quash Commissioner Parker and Warden Mays' depositions, but issued limitations on the time and scope of depositions. Other 2 (sealed); X 1364-89 (redacted); X 1350-52 (6/28/18 order to redact 5/24/18 order pursuant to 6/13/18 order (VI 738-45a) and place on public docket). Later that day, the court issued a "supplement" to that order, clarifying the process for certifying questions for the court during the depositions. V 701-04. The

court specified that it would rule on any certified questions at the June 12, 2018 hearing (four weeks before trial). V 703.

On May 29, 2018, Defendants filed a motion for summary judgment. V 704a-VI 704bbbb.

On June 1, 2018, Plaintiffs filed a second motion to compel seeking an order allowing them to depose Debbie Inglis (TDOC Deputy Commissioner of Administration), a TDOC attorney, and the Riverbend Associate Deputy Warden, each of whom has knowledge of Defendants' efforts to obtain Pentobarbital. I 107-III 355 (under seal); XVII 2429-XIX 2678 (redacted motion and exhibits); VI 740 (6/13/18 order for motion to be placed under seal and for parties to refile with the names of the staff attorney and assistant warden redacted).

On June 1, 2018, Defendants' moved to permit their medical expert, Dr. Li, to testify by evidentiary deposition in lieu of appearance at trial, asserting that he would be on safari in Tanzania during the trial. VI 705-16.

On June 8, 2018, Plaintiffs responded in opposition to allowing Defendants' expert Dr. Li testify by evidentiary deposition in lieu of appearance at trial, as (1) Defendants intentionally chose Dr. Li knowing he would be on vacation throughout the time period set for trial⁵; and (2) Plaintiffs would be prejudiced by not having their own experts present to assist with questioning Dr. Li as would be the case at

⁵ Dr. Li testified that he was first contacted about participating in this case on May 3, 3018. XLVIII 118.
trial, as Plaintiffs had arranged to have their experts present for the testimony of Defendants' expert witnesses. VI 717-33.

On June 8, 2018, Defendants responded in opposition to Plaintiffs' second motion to compel deposition testimony. III 356-66 (under seal).

On June 11, 2018, Plaintiffs filed the depositions of Commissioner Parker and Warden Mays. III 367-69 (Pls.' notice, under seal); III 370-V 731 (Parker, under seal); VI 732-900 (Mays, under seal).

On June 11, 2018, Plaintiffs filed a reply in support of their second motion to compel. VII 901-66 (under seal); XVII 2363-2428 (redacted reply and exhibits).

On June 12, 2018, Plaintiffs filed notice of intent to request at the status conference to be held later that day an extension of time to file a response to Defendants' motion for summary judgment to request that the court allow them the full thirty days contemplated by the Tennessee Rules of Civil Procedure to respond to a motion for summary judgment. VI 734-37. Plaintiffs' counsel represented in that motion the "punishing" litigation schedule that had them still actively engaged in discovery at the same time they were to be responding to a motion for summary judgment, as follows:

- June 11, 2018 deposition of Plaintiffs' expert in Tulsa, Oklahoma
- June 12, 2018 tour of the execution chamber at Riverbend followed later in the day by a scheduling conference with the court
- June 13, 2018 deposition of Plaintiffs' experts in Miami, Florida
- June 15, 2018 deposition of Plaintiffs' expert in Boston, Massachusetts

- June 20, 2018 deposition of Plaintiffs' expert in Franklin, North Carolina
- June 25, 2018 deposition of Plaintiffs' expert in Atlanta, Georgia
- June 27, 2018 deposition of Defendants' expert Dr. Evans (which previously had been scheduled on June 21, 2018, but was rescheduled to June 27, 2018 because of the motion for summary judgment hearing).

VI 735; see also XXII 14-18 (representations by Pls.' counsel at 5/21/18 hearing

regarding litigation schedule).

On June 12, 2018, the trial court issued an order in anticipation of an interim

status conference scheduled for later in the day ruling as follows:

- denying Defendants' motion to permit Dr. Li to testify via deposition;
- denying Plaintiffs' certified question from Commissioner Parker deposition;
- notice to counsel to be prepared to address the elimination of summary judgment proceedings as a result of the lack of time;⁶ and
- notice for counsel to be prepared to address whether the TDOC staff attorney's deposition would be cumulative of Debbie Inglis' deposition.

Other 1 (under seal); X 1390-98 (redacted); X 1350-52 (6/28/18 order to redact 6/12/18 order pursuant to 6/13/18 order (VI 738-45) and place on public record). As to Plaintiffs' certified question, the court denied Plaintiffs' request to have Commissioner Parker respond to the question they certified during his deposition: "Which Departments of Correction [has Commissioner Parker] consulted with"? Other 1 (6/12/18 order at pp. 5-6, sealed). The court found that the question was not

 $^{^6}$ The court notes in this order the rigorous litigation schedule between June 11, 2018 and the start of the trial on July 9, 2018 as represented in Plaintiffs' motion for extension of time to respond to Defendants' summary judgment motion. Other 1 (6/12/18 order at 4, n.1).

permitted under the court's May 24 2018 order limiting the scope of depositions. *Id.* Plaintiffs appeal this order denying their right to obtain Commissioner Parker's response to this certified question.

On June 13, 2018, the trial court issued an order (1) granting Plaintiffs' second motion to compel, which sought to compel the deposition of Debbie Inglis, but imposing unwarranted restrictions on the questions they could ask her; and (2) denying their right to depose the TDOC attorney and the Riverbend Associate Deputy Warden and. VI 738-45. Plaintiffs appeal the denial of their right to depose these individuals who had information relevant to their claims and the restrictions on the scope of the Inglis deposition that are contrary to the law. In the June 13th order, the trial court also ruled that it was eliminating summary judgment proceedings because of the short amount of time remaining before trial. *Id.* at 741-43.

On June 19, 2018, Defendants renewed their motion to permit Dr. Li to testify by evidentiary deposition, or to testify out of order, or to continue the trial, representing that they could not secure an expert witness to replace him. VIII 1070-79.

On June 19, 2018, the court entered an order that, *inter alia*, the June 20, 2018 telephone conference would proceed with modified topics. VIII 1080-84. The conference had been scheduled for Defendants to provide notice of whether they have determined to use a substitute witness for Dr. Li and, if so, to schedule discovery of that witness. VIII 1081. However, the court held that, based on

Defendants' renewed motion regarding Dr. Li, it was inclined to allow Dr. Li to testify out of order on July 23, 2018.

On June 20, 2018, the court held a telephone conference regarding Dr. Li. XXIII. Plaintiffs' stated the following concerns about having Dr. Li testify out of order on July 23, 2018: (1) their experts Dr. Lubarsky and Dr. Edgar could not be present in court on July 23, 2018, which would prejudice them by impairing their ability to cross examine Dr. Li, *id.* at 5-7; (2) Plaintiffs still did not have an expert report from Dr. Li, impairing their ability to conduct meaningful discovery, *id.* at 8-9; and (3) continuing the trial would be unfair because Plaintiffs had already made travel arrangements for fourteen witnesses and because Mr. Irick should not be forced to have to ask for a stay of execution to allow him to litigate his lethal injection challenge, which the State had confirmed by email that day would be opposed, *id.* The court took the matter under advisement. *Id.* at 14.

On June 20, 2018, Defendants filed Dr. Li's expert report. VIII 1088-96 (report and C.V.); VIII 1085-87 (Defs.' notice of filing).

On June 21, 2018, counsel for Defendants informed Plaintiffs' counsel for the first time an hour before the deposition of Debbie Inglis was to begin that Defendants intended to use compounded Midazolam to carry out Protocol B in Plaintiffs' executions. Plaintiffs filed a notice informing the court of this fact and requesting an emergency status conference. VIII 1097-1100. The trial court responded, denying Plaintiffs' request for an emergency status conference and

requesting briefing on the issues presented by the use of compounded Midazolam. VIII 1101-05.

On June 22, 2018, Plaintiffs responded in opposition to Defendants' renewed motion to permit Dr. Li to testify by deposition, or out of order, or for a continuance of the trial date, arguing (1) Defendants have the power to ameliorate the pressure of the litigation and solve the problem of Dr. Li's unavailability by requesting that Governor Haslam issue a reprieve from the pending execution dates; (2) Defendants' motion fails to state sufficient facts or law warranting reconsideration of the Court's June 12, 2018 order; (3) any minimal prejudice to Defendants is the result of Defendants' lack of diligence; (4) Plaintiffs will be prejudiced if Dr. Li is permitted to testify by deposition or out of order; and (5) Plaintiff Irick will face irreparable harm if the motion results in a delay of proceedings such that he cannot litigate his claims and obtain appellate review before his execution date. IX 1106-17.

On June 25, 2018, Plaintiffs filed a motion and memorandum of law regarding Defendants' new, unwritten protocol using compounded Midazolam—a high-risk sterile injectable. IX 1150-1227 (motion, memorandum, exhibits not under seal). Plaintiffs asserted that the then-operative lethal injection protocol—the January 18, 2018 protocol—as written, did not provide for compounded Midazolam; that compounded Midazolam created an additional risk of inflicting severe pain above and beyond that presented by the use of commercially manufactured Midazolam; and that Defendants' intention to use compounded Midazolam called into question the veracity of the deposition testimony of Ms. Inglis, Warden Mays,

and Commissioner Parker. IX 1153-59. Plaintiffs requested (1) leave to amend their Rule 26 disclosures to include expert opinions regarding the use of high-risk sterile injectables; and (2) leave to amend their complaint to add factual allegations and new legal claims regarding the unwritten protocol involving the use of compounded Midazolam and to add as-applied claims on behalf of Plaintiffs Irick, Zagorski, and Miller, the plaintiffs with execution dates already set. IX 1151-52, 1160, 1163. Plaintiffs also filed an exhibit in support of this motion under seal—an internet screenshot that showed that the Defendants' supplier of lethal injection chemicals ("Direct Source") was not licensed to compound high-sterile injectables such as Midazolam. VII 967 (Pls.' notice of filing sealed exhibit, under seal); Other 3 (sealed exhibit showing pharmacy supplying lethal injection chemicals to Tennessee was not at that time licensed to compound high-risk sterile injectables). In addition to filing the exhibit under seal, Plaintiffs also redacted all identifying information from it. Other 3.

On June 26, 2018, the court entered an order granting Defendants' renewed motion and permitting Dr. Li to testify on July 23, 2018. IX 1228-32.

On June 26, 2018, the trial court ordered Defendants to respond to Plaintiffs' assertions about Midazolam and ordered them also to respond to a list of questions created by the court on the basis of Plaintiffs' June 27, 2018 filing. IX 1233-39.

On June 27, 2018, Defendants responded to the Plaintiffs' motion regarding compounding and the court's questions. IX 1240-58.

On June 27, 2018, the trial court issued an order ruling on Plaintiffs June 25, 2018 motion regarding Defendants' new, unwritten protocol using compounded Midazolam. X 1259-65. The court canceled oral argument set for the following day on Plaintiffs' June 25, 2018 motion regarding the use of compounded Midazolam; granted Plaintiffs leave to amend their Rule 26 disclosures to include expert opinions regarding the use of high-risk sterile injectables to carry out the new unwritten protocol; held in abeyance a full ruling on Plaintiffs' forthcoming motion for leave to amend the complaint; granted an extension of time for the filing of pretrial briefs; and requested additional briefing on *Bucklew* in the pretrial briefs. *Id.*

On June 28, 2018, Plaintiffs filed a motion for leave to file a Second Amended Complaint seeking to add (1) new factual allegations and facial legal claims regarding the new unwritten protocol; (2) a new as-applied challenge on behalf of Plaintiffs Irick, Zagorski, and Miller—those with execution dates—on the basis of individual characteristics that would present additional risks of severe pain during the execution as a result of the use of compounded Midazolam; and (3) as-applied claims related to the Direct Source lacking proper credentials or facilities to prepare high-risk sterile compounds. X 1275-1349.

On June 28, 2018, the trial court issued an order that, "pursuant to page 3 of the June 13, 2018 *Memorandum and Orders*, redacted versions of the May 24, 2018 *Memorandum And Order Denying Motion For Protective Order Seeking To Quash Parker And Mays Depositions But Issuing Limitations On Time And Scope Of*

Depositions; And Additional Orders On Deadlines On Expert Disclosures And Defendants' Summary Judgment Filing, and June 12, 2018 Memorandum and Orders shall be posted on the public docket." X 1350-51 (6/28/18 order); X 1364-89 (redacted 5/24/18 order); X 1390-98 (redacted 6/12/18 order).

On June 29, 2018, the trial court issued an order granting leave to amend the complaint to add facial challenges to the new unwritten protocol but denying leave to add the two as-applied challenges. X 1353-63. Plaintiffs appeal this order.

On July 2, 2018, Plaintiffs filed a motion to reconsider the court's June 29, 2018 order regarding motion for leave to amend the complaint as to allegations regarding the Direct Source and/or a request for clarification regarding the admissibility of proof regarding the Direct Source's lack of credentials and history of dishonesty as it relates to Plaintiffs' as-applied challenge and proof of lack of good faith on the part of the defendants. X 1399-1407; VII 967 (under seal, Pls.' notice of filing exhibit under seal); Other 5 (under seal, exhibits 1-3). Plaintiffs' exhibits which redacted all information that could potentially identify the Direct Source or its pharmacist—were (1) a webpage showing that Direct Source was not licensed at that time to compound sterile high-risk injectables, Other 5, Ex. 1 (sealed); (2) an "Agreed Board Order" showing that the relevant state Board of Pharmacy took disciplinary action in 2014 against the Direct Source's owner for failing to reveal conviction of a misdemeanor crime on the Application for Pharmacy License, Other 5, Ex. 2 (sealed); and (3) an "Agreed Board Order" showing that the relevant state Board of Pharmacy took disciplinary action in 2017 against the Direct Source's chief

pharmacist for failing to properly supervise a pharmacy technician while acting as pharmacist-in-charge at a previous pharmacy, Other 5, Ex. 3 (sealed).

The trial court responded to Plaintiffs' motion to reconsider later that day— July 2, 2018—with an order requiring Defendants to file a response to the allegations in Plaintiffs' motion to reconsider. XI 1408-12. Specifically, the court ordered Defendants to respond to ten specific questions, which were based on Plaintiffs' allegations that TDOC planned to obtain lethal injection chemicals for the upcoming executions from a pharmacy (the Direct Source) that was not properly licensed and had facility that was not authorized to conduct high-risk sterile compounding. *Id*.

On July 3, 2018, Defendants responded to Plaintiffs' July 2, 2018 motion to reconsider and answered the ten questions presented in the trial court's July 2, 2018 order. XII 1564-72. Defendants conceded that the Direct Source "may have omitted some required information from a 2013 Application for Pharmacy License," which resulted in a "board investigation," and was "resolved by Agreement with no admission or denial of the truth of the matters;" that a pharmacist with Direct Source had another disciplinary matter with the Board involving improper supervision of a pharmacy technician; and that Direct Source was not yet licensed to distribute pharmaceutical products in Tennessee. XII 1568-69.

On July 3, 2018, Plaintiffs filed a reply in support of its July 2, 2018 motion to reconsider the order denying in part their motion to amend to add as-applied claims. XII 1577-81.

On July 3, 2018, Plaintiffs filed the Second Amended Complaint. XI 1416-1563. Defendants moved to strike the Second Amended Complaint asking the court to order Plaintiffs to file a corrected version that excludes the twelve claims the court had already dismissed. XII 1573-76. Plaintiffs' responded in opposition, arguing that Defendants' proposal would cause confusion on appeal, as Plaintiffs intended to appeal the court's dismissal as to a number of their claims and keeping the paragraphs the same would make it easier for Defendants to answer. XII 1582-84. Defendants replied in support of their motion to strike.

On July 3, 2018, the trial court entered an order on several motions. XII 1585-88. The court (1) denied Plaintiffs' July 2, 2018 motion to reconsider the June 29, 2018 order denying Plaintiffs' June 29, 2018 motion to amend to add two asapplied challenges related to the qualifications of the Direct Source and the individual risks faced by the three men with execution dates; (2) stated its intention to allow Plaintiffs to make an offer of proof at trial, through the testimony of Debbie Inglis, regarding their allegations that John/Jane Doe Pharmacists are not properly licensed in the State of Tennessee; do not have adequate facilities to compound high-risk sterile injectables; and have a disciplinary history that calls into question their competence to provide sterile, stable, potent chemicals for lethal injections in the State of Tennessee; and (3) denied Defendants' motion to strike the second amended complaint and submit corrected version. *Id.*

On July 5, 2018, both parties filed their trial briefs. XII 1697-1711 (Defs.' Brief); XIII 1712-1814 (Pls.' Brief); XIII 1815-XV 2052 (Pls.' Exhibits).

On July 5, 2018, Defendants also filed a notice of filing a new lethal injection execution manual, revised July 5, 2018. XII 1589-90. The July 5th protocol eliminated Protocol A (pentobarbital), purportedly clarified the use of commercially manufactured drugs or compounded preparations, added a two-minute wait time between the administration of Midazolam and the consciousness check, and added to the consciousness check pinching the inmate's trapezius muscle with the thumb and two fingers and twisting and added that calling the inmate's name during the consciousness check should be loud. XII 1589-90 (Defendants' notice, characterizing changes); XII 1592-1690 (July 5, 2018 Lethal Injection Execution Manual).

The trial court issued an order the same day requiring Defendants to file by that afternoon a notice identifying the specific sections and pages where changes were made to the Lethal Injection Manual. XII 1691-93. Defendants filed a red-lined version of the new Lethal Injection Manual that afternoon. XII 1694-96 (Defs.' notice of filing); Ex. 3, at Vol. 2, pp. 206-318 (red-lined version).

On July 5, 2018, Defendants filed an answer to the Second Amended Complaint. XV 2053-94.

On July 6, 2018, Defendants filed a motion for protective order prohibiting Plaintiffs from disclosing the identity or identifying information of potential execution participants and memorandum of law in support. XV 2095-99.

On July 8, 2018, Plaintiffs filed a response to Defendants' motion for protective order, which noted that Plaintiffs had not disclosed any information that would identify potential execution participants and had, in fact, redacted all

identifying information from the document that was filed under seal on June 25, 2018, showing that the Direct Source was not authorized to compound high-risk sterile injectables. XV 2100-10. Plaintiffs also noted that Defendants' general counsel provided the identifying information about their Direct Source in documents provided in response to a Tennessee Public Records Act request, so other individuals may have already also received the same identifying information from information or documents provided by Defendants themselves. XV 2104-05. Last, Plaintiffs noted that, although they had not and did not intend to disclose identifying information of potential execution participants, neither the Public Records Act provision that exempts such information from disclosure under the Act, Tenn. Code. Ann. § 10-7-504(h)(1), *West v. Schofield*, 460 S.W.3d 113 (Tenn. 2015), nor any other provision in the Tennessee Code or the Tennessee common law create a prior restraint that prohibits disclosure of the identity of execution participants by private citizens. XV 2105-08.

On Monday, July 9, 2018, the trial began. The trial court issued an order that morning stating that, although "the record does not show that the Plaintiffs have disseminated or breached confidentiality with respect to any of the information referred to in Defendants' *Motion*," a protective order prohibited any such disclosure would necessary "[g]iven the confidential and highly sensitive nature of the information." XV 2111-13.

On Tuesday July 10, 2018—the second day of trial—the *Tennessean*, a local newspaper, notified the trial court of its request to cover, photograph, and videotape the trial proceedings pursuant to Rule 30. XXXIX 1491-92.

On Wednesday July 11, 2018—the third day of trial—the trial court entered an *Order Concerning Upcoming Offer of Proof* stating its intention to be present and preside at the offer of proof that was to be held the afternoon of July 13, 2018, and ordering the *Tennessean* to file by the following day a request to be present at the offer of proof if it so desired, which it did. XV 2117-19.

On Thursday July 12, 2018—the fourth day of trial—the court indicated its intention to postpone the offer of proof from the following day as originally planned to the following Monday, July 16, 2018. XXXIII 995-96. The court also entered an order setting a hearing for July 16, 2018 on measures to be implemented during the offer of proof to comply with its July 9, 2018 protective order.

On Monday July 16, 2018—the sixth day of trial—Plaintiffs filed notice of their position as to the media's presence at the offer of proof, stating that they would defer to the Court to craft necessary restrictions on public access to the offer of proof, but sought to ensure that any such restrictions not impede their ability to present evidence and develop the record as to the issues involved with the Drug Supplier. *See also* XXXIX 1491-1506 (July 16, 2018 argument).

On July 16, 2018, Defendants also filed a response about the protocol for maintaining confidentiality at the offer of proof, arguing that (1) there was sufficient evidence in the record to preserve a claim of error for appeal; (2) if the

court thought Ms. Inglis' testimony was necessary, questioning should be limited to the questions set forth in the July 3, 2018 order allowing the offer of proof; and (3) if the court intended to allow questioning beyond the scope of the court's previous order, the court follow the procedures set forth in Tennessee Rule of Evidence 103(b)—pertaining to attorney/client privileged communications, namely reducing Ms. Inglis' testimony to writing and having the court review it in camera.

The court heard argument on the *Tennessean*'s motion to be present for the offer of proof on July 16, 2018. XXXIX 1491-1506. The court also heard argument on Plaintiffs' motion in limine regarding Defendants' inappropriate cross-examination of Plaintiffs' experts using summaries of expert opinions in court opinions from other jurisdictions. *Id.* at 1375-77 (discussing cases cited by Plaintiffs). The next day, the court ruled that this line of questioning was inappropriate and would be stricken from the record: "This is the phantom witness that the Court said cannot be used to impeach a witness. So I stand by that ruling. This will not come into evidence." XLIII 1887 (7/17/18 ruling); XVII 2346 (8/14/18 order on transcription of matters stricken at trial); Other 4 (stricken portions of cross examination of Dr. Stevens); Other 6 (stricken portions of cross examination of Dr. Greenblatt).

On Tuesday July 17, 2018—the seventh day of trial—the trial court entered an order "regulating" Plaintiffs' offer of proof. XV 2120-24. The court ruled that the testimony of Mr. Leonard, a paralegal in the Office of the Federal Public Defender for the Middle District of Tennessee who intended to testify about how Plaintiffs were able to determine the identity of the Direct Source, would not be permitted.

XV 2122. The court also ordered that Plaintiffs' questioning of Ms. Inglis would be restricted to asking specific questions outlined in the court's order, without "follow up questions" or "deviation." XV 2122-23. Plaintiffs appeal this order. Given the court's restrictions that thwarted Plaintiffs' ability to establish the facts they intended to establish for purposes of appeal, Plaintiffs informed the court that they would not question Ms. Inglis and presented a proffer of what Plaintiffs believe the proof would have shown. XLII 1682-89.

Plaintiffs' case ended on the afternoon of July 17, 2018, and they orally moved under Rule 15.02 to amend the complaint to conform to the evidence presented at trial that a two-drug protocol that omitted the vecuronium bromide the paralytic used as the second drug—would satisfy the *Glossip/West* requirement of an alternative method of execution. XLIII 1928-44.

On Wednesday July 18, 2018—the eighth day of trial—the court heard argument on Plaintiffs' oral Rule 15.02 motion to amend and denied it from the bench. XLV 1958-91. Plaintiffs appeal this order.

On July 18, 2018, the court heard argument on Defendants' oral motion for involuntary dismissal, and denied the motion. XLV 1991-2030 (argument); XLV 2030-31 (court's ruling); XV 2125-36 (Defs.' written motion).

On July 18, 2018, after the court denied their involuntary dismissal motion, Defendants began their case, presenting the testimony of Dr. Evans. XLV 2031-XLVI 2022.

At the end of Dr. Evans' testimony on Wednesday July 18, 2018, the court adjourned until July 23, 2018—the following Monday—when the court had granted permission for Defendants' expert Dr. Li to testify.

On July 19, 2018, the court issued a written order denying Plaintiffs' Rule 15.02 motion to amend. XV 2137-40. The court reiterated its ruling from the bench that the Plaintiffs could have pled a two-drug protocol as an alternative method when they filed the lawsuit and that the issue had "not been tried by express consent." XV 2138. The court added that its ruling "is separate from and does not affect that by express consent of the parties . . . the pleadings have been amended" such that the execution protocol being challenged by Plaintiffs is the July 5, 2018 protocol that eliminated pentobarbital as an option. XV 2138-39. Plaintiffs here do not challenge the court's ruling that the legal issue before the court in the trial related to the July 5, 2018 protocol, but instead only challenge the ruling denying the motion to amend to conform to the evidence of the two-drug protocol as an alternative method of execution.

On July 20, 2018, Plaintiffs Miller, Sutton, West, and McKay moved to reconsider the court's Rule 15.02 motion, asking that they be allowed to amend their complaint to add separate causes of action challenging the July 5, 2018 protocol and that the court bifurcate consideration of the claims arising out of the July 5th Protocol. XV 2141-59 (Miller Pls.' mot. and mem.); XV 2160-66 (Defs.' response); XVI 2173-77 (Miller Pls.' reply). Plaintiffs here did not join in that motion.

On Monday July 23, 2018—the ninth day of trial—Defendants presented the testimony of Dr. Li and concluded their case. XLVIII 9- XLIX 186.

On Tuesday July 24, 2018—the tenth day of trial—the parties offered closing arguments. L 4-95.

On Thursday July 26, 2018, the court denied the Miller plaintiffs motion to reconsider the court's Rule 15.02 motion. XVI 2216-28.

On Friday July 27, 2018, three days after the conclusion of trial, the court issued its order dismissing Plaintiffs' remaining claims with prejudice. XVI 2229-79. Plaintiffs appeal this order's ruling as to their method-of execution claims, their substantive due process/shocks the conscience claims, and their right to counsel and access to the courts claims. They do not appeal the ruling dismissing their procedural due process claims. The pertinent parts of the trial court's findings of fact and conclusions of law are as follows:

Count I: Method-of-execution constitutes cruel and unusual punishment

- "The Midazolam is to provide pain relief. Vecuronium bromide paralyzes the inmate. Potassium chloride stops the heart within 30 to 45 seconds of injection." XVI 2234.
- "In issue were portions of a complaint containing 764 paragraphs and 104 pages. 23 witnesses testified and 139 exhibits were admitted into evidence." *Id.* 2236.
- "The Court finds that in this lawsuit the Plaintiffs have failed to prove the essential element that there exists an available alternative." *Id.* 2239.
- Commissioner Parker "delegate[ed] the task of investigating supplies of pentobarbital to a member of their staff. *Id.* 2242; *see also id.* 2246 (referencing "the staffer delegated to research sources").
- "The Inmates presented the testimony of four well-qualified and imminent experts. The Court finds that these experts established that Midazolam does not elicit strong analgesic effects and the inmate being executed may

be able to feel pain from the administration of the second and third drugs." *Id.* at 2251; *see also id.* at n.7 (detailing experts' credentials).

- The United States Supreme Court "would not find the facts established in this case to violate the Constitution" because:
 - 1. The Court "has never invalidated a State's chosen method of execution."
 - 2. The Court "has recognized and is aware of the risks of Midazolam."
 - 3. The Court has never found "Midazolam's use in executions . . . to be unconstitutional or pose an unacceptable risk of pain."
 - 4. "[A]lthough dreadful and grim, it is the law that while surgeries should be pain-free, there is no constitutional requirement for that with executions."

Id. at 2252-53.

- Tennessee's protocol is not cruel and unusual because the 20 official timelines from Midazolam-based executions presented at trial showed the average duration from the time Midazolam is injected until the time of death is 13.55 minutes, with the longest time being 18 minutes and the shortest being 10 minutes. *Id.* at 2254-57.
- Eye witnesses to executions: "Eleven Federal Public Defenders and a law professor/self-employed attorney testified. These witnesses testified that there were signs such as grimaces, clenched fists, furrowed brows, and moans indicative that the inmates were feeling pain after the Midazolam had been injected and when the vecuronium bromide was injected. These witnesses' calculations of the duration of the executions was within a plus one minute of the Official Documentation." *Id.* at 2257-58.
- The Court concluded Plaintiffs had not shown the other *Glossip* prong of objectively intolerable risk of harm on the basis of (1) the United States Supreme Court and other courts' determinations that Midazolam does not pose a constitutionally unacceptable risk of severe pain; (2) an execution, unlike a medical procedure, "is not required to be painless"; and (3) Midazolam executions last 10 to 18 minutes. *Id.* at 2258.
- TDOC's decision to use Midazolam is not deliberately indifferent because the U.S. Supreme Court knew of "Midazolam's propensity" in *Glossip. Id.* at 2259.
- The use of vecuronium bromide, the paralytic second drug in the protocol, is not arbitrary because other courts have found it is not arbitrary. *Id.* at 2260-61.
- Plaintiffs' other challenges to the protocol also fail, such as the challenge to the use of compounding, problems with oral or written instructions

from the drug compounder on handling and storage, and insufficient consciousness checks. These challenges because other cases have so held and because Dr. Evans, Defendants' "expert pharmacologist,"⁷ established that "if the July 5, 2018 protocol is followed as written, it poses no risk." *Id.* at 2261-63

Count VIII: Substantive due process—shocks the conscience

• Plaintiffs' substantive due process- shocks the conscience claim fails because it is subsumed by Count I, the method-of-execution claim. *Id.* at 2264-68.

Count V: Right to counsel and access to courts

- The court construed Plaintiffs' claim as not seeking "telephone access or to change the sight view," but instead that the court's ruling the protocol as unconstitutional on this basis would cause executions to be halted. *Id.* at 2271, n.8.
- Although the TDOC Commissioner and Assistant Commissioner testified "that they would not object to Counsel having access to telephones, this Court does not have the authority in this case to order that." *Id.* at 2272; *accord id.* at 2275.
- Although the parties could reach an agreement on this, the "constitutional ramifications . . . must be dismissed," *id.* at 2272, because (1) "a facial challenge is the most difficult constitutional challenge to make," *id.*; (2) "[t]he presumption of constitutionality applies with even greater force when a party brings a facial challenge to the validity of a statute," *id.* at 2273; (3) "it is premised and based on speculation that during the execution something will go wrong that would necessitate the need for access to courts," which "does not state a claim in a facial challenge as recognized by the Tennessee Supreme Court in [the 2017 *West* decision], *id.* at 2273-74; and (4) it "is dependent upon the Inmates' succeeding on their Count I claim which they did not do," *id.* at 2274.

Three days later, on Monday July 30, 2018, Plaintiffs filed a notice of appeal.

XVI 2280-83.

On Tuesday July 31, 2018, Plaintiffs filed their designation of the record for

appeal. XVI 2284-97; XVII 2349 (Pls.' amended designation, 8/14/18).

⁷ Contrary to the trial court's characterization, Dr. Evans is a pharmacist, not a pharmacologist.

On August 6, 2018, Plaintiffs filed notice of filing pre-trial hearing transcripts. XVI 2298-2300.

On August 6, 2018, this Court denied Plaintiff Billy Ray Irick's request to stay his execution by lethal injection to obtain review of the trial court's ruling in this case. *See State v. Irick*, No. M1987-00131-SC-DPE-DD (Tenn. Aug. 6, 2018); *id.* (Lee, J., dissenting).

The United States Supreme Court also declined to stay Mr. Irick's execution to allow appellate review of the trial court's ruling in this case. *Irick v. Tennessee*, 585 U.S. __, __ (2018). Justice Sotomayor filed a powerful dissenting opinion: "If the law permits this execution to go forward in spite of the horrific final minutes that Irick may well experience, then we have stopped being a civilized nation and accepted barbarism." *Id.* (Sotomayor, J., dissenting).

On August 9, 2018, the trial court granted in part Plaintiffs' emergency motion to secure, retain, and preserve the physical evidence from Billy Ray Irick's execution, scheduled for that day. XVI 2301-10 (Pls.' Motion); XVII 2315-19 (Defs.' Resp.); XVI 2311-14 (8/9/18 order that Pls.' reply address how attached TRO sought by Irick to enjoin autopsy related to the motion to preserve evidence); XVII 2320-25 (Pls.' Reply); XVII 2326-32 (order granting motion to preserve evidence).

On August 13, 2018, exactly two weeks after Plaintiffs filed their notice of appeal to the Tennessee Court of Appeals, this Court, acting *sua sponte*, assumed jurisdiction over this appeal and ordered the appeal transferred from the Court of Appeals to the Supreme Court. XVII 2341-44 (reach down order). As Justice Lee

forcefully articulated in her dissenting opinion and as discussed further below, the Court "impos[ed] unrealistic deadlines on the chancery court clerk, the chancery court judge, the parties, and this Court to fast-track the process," creating a "rocket docket" for the "apparent purpose . . . [of] dispos[ing] of this appeal before the scheduled executions of plaintiffs Edmund Zagorski on October 11, 218, and David Earl Miller on December 6, 2018." XVII 2336 (Justice Lee's dissent). As Justice Lee noted,

The deadlines mandated by the majority allow no room for extensions for cause and are not realistic, reasonable, or conducive to a deliberate and thoughtful consideration of the important issues presented in this appeal. These short deadlines call into question whether the parties will receive meaningful appellate review of the chancer court's decision.

XVII 2337.

On August 14, 2018, counsel for Plaintiffs emailed the chancery court's law clerk inquiring about the proper way to handle the portions of the transcript that the Chancellor ordered stricken, as the court reporters were unable to remove portions of the transcript without an order from the court. XVII 2345. The trial court responding by filing an order instructing the court reporters on the proper procedure. XVII 2346-48.

On August 21, 2018, Plaintiffs filed notice of filing trial transcripts. XIX 2685.

STANDARD OF REVIEW

I. Standard of review regarding constitutional claims

"The resolution of a constitutional claim after an evidentiary hearing 'generally presents a mixed question of law and fact.' *Abdur'Rahman v. Bredesen*,

181 S.W.3d 292, 305 (Tenn. 2005). 'On appeal, our standard of review is de novo with a presumption of correctness extended only to the lower court's findings of fact.' *Id.*" *West v. Schofield*, 519 S.W.3d 550, 563 (Tenn. 2017).

II. Constitutional principles governing the distinction between and a facial versus an as-applied challenge

Plaintiffs' claims that proceeded to trial challenge the constitutionality of Tennessee's newest lethal injection protocol, in which the Defendants will execute inmates with an entirely new cocktail of lethal drugs—never before used in Tennessee—consisting of compounded Midazolam, possibly compounded vecuronium bromide, and possibly compounded potassium chloride. Each of Plaintiffs' remaining four constitutional claims that proceeded to trial alleges that the Protocol is facially unconstitutional—under both the state and federal constitutions- which requires Plaintiffs to establish "that no set of circumstances exist under which [the Protocol] would be valid." Speet v. Schuette, 726 F.3d 867, 872 (6th Cir. 2013) (quoting United States v. Stevens, 559 U.S. 460, 472 (2010)); accord Waters v. Farr, 291 S.W.3d 873, 921 (Tenn. 2009) ("[T]he challenger must establish that no set of circumstances exists under which the statute would be valid."). Plaintiffs' challenge is facial even though the Protocol only applies to a subset of Tennesseans—those who have been sentenced to the death penalty. The United States Court of Appeals for the Sixth Circuit explained this concept in *Green* Party of Tennessee v. Hargett, 791 F.3d 684 (6th Cir. 2015), in which minor political parties alleged that Tennessee's election statutes—which only applied to them—

unconstitutionally burdened their ability to get on the ballot:

By their own terms, these [ballot-access and ballot-retention] statutes apply only to recognized minor parties. Invalidating the statutes for recognized minor parties would *strip the statutes of each and every application they have*. By challenging the statutes as applied to recognized minor parties, the plaintiffs have in effect asserted a facial challenge.

Id. at 692. Similarly, if Plaintiffs prevail here, the Court's remedy would similarly "strip" the State's current lethal injection protocol "of each and every application" it is intended to have. That is, if the Plaintiffs demonstrate that the Protocol "cannot be constitutionally applied to anyone," the State could not execute *anyone* on Tennessee's death row using the current protocol. *Waters*, 291 S.W.3d at 922 (citing 1 Lawrence H. Tribe, American Constitutional Law § 3–31, at 611 (3d ed.2000)), In contrast, "an 'as applied' challenge only requires the challenger to demonstrate that the statute operates unconstitutionally when applied to the challenger's particular circumstances." *Id.* at 923 (citations omitted).

As the United States Supreme Court has explained, "the distinction between facial and as-applied challenges is not so well defined that it has some automatic effect or that it must always control the pleadings and disposition in every case involving a constitutional challenge." *Citizens United v. FEC*, 558 U.S. 310, 331 (2010); accord Green Party, 791 F.3d at 691–92 (quoting *Citizens United*). As the Court noted, "[t]he distinction is both instructive and necessary, for it goes to the *breadth of the remedy* employed by the Court, not what must be pleaded in a complaint." *Id.* (citing *U.S. v. Treasury Emp.*, 513 U.S. 454, 477–478 (1995)) (contrasting "a facial challenge" with "a narrower remedy")) (emphasis added). This is consistent with the state and federal case law cited above, which emphasizes the different remedy that results from a plaintiff prevailing in a facial versus and asapplied challenge. As the Tennessee Supreme Court has held: "A facial challenge to a statute involves a claim that the statute fails *an applicable constitutional test and should be found invalid in all applications.*" *Waters*, 291 S.W.3d at 921 (citing *U.S. v. Salerno*, 481 U.S. 739, 745 (1987)) (emphasis added). Thus, although the remedy for a successful facial constitutional challenge is different than the remedy for a successful as-applied challenge, the "applicable constitutional test" referred to by *Waters* is the same under either type of challenge.

Throughout this litigation, Defendants have argued that the "applicable constitutional tests" for Plaintiffs' claims—and the resulting scope of inquiry for the Court—are different because Plaintiffs' constitutional challenge is a facial one. Defendants accomplish this mischief by misinterpreting *West v. Schofield*, 460 S.W.3d 113 (Tenn. 2015), in which the Court stated: "The Protocol must be assessed *on its face* against the constitutional challenges levied by the Plaintiffs." *Id.* at 126 (emphasis in original). Defendants have argued that this means the Court can only consider the four corners of the Protocol to determine whether it is constitutional and have endeavored to improperly cabin Plaintiffs' discovery on that basis. But Defendants have taken the quote from *West* out of context and far further than it can logically extend. The sentence before the one that uses the "on-its-face" phrase states: "As to the facial challenge, we hold that the John Doe Defendants' identities are not relevant to a determination of the constitutionality of the Protocol as

written." *Id.* The sentence after that phrase concludes: "The identities of the persons who may facilitate or carry out the Protocol are not relevant to a determination of whether the Protocol passes constitutional muster." *Id.* Thus, the context of the "onits-face" phrase is the Court's conclusion that the identities of those carrying out the Protocol are not relevant to a facial challenge to the then-existing lethal injection protocol's constitutionality.

But in analyzing Plaintiffs' claims, the "applicable constitutional tests," Waters, 291 S.W.3d at 921, require the Court to consider more than the words contained within the four corners of the Protocol. For example, the Court cannot analyze Plaintiffs' method-of-execution claims without analyzing their proof under the first *Glossip* prong, which requires Plaintiffs to prove that the Protocol presents a risk that is sure or very likely to cause needless suffering. *Glossip*, 135 S. Ct. at 2737 (quoting *Baze*, 553 U.S. at 52); *West*, 519 S.W.3d at 564. The evidence needed to satisfy this prong is clearly outside the "face" of the Protocol. Thus, it is completely incorrect to say, as Defendants have, that consideration of Plaintiffs' claims requires looking only to the words contained in the four corners of the Protocol. Defendants' interpretation of the "on its face" language from *West* takes it out of context and runs contrary to all existing case law governing the analysis of facial constitutional challenges. Their interpretation would make it impossible for the Court to follow binding case law that guides the analysis of Plaintiffs' claims and would, therefore, effectively insulate the State's execution methods from court review. The Defendants' interpretation of *West* is simply wrong.

STATEMENT OF FACTS

I. The Science: The testimony of four expert witnesses, representing four different scientific perspectives.

a. Testimony of Dr. Craig W. Stevens, PhD, neuropharmacologist.

Plaintiff's first witness was Dr. Craig W. Stevens, a Professor of Pharmacology from Oklahoma State University. XXIV 72-165; Ex. 4, *Curriculum vitae*, at Vol. 3, pp. 319-332. Dr. Stevens received his Ph.D. from the Mayo Graduate School of Medicine. XXIV 73; Ex. 4, p. 319. He is the published author of over one-hundred peer-reviewed articles, book chapters and reviews; he is also the coauthor of the textbook, "Pharmacology," which is presently in its 5th Edition. XXIV 74-75; Ex. 4, p. 329. His research specialty is neuropharmacology, which is the study of how drugs affect the brain. XXIV 74-75. Dr. Stevens was admitted by the Chancellor as an expert in the field of pharmacology. *Id*.at 116-17. Like all defense experts, his testimony was witnessed by the Defendants' pharmacy expert, Dr. Roswell Lee Evans, who acknowledged the accuracy of his scientific testimony regarding Midazolam. XLV 2070, XLVI 2163-64

> 1. Dr. Stevens provided an abbreviated version of a year-long, graduate-level course on Central Nervous System pharmacology; he explained the crucial concept "mechanism of action."

As the plaintiff's first expert, it was Dr. Stevens' roll to compress a graduate level course in neuropharmacology into an hour. XXIV 79.⁸ Dr. Stevens attempted

⁸ Counsel will now try to compress this hour long course into a dozen pages. This may seem pedantic or too-detailed-to-be-relevant. However, it is the desire of counsel to provide this Honorable Court with sufficient knowledge so that Dr.

to provide an accurate, but simplified, explanation for how drugs affect the central nervous system. *Id.*

The essential term that he explained – and which would become crucial to his later testimony, as well as that of the other experts, was "mechanism of action." XXIV 80. A drug's mechanism of action is "[t]he mechanism by which a drug produces an effect on a living organism or in a biochemical system. A pharmacologist describes a drug's mechanism of action by identifying the specific molecular targets to which a drug binds and/or whose biochemical action it influences." *Id.* at 80-81. The mechanism of action of a drug "is of prime importance...It's the nature of the drug, how a drug works, basically. So we stress to graduate students and medical students, if nothing else, know at least the mechanism of action of the drug." *Id.* at 81.

> A. The central nervous system is made up of approximately 86 billion neurons, that each have roughly 10,000 connections to other neurons—it is these connections that produce the essential nature of neurons; and at each connection neurons 'speak' with a very simple language of excitatory and inhibitory neurotransmitters.

There are approximately 86 billion neurons in the central nervous system; each of these neurons has connections to roughly 10,000 other neurons; it is these connections that form the "essential nature" of neurons and of the central nervous system. XXIV 87-88. Neurons "speak" in a simple language of excitatory

Stevens' science can be assessed on its merits, and properly contrasted with the science (or lack thereof) presented by Defendants.

neurotransmitters, such as glutamate, and inhibitory neurotransmitters, such as GABA and endorphins. *Id.* at 90-92, 96. Neurons "summate" all of the inhibitory and excitatory impulses they receive, and if there is sufficient excitation, they "fire" or have an "action potential" causing the release of more neurotransmitters to the 10,000 +/- neurons with which they are connected. *Id.* at 90-93. If inhibitory neurotransmitters are predominant, then a neuron remains inactive. *Id.* In the time it took Dr. Stevens to say a single sentence, the neurons in his brain engaged in "countless, millions, billions" of summations of inhibitory and excitatory neurotransmitters. *Id.* at 93.

People are not necessarily inhibited by lots of inhibitory neurotransmitters. *Id.* at 95. Each neuron only "fires" one type of neurotransmitter; each neuron is either inhibitory or excitatory, and if inhibitory neurons are inhibited it paradoxically, creates excitation. *Id.* at 92-95. Dr. Stevens shared the typical example of alcohol, which, in smaller doses inhibits a person's inhibitions, leading to garrulous behavior and trips to the dance floor. *Id.*

B. Three basic mechanisms of action: (1) independent effect on the brain; (2) enhancement of other chemicals in the brain; (3) blocking of other chemicals in the brain.

In "simplistic terms" there are three basic mechanisms of action that a drug may possess (and a drug may possess more than one). XXIV 81. Some drugs bind to receptors and independently produce an effect; for instance morphine binds to the opioid receptor directly leading to suppression of pain. *Id.* Other drugs work with and enhance the efficacy of neurotransmitters; this is the mechanism of action of

Midazolam, which enhances the potency of the inhibitory neurotransmitter GABA. *Id.* at 81-82. Finally, a third mechanism of action is to block a neurotransmitter, preventing an effect; for instance beta blockers inhibit the impact of epinephrine. *Id.* at 82.

C. The basic terminology of sedation: "the plane of general anesthesia" is crucial, only at this level is a human rendered insensate to pain.

Drugs that have a mechanism of action that brings about sleep are called hypnotics, drugs that reduce anxiety are called sedatives – sedative-hypnotics are drugs that do both. XXIV at 83. Such drugs do not inhibit pain; that is the role of analgesics, which have different mechanisms of action. *Id.* at 84, 86. There are three levels of sedation, above the plane of general anesthesia, labelled mild, moderate or deep sedation; in any of those states a person still feels pain and can respond to pain. *Id.* "The plane of general anesthesia" is a deeper level of sedation, defined as "a drug-induced loss of consciousness during which patients are not rousable, even by painful stimulation." *Id.* at 85. A person in the plane of general anesthesia demonstrates four states: unconsciousness (lack of all awareness), amnesia (no subsequent memory), analgesia (unable to feel pain) and immobility. *Id.* at 85-6. The crucial distinction is that "under sedation people feel and are responsive to pain, and under general anesthesia they do not." *Id.* at 86.

Dr. Stevens' produced a "Glossary of Simplified Pharmacological Terms," as an aid to the Chancery Court (and it may be an aid to this Honorable Court as well). XXIV 80; Ex. 7, *Glossary*, at Vol. 3, pp. 348-351. This contains further definitions of the relevant terms that will not be repeated here.

D. Diagramming basic neuropharmacological principles.

Dr. Stevens provided multiple diagrams to the court, in an attempt to better convey the complex processes that he described. To begin with, he presented a simplified diagram of a neuron, with only two (instead of 10,000) connections to other neurons. XXIV 90; Ex. 8, *Simplified Diagram*, at Vol. 3, p. 352.



Simplified Diagram of Neurons

Dr. Stevens also provided two graphical representations of how excitatory and inhibitory neurotransmitters impact a neuron to either cause an action potential (or "firing" of the neuron), or to prevent one from occurring. XXIV 90-94; Ex. 9, Actions of Excitatory and Inhibitory Neurotransmitters, at Vol. 3, p. 353 and XXIV 101-02; Ex. 12, Summation of Excitatory and Inhibitory, at Vol. 3, p. 356.



The first diagram, represents the excitatory impact of the neurotransmitter, glutamate, and the inhibitory effect of the neurotransmitter, GABA. XXIV 92-93.



The second diagram better represents the reality that many different inputs reach every neuron, some will be excitatory (again in the diagram glutamate) and others inhibitory (GABA). XXIV 101. Dr. Stevens explained that "in real life you have 10,000 of these inputs" and that "all these electrical potentials will be summated to make kind of the final decision of that neuron to fire or not." *Id.* at 101-102.

2. The single, limited mechanism of action of Midazolam, compared with the multiple mechanisms of more potent pharmaceuticals.

Midazolam is a benzodiazepine drug. XXIV 102-03. Like all benzodiazepines, Midazolam's sole mechanism of action involves the GABA receptor. *Id.* at 104-110. A significant focus of Dr. Stevens' testimony was on this single, limited mechanism of action, as compared with the three mechanisms of barbiturates (such as Pentobarbital) and the five of halogenated anesthetic gases. XXIV 102-135.

A. The GABA receptor.

GABA is a major inhibitory neurotransmitter. XXIV 94. Every neuron has thousands of GABA receptors that GABA binds to. *Id.* at 100. The GABA receptors are somewhat like pores in the skin of the neuron. *Id.* at 100. The neurotransmitter GABA binds to specific sites on the GABA receptor which causes a chloride ion channel to open. *Id.* at 98-100. When that channel opens, negatively charged chloride ions enter the neuron, leading to a negative charge on the inhibition side of the equation. *Id.* at 99-100; *see also* Ex. 9 and 12, *supra*.

There are also sites on the GABA receptor where various drugs can bind; benzodiazepines bind in one location on the surface of the receptor, while barbiturates bind at two sites below the cell membrane. *Id.* at 99-100; Ex. 11, *GABA Receptor*, at Vol. 3, 355. Ethanol and general anesthetics, among other drugs, also have unique binding sites. XXIV 100; Ex. 11.



B. Midazolam has a single mechanism of action, while Pentobarbital has three mechanisms; due to this scientific reality Midazolam is not capable of causing the same effects as Pentobarbital.

Midazolam works in conjunction with the neurotransmitter GABA. XXIV 106-07. When both GABA and Midazolam are bound in their respective locations on a GABA receptor, the chloride ion channel opens at a more rapid frequency, admitting more negatively charged ions than it would with GABA, alone. *Id.* However, if Midazolam is bound to the GABA receptor, but GABA is not present, then the channel remains closed. *Id.* at 108. Dr. Stevens used a diagram from his textbook, *Pharmacology*, to further illustrate the mechanism of action of Midazolam, and to compare it to barbiturates such as Pentobarbital. XXIV 104; Ex. 14, *Mechanisms of Action at the GABA receptor*, at Vol. 3, 358.



Midazolam and Pentobarbital Mechanism of Actions at the GABA receptor

FIGURE 19.2. Receptor sites for γ -aminoburyric acid (GABA), benzodiazepines, barbiturates, and ethand on the GABA_A chloride ion channel. The GABA_A chloride ion channel is a protein complex pentameric form that has varying combinations of α , β , and γ subunits. GABA binds to a site near the junction of α and β subunits, and this causes conformational changes that open the chloride ion channel and lead to neuronal membrane hyperpolarization. Benzodiazepines bind to an allosteric site formed by the cleft between α and β file Appellate Courts subunits, and this facilitates GABA binding and increases the frequency of chloride channel opening. Barbiturates and fixe of the Appellate Courts and in the absence of GABA. Ethanol (ethyl alcohol) binds to a distinct site on the ionophore and enhances chloride influx. The ionophore also contains binding sites for steroids and inhalational anesthetics.

In the diagram, as he explained, red circles represent chloride ions, green triangles GABA, yellow circles benzodiazepines (also labelled "BDZ"), like Midazolam, and blue diamonds barbiturates ("BARB"), like Pentobarbital. XXIV 105-08. Barbiturates have two different mechanisms of action at the GABA receptor: (1) they work with GABA and increase the duration that the ion channel remains open, and (2) they work independently of GABA to open the ion channel. *Id.* at 108-109. Their first mechanism of action, which increases the duration of the channel's opening, lets in more chloride and has a greater inhibitory effect than does Midazolam's mechanism which increases frequency. *Id.* at 107. Barbiturates' second mechanism of action produces inhibition, in the absence of GABA, which, yet again, causes barbiturates to be much more potent than benzodiazepines. *Id.* at 107-10. Indeed, Dr. Stevens explained that the diagram graphically represents this difference in potency, with more "red" chloride ions coming through via the two mechanisms of action of barbiturates at the GABA receptor, than via the single action of benzodiazepines. *Id.* at 109-10.

However, barbiturates have a third mechanism of action, they block glutamate, an excitatory neurotransmitter, from binding to glutamate receptors. XXIV 111; Ex. 10, *Neurotransmitters, Receptors and Effects on Neurons*, at Vol. 3, 354. This third mechanism of action, blocking excitation, makes barbiturates "very powerful." XXIV 111.

Dr. Stevens explained that in stressful situations, such as during an execution, a person would release significant quantities of excitatory neurotransmitters. XXIV 110. Noxious stimuli, such as pulmonary edema, suffocation and/or chemical burning, would also cause the release of excitatory
neurotransmitters. XXV 156, 161. In these circumstances, "barbiturates would still work," but excitation could overcome the impact of benzodiazepines. XXIV 110.



Neurotransmitters, Receptors, and Effects on Neurons

i. Different mechanisms of action, different uses.

Due to the different mechanisms of action of benzodiazepines and barbiturates, they are used differently in real world practice. XXIV 112. Before the invention of benzodiazepines, barbiturates were used as sedative-hypnotics (drugs that bring about sleep and reduce anxiety). *Id.* This was unfortunate, and many people died from overdoses. *Id.* at 112, 125-6. Benzodiazepines are much safer, and cannot cause a fatal overdose in a healthy person, thus they are now the preferred sedative-hypnotics. *Id.* at 112-13. Benzodiazepines' mechanism of action is insufficient to produce enough inhibition to stop breathing or stop the heart. *Id.* at 113. They only risk causing respiratory depression when used in conjunction with other depressant medications, such as opioids. *Id.* at 114. For instance, Midazolam is often used with Fentanyl during colonoscopies; the Fentanyl is used to prevent pain (something Midazolam cannot do). *Id.* at 114-15.

Dr. Stevens explained that barbiturates, if given in sufficient quantity, with their three mechanisms of action, can bring a person to a plane of general anesthesia, or even into a coma. XXIV 115, 125. Midazolam and other benzodiazepines, with their limited mechanism, cannot do so. *Id.*

ii. Anesthetic gases have five-mechanisms of action;
like barbiturates, they both increase inhibition and
block excitation; this makes them yet more potent,
and again illustrates the limitations of Midazolam.

To further demonstrate the limited nature of Midazolam's single mechanism of action, Dr. Stevens presented another diagram from his textbook, which depicted the five mechanisms of action of halogenated anesthetic gases of the sort used in surgery. *Id.* at 115-16; Ex. 15, *Five Mechanisms of Action of a General Anesthetic,* at Vol. 3, at p. 359.

<u>Five</u> mechanisms of action of a general anesthetic



The halogenated anesthetic gases (1) enhance inhibitory GABA, in a manner similar to both benzodiazepines and barbiturates, and (2) they block excitatory glutamate as do barbiturates, however (3) they also enhance one other inhibitory neurotransmitter, glycine, while (4 and 5) blocking two other excitatory neurotransmitters, $5HT_3$ (serotonin) and neuronal nicotine. *Id.* Thus, to a greater extent than barbiturates (and completely differently from benzodiazepines) they work "on both sides of the electrical equation." *Id.* at 119. Because of the different mechanism(s) of action of the three classes of drugs,

Dr. Stevens opined to a reasonable degree of scientific certainty that barbiturates and halothane gas can render a person insensate to pain and noxious stimuli, while benzodiazepines, including Midazolam, cannot. *Id.* at 121-22.

C. Because of Midazolam's single limited mechanism of action it has a ceiling effect, and it can never-regardless of dose--render a human insensate to pain, or unarousable by noxious stimuli; it can never bring a human to a plane of general anesthesia.

Dr. Stevens introduced another diagram from his textbook. XXIV 123; This diagram conceptually displayed the dose-response curves of barbiturates (linear) and benzodiazepines (curved). XXIV 123-25.



'Ceiling effect' of midazolam, a benzodiazepine

FIGURE 19.3. Dose-response curves of barbiturates and benzodiazepines. The barbiturates exhibit a linear dose-response effect, which progresses from sedation to respiratory depression, coma, and death. Benzodiazepines exhibit a ceiling effect, which precludes severe CNS depression after oral administration of these drugs. Intravenous administration of benzodiazepines at clinical doses does not produce significant respiratory depression, except when other CNS depressants are coadministered. Benzodiazepines administered by either route do not produce anesthesia.

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The dose dependent limitation on benzodiazepines does not apply to duration. XXIV 128. The ceiling effect only limits the efficacy of Midazolam; regardless of dose, "you won't get a higher or greater effect beyond sedation." *Id.* Duration of effect is governed by how long the drug stays in the human body; it takes the human body longer to eliminate larger doses. *Id.*

i. The ceiling effect is not some magical property of Midazolam: other medications such as aspirin have ceiling effects.

The ceiling effect is non-controversial and well-known, and it is not unique to benzodiazepines. XXIV 127. In teaching medical students, Dr. Stevens uses aspirin to demonstrate a ceiling effect. *Id.* Two or three aspirin can address the pain from a headache, but no quantity of aspirin, whether ten, or an entire bottle, can stop the pain of an amputated leg. *Id.* The opioid morphine, however, is a different class of drugs that do not have a ceiling and can treat such pain. *Id.* at 127-8. It also due to the lack of a ceiling that fatal overdoses can be caused by morphine. *Id.* at 128.⁹

There are two attributes to a ceiling effect: (1) maximum potency and (2) the dose at which maximum potency is reached.

There are two pertinent variables to a drug's ceiling effect, which are depicted on the x and y axes of Exhibit 16(a). XXIV 128-29; Ex. 16(a). The first variable, is the maximum effect that can be reached. XXIV 129. The second

⁹ Large enough doses of aspirin can be fatal, due to destroying the liver and kidneys. However, this is not a product of aspirin's sedative mechanism of action, rather it is "general poisoning." XXIV 129-30.

variable is at what dose is the maximum effect reached. *Id.* This second variable is harder to identify, as it depends on the specific response that is being measured. *Id.* This second variable is important, however, as professionals do not want to provide unnecessarily large doses of medication that can cause "nonspecific or topic effects," such as poisoning. *Id.* at 129-30.

iii. The scientific proof of Midazolam's ceiling: (1) mechanism of action, (2) real world experience and (3) peer reviewed scientific studies.

Dr. Stevens was confident that Midazolam can not render a normal human insensate to pain, or bring them to the plane of general anesthesia. XXIV 121-22. His conclusion is based on (1) the pharmacology of Midazolam, (2) real world experience, ¹⁰ and (3) peer reviewed science. ¹¹ *Id.* at 130-135.

He explained that Midazolam's mechanism of action—which is "the nature of a drug,"—was his "prime consideration." XXIV 130. Midazolam's limited impact on the GABA receptor (as described above) is not "potent enough" to bring someone to the plane of general anesthesia. *Id.* at 130-31. Moreover, Midazolam's inability to address the excitatory side of the equation was an additional limitation. *Id.* From a pharmacologist's perspective, the mechanism of action is the "main and prime reason" that explains the ceiling effect. *Id.* at 130-31.

¹⁰ This will be explored in greater detail, when discussing the testimony of a practicing anesthesiologist, Dr. David Lubarsky.

¹¹ This will be explored in greater detail, when discussing the testimony of the leading scholarly researcher on Midazolam, Dr. David J. Greenblatt.

Dr. Stevens received further confirmation of his scientific conclusion through the real world practice of anesthesiologists. He observed, "[n]obody uses it as a general anesthetic....if it worked as a general anesthetic it would be used as one, companies would market it as one, they would push it as one." XXIV 131. Similarly, he noted that the FDA has never approved Midazolam for use as a general anesthetic. *Id.*

Finally, Dr. Stevens was able to point to peer-reviewed scientific studies that confirm the ceiling effect, and confirm that Midazolam cannot render a person insensate to pain. XXIV 132-35; *see also* Ex. 6, *Studies reviewed*, at Vol. 3, pp. 335-347. Every study that has been performed on Midazolam, and that measured depth of sedation, found that Midazolam did not reach the level of general anesthesia. XXIV, 132; Tr. July 9, 2018, part 2, XXV 216. Dr. Stevens emphasized a paper by Miyake, done in 2010, which involved 24 subjects, half of which received 0.2 mg per kg of Midazolam, and half received 50% more, 0.3 mg/kg.¹² XXIV 132-33. Using an EEG to measure sedative effect, the paper determined that there was no greater effect from the 50% larger dose. XXIV 134. Regardless of dose, in the Miyake study, Midazolam did not bring the subjects to a plane of general anesthesia. XXV 216. The authors of the paper concluded that full saturation of GABA binding sites was reached with the 0.2 mg/kg dose. XXIV 134-35.

iv. Larger doses do not change the mechanism of action; a 500 mg dose of Midazolam cannot break through the ceiling.

 $^{^{12}}$ A man weighing 220 pounds would weigh 100 kg. Thus, 0.2 mg/kg would lead to a dose of 20 mg, and 0.3 mg/kg would lead to 30 mg. XXIV 133-34.

A 500 mg dose of Midazolam has the same mechanism of action as a smaller dose. XXV 216-17. Larger doses cannot work independent of GABA. *Id.* at 217. Larger doses do not affect strychnine. *Id.*; Ex. 15, *supra*. Larger doses do not block the excitatory neurotransmitters 5HT₃ and glutamate. XXV 217; Ex. 15.

Once a ceiling is reached, there is simply no science which supports the conjecture that a large enough dose would break through the ceiling. XXV 217-18. Once a flat-line on efficacy is reached, the curve will never start going upward again. *Id.* at 218.

3. The painful pharmacological effects of the three-drugs in Tennessee's protocol: inmates will suffer severe pain and terror.

Dr. Stevens concluded, to a reasonable degree of scientific certainty, that Tennessee's three-drug protocol would cause "severe pain and terror." XXV 160. He explained that Midazolam was incapable of rendering an inmate insensate to pain, and thus inmates would suffer suffocation, and chemical burning. *Id.* at 160-61. Midazolam is also incapable of rendering the inmate insensate to pulmonary edema. *Id.* at 161-62.

A. Midazolam is a strong acid, pH 3.0; 100 ml of acid is an immense quantity of acid to inject into a human being.

Dr. Stevens was asked about the findings of Dr. Mark Edgar, a pathologist, who had concluded that the "vast majority of people who have been executed using

Midazolam, had pulmonary edema."¹³ XXIV 135. Whether this conclusion was scientifically valid was outside of Dr. Stevens' expertise. *Id.* at 135-36. However, he was able to provide some contextual information. *Id.* at 136-140.

Midazolam is not water soluble in its native state; only in a solution with a pH below 4.0, can it begin to be dissolved. XXIV 136. At lower pH levels it begins to change into an "open-ring" form called benzophenone. *Id.* at 136-37. Midazolam for injection is thus dissolved in a "very acidic solution," with a pH of 3.0. *Id.* at 137. Human blood is slightly more alkaline than neutral, with a pH of 7.4 (neutral is 7.0). *Id.*

Dr. Stevens examined two syringes, one a 5 cc syringe, which could contain a 25 mg dose of Midazolam, and a second 100 cc¹⁴ syringe that would be needed to hold an undiluted dose of 500 mg of Midazolam. XXIV 139-40; Ex. 18, Syringes— *Retained in Clerk and Master's office*. A typical human has 4 to 5 liters of blood, which is equal to 4,000 to 5,000 cc's. *Id.* at 140. 40 or 50 100 cc syringes would contain the total blood supply of a normal human. *Id.*¹⁵

B. Vecuronium bromide is a paralytic, which will first paralyze the small muscles of the face, preventing obvious

¹³ The substance of this will be explored in greater detail when discussing the testimony of Dr. Edgar.

¹⁴ cc's and ml's are the same.

¹⁵ As the physical syringes are kept by the clerk and master, another illustration may be of assistance. A 100 cc syringe holds 1/20th the liquid of a 2 liter bottle of Diet Coke. If both doses of Midazolam were used, then 1/10th of that bottle would be injected into the inmate's vein.

reaction, then the limbs, and finally the lungs, causing suffocation.

The second drug in the three-drug protocol, vecuronium bromide is a muscle paralytic. XXV 153. Dr. Stevens explained, pharmacologically, how vecuronium causes paralysis.¹⁶ Its real world impact is to cause progressive paralysis: "it starts with the smaller facial muscles, works its ways eventually to the skeletal muscles that...make our hands, arms and fingers move, and eventually goes to the more internal muscles like the diaphragm and the intercostal muscles that help you breathe." *Id.* at 154-55. At sufficient doses, respiration will cease. *Id.* at 155.

Vecuronium does not have a direct effect on the brain. XXV 156. However, if a person is not in a "state of general anesthesia, and you're using vecuronium, it can be quite horrific." *Id.* Midazolam is not capable of rendering the inmate insensate to suffocation, caused by the paralysis of the lung muscles. *Id.* at 156-57. Suffocation is a noxious stimuli, which will cause the release of more excitatory neurotransmitters. *Id.* These excitatory neurotransmitters will further reduce the efficacy of Midazolam, as it "battles" against them. *Id.* at 157.

C. Potassium chloride is a depolarizing chemical that activates every pain-sensing neuron in the body; it will stop the human heart, causing death.

Dr. Stevens also explained the mechanism of action of potassium chloride, the third drug in Tennessee's protocol. XXV 158-59. The effect of the potassium is

¹⁶ The scientific mechanism does not appear relevant to any issue in dispute, so it will not be explored, further.

to stop the human heart in a state of contraction. *Id.* The heart will stop beating, approximately, 45 seconds after injection. *Id.* at 159. Based on Dr. Stevens' review of Tennessee's protocol, the injection of potassium will be the cause of the inmate's death. *Id.* at 159-60.

If a person is not in a plane of general anesthesia, when the potassium is injected, they will suffer extreme pain. XXV 159. Potassium chloride "burns" throughout the veins upon injection." *Id.* Multiple studies have established this. *Id.*

4. Dr. Stevens' final conclusions about the neuropharmacological impact of the three-drug protocol: it will cause severe pain and mental anguish; a two-drug protocol that did not include vecuronium would be less painful and cause less suffering; a one-drug protocol using Pentobarbital, if done properly, would not involve pain at all.

Dr. Stevens concluded that the three-drug protocol would cause an inmate "severe pain and terror." XXV 161, 219. The three-drug protocol posed a "substantial risk of severe pain." *Id.* at 218.

To a reasonable degree of scientific certainty, Midazolam cannot render an inmate insensate to pain, regardless of dose. *Id.* at 161, 164. The vecuronium will cause the sensation of suffocation, while the potassium will cause feelings of burning. *Id.* at 161-62, 220. To the extent that inmates suffer pulmonary edema from having 100 (or 200) ml of acid injected into their veins, that would be another painful stimuli they would suffer that Midazolam could not protect against. *Id.* at 161-62, 164.

500 or 1,000 mg of Midazolam will be no more effective in rendering an inmate insensate than would a dose of 20 or 30 mg (given to a 220 pound man). XXV 162. None of those doses could render an inmate unaware of suffering. *Id.*

A two-drug protocol, that did not include vecuronium would be less painful and would cause less suffering, as it would lessen the amount of time the inmate experiences the pulmonary edema prior to death. XXV 162-63. A single-drug Pentobarbital protocol would render an inmate insensate to pain, and then cause their death; it would not involve severe pain. *Id.* at 163, 218.

b. The Testimony of David J. Greenblatt, M.D., Louis Lasagna Endowed Professor of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine and special and scientific research staff at Tufts Medical Center

Plaintiffs' second expert witness was Dr. David J. Greenblatt. His testimony covered two days. TE Vols. XXVIII, XXXIX. Dr. Greenblatt is one of the foremost medical researchers on the benzodiazepine class of drugs, which includes Midazolam. He has studied and researched Midazolam from its earliest introduction into United States markets, including participating in the research that led to its approval for use by the Food and Drug Administration. Dr. Greenblatt's testimony was clear, consistent, and unwavering: Midazolam is incapable of inducing a state of anesthesia wherein a person would be insensate to the torturous effects of vecuronium bromide and potassium chloride as used in the Tennessee lethal injection protocol; the pharmacokinetics of Midazolam make it almost certain that its sedative – versus anesthetic – effects will not have reached their maximum by level by the time vecuronium bromide and potassium chloride are injected into an inmate under the Protocol; Midazolam has no analgesic properties that would block the torturous effects of vecuronium bromide and potassium chloride as used in the protocol; and the pH of Midazolam solution in the amount called for by the protocol would inflict severe damage to lung tissue which would very likely result in rapid onset of pulmonary edema.

1. Dr. Greenblatt has an excellent record as an academic and medical scientific researcher that spans more than 40 years, focusing on benzodiazepine drugs

Dr. Greenblatt earned his medical degree from Harvard University in 1970. Id. p. 471; Ex. 38, Greenblatt Curriculum Vitae, at Vol. V, p. 628. Following two years of residency training at New York and Boston hospitals and a two-year clinical fellowship in clinical pharmacology at Harvard Medical School, he took a joint appointment at Harvard Medical School and Massachusetts General Hospital. TE Vol. XXVIII, p. 472; Ex. 38, Vol. V, p. 628. In 1979 he joined the faculty at Tufts University School of Medicine and the affiliated hospital, Tufts Medical Center, where he has taught and done research in clinical pharmacology for the last 39 years with appointments in the departments of pharmacology and experimental therapeutics, anesthesiology, medicine, and psychiatry. TE Vol. XXVIII, pp. 473-74; Ex. 38, Vol. V, p. 628. He is licensed to practice and board certified in clinical pharmacology. TE Vol. XXVIII, pp. 474. Dr. Greenblatt is presently the Louis Lasagna Professor of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine. Louis Lasagna is considered the father of clinical pharmacology. Ex. 38, Vol. V, pp. 628; TE Vol. XXVIII, p. 474-75. Clinical

pharmacology is a branch of internal medicine. The principal focus is on drug effects in humans, drugs' mechanisms of actions, their proper therapeutic uses, adverse reactions that occur, patterns of use in the general population, and factors that influence the effects of the drug (age, gender, disease states, drug interactions). TE Vol. XXVIII, p. 487.

Over his career, Dr. Greenblatt has published more than 775 original research articles in peer-reviewed journals. His publications include more than 200 focusing on the benzodiazepine class of drugs, and more than thirty on research specifically on Midazolam. TE Vol. XL, pp. 1534-35; Ex. 38, Vol. V, p. 631-87. According to Google Scholar, his articles have been cited more than 65,000 times, and his h-index score is 118.¹⁷ He has served as editor in chief of two peer-reviewed journals, *The Journal of Clinical Psychopharmacology* and *Clinical Pharmacology in Drug Development*, as well as serving on the boards of a number of other scientific and medical research journals. TE Vol. XXVIII, p. 476; Ex. 38, Vol. 5, p. 630. In 1985, Dr. Greenblatt was one of four researchers who co-authored an article entitled "Midazolam: Pharmacology and Uses." Ex. 40, Vol. 5, p. 711. The article is a review of the research on Midazolam at that time and drew on the research that was done in preparation to submit the drug for FDA approval. It has been cited

¹⁷ H-index is a metric to compare scholarship that considers both number of publications (productivity and number citations (impact). It is accepted and relied on in scientific research academia. TE Vol. XXVIII, p. 474-75. The creator of the index estimated that after 20 years of research, an h-index of 20 is good, 40 is outstanding, and 60 would be truly exceptional.

more than 1000 times, making it a "citation classic" among peer-reviewed medical publications.

2. Dr. Greenblatt participated in the earliest research on Midazolam in the United States which became part of its review and approval for use by the F.D.A.

Dr. Greenblatt became involved with the study of Midazolam in the early 1980's. He was part of a group of researchers that developed a method for measuring levels of the drug in plasma. TE Vol. XXVIII, p. 480. He participated in a number of studies of the drug including factors that influenced how it is distributed, metabolized, and cleared in the body. TE Vol. XXVIII, p. 481. He also participated in studies that measured the effects of the drug on the electroencephalogram relative to the dose and level of drug in the plasma. Those studies went into the New Drug Application for Midazolam that was submitted to the F.D.A., which reviewed them as part of its decision to approve the drug for general use in clinical practice.

3. Dr. Greenblatt testified in agreement with Dr. Stevens on the pharmacology of Midazolam

In his testimony, Dr. Greenblatt gave an explanation of how Midazolam works in humans that aligned with the testimony of Dr. Stevens. In human brain cells there are channels that open and close to permit or prevent the entry of chloride into the cell as part of normal brain chemistry. The entry of chloride ions into brain cells makes it more difficult for brain cells to transmit signals, thereby creating drowsiness and sedation. TE Vol. XXVIII, p. 493. On these channels, there are receptors to which certain specific materials bind and affect the opening of

the channel. One such substance is gamma-aminobutyric acid, called "GABA." TE Vol. XXVIII, p. 492. When GABA binds to GABA receptors on the chloride channel, the channel opens allowing chloride to flow into brain cells. There are also specific receptors to which benzodiazepine drugs, including Midazolam, bind. TE Vol. XXVIII, p. 491. These drugs increase the frequency of the opening of the chloride channel, thereby allowing more chloride into the cell and causing sedation. TE Vol. XXVIII, p. 493. For this reason, benzodiazepines are referred to as "GABA facilitators." TE Vol. XXVIII, p. 492.

4. Dr. Greenblatt was unequivocal in his opinion that Midazolam is incapable of inducing a level of anesthesia where a person would be insensate to the torturous effects of vecuronium bromide and potassium chloride as used in the Tennessee lethal injection protocol

Relying on more than 35 years of research and study on Midazolam, Dr. Greenblatt was clear and unwavering in his opinion: Midazolam alone cannot under any circumstances render a person insensate to or unaware of noxious stimuli.

A. Midazolam's effects are based on a physical function in brain cells that is innately limited, which limits the effect of the drug

As Drs. Greenblatt and Stevens explained, Midazolam induces sedation by enhancing the effect of GABA by increasing the frequency of the opening of the chloride channel in brain cells. Dr. Greenblatt further testified that that opening is a physical pulsatile operation that is innately limited: the channel can only open so frequently. TE Vol. XXVIII, p. 499. Furthermore, Midazolam only alters the frequency of the opening of the chloride channel. It has no effect on the duration of the opening of the chloride channel. TE Vol. XXVIII, p. 493. This intrinsic physical limitation of the frequency of the opening of the chloride channel in turn limits the amount of chloride ion that can enter a brain cell and induce sedation.

This phenomenon may be called a "ceiling effect." Dr. Greenblatt referred to it as the pharmacological limitation of the drug.

B. Midazolam is not used alone to induce general anesthesia; where it is used alone as a sedative it is because it allows a patient to be roused during a procedure

Dr. Greenblatt adopted the definition of general anesthesia offered by Dr. Stevens: "a drug-induced loss of consciousness during which a person is not rousable, even by painful stimulation." TE Vol. XXVIII, p. 498 (emphasis added). He testified that the physical limitation of the operation of Midazolam in humans – the increased frequency of the pulsatile opening of the chloride channel in brain cells – and the consequent ceiling effect is the reason that Midazolam is not used by itself to induce general anesthesia in medical settings. TE Vol. XXVIII, p. 496. It is not capable of creating a state of anesthesia where a person would not be rousable by pain. It is used to relax patients and prepare them for stronger anesthesia. It is also used for medical procedures that require light sedation, but in those cases it is always used with an adjunctive analgesic, i.e. pain-blocker. TE Vol. XXVIII, p. 497. Midazolam by itself has no effect on preventing the sensation of pain. TE Vol. XXVIII, p. 498. Moreover, when it is used alone as a sedative in procedures, it has an amnestic effects that prevents a person from remembering the pain that they do experience. But a person would experience the pain when it happened.

Dr. Greenblatt testified that Midazolam's inability to induce a state of general anesthesia is an accepted fact in the medical community. TE Vol. XXVIII, p. 513.

C. There is a "ceiling effect" – a limit on the sedative effect – for Midazolam that has been demonstrated in scientific research

Dr. Greenblatt testified that he had conducted two research studies and published the results that demonstrated the sedative limits of Midazolam. Ex. 44, "*Kinetics and EEG Effects of Midazolam during and after 1-Minute, 1-Hour, and 3-Hour Intravenous Infusions,*" (J. Clin. Pharmacol. 2004; 44:605-611), and "Pharmacokinetic and electroencephalographic study of intravenous diazepam, Midazolam, and placebo," (Clin. Pharmacol. Ther. 1989, 45:356-68), pp. 778-794. In the 1989 study, subjects were administered a singles dose of Midazolam correlated to their body weight and then monitored on an EEG. Dr. Greenblatt testified that for purposes of measuring sedation, an EEG is a "direct window on the brain [because it] is fully objective. You don't have to ask the subject to do anything [like say how tired or try to remember something,] except lie there and let their brain waves be recorded by electrodes." TE Vol. XXVIII, p. 524. In his study, the EEG demonstrated that when Midazolam reached a certain level of plasma concentration, the sedative effect levels off and does not increase anymore.



Fig. 4. Relation of plasma concentration of diazepam or midazolam to change over predose baseline in percentage of total EEG activity falling in the 13 to 30 Hz frequency range. Each point is the mean for all 11 subjects at the corresponding time. Lines represent functions consistent with equation 1, determined by nonlinear least-squares regression analysis. EC_{30} indicates the plasma concentration of either drug at which the change in EEG activity is 50% of the maximal change.

Ex. 44, "Pharmcokinetic and electroencephalographic study of intravenous diazepam, Midazolam, and placebo," p. 790. The study revealed the same result for another benzodiazepine, diazepam. The 2004 study, which administered Midazolam over three different time frames, showed the same ceiling effect – as the concentration of Midazolam increased, its effect on EEG plateaued and did not continue to increase. In fact, the effect from the quickest administration – a one minute infusion – actually <u>diminished</u> as the concentration increased.



Figure 4. Mean change over baseline in percent sigma-beta electroencephalographic (EEG) amplitude (y-axis) in relation to the hypothetical effect-site midazolam concentration (x-axis). The solid line represents the function described by equation (3) using data from all three trials simultaneously. $E_{\rm max}$, maximum pharmacologic effect; EC_{50} , effect-site concentration corresponding to 50% of maximum effect.

Ex. 44, "Pharmacokinetic and electroencephalographic study of intravenous

diazepam, Midazolam, and placebo," p. 782.

Dr. Greenblatt testified that the ceiling effect had also been demonstrated in

a study published in the journal, Clinical Pharmacology and Therapeutics. Ex. 43,

"Electroencephalographic effects of benzodiazepines. II. Pharmacodynamic

modeling of the electroencephalographic effects of Midazolam and diazepam," (Clin.

Pharmacol. Ther. 1990; 48:555-67), pp. 765-77. In that study, researchers

administered three different size doses of Midazolam to subjects. There was no increase in the depth of sedation, as measured by the difference in effect in subjects' EEG, between the middle and largest dose.

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Fig. 2. Electroencephalographic (EEG) drug effect versus time profiles from three midazolam experiments in subject S. The time to peak (3, 15, and 23 minutes) and the time from peak to 50% of peak is roughly proportional to the dose administered. All three doses produced similar height of peak effect. Subject was unconscious in all experiments.

In fact, similar to the results in Dr. Greenblatt's 2004 study, the larger dose had a <u>lesser</u> effect on the EEG. Ex. 43, "*Electroencephalographic effects of benzodiazepines. II*", p. 770.

Dr. Greenblatt's opinion that Midazolam has a ceiling effect that prohibits it from inducing a level of general anesthesia where a person would not feel painful stimuli because of innate physical limitations in the pulsatile nature of the chloride channel opening in brain cells and corollary limitations on the amount of chloride ion that can enter a brain cell under the effect of Midazolam is plainly supported by research. D. Dr. Greenblatt studied patients who ingested massive overdoses of benzodiazepines and found that they were in a sedated state where they were still capable of being roused and responded to noxious stimuli

Dr. Greenblatt testified that in light of the scientifically accepted fact that Midazolam, and benzodiazepines generally, are incapable of inducing a state of general anesthesia, it is unnecessary and would be unethical to conduct studies on the effects of doses as massive as that in the Tennessee lethal injection protocol. TE Vol. XXVIII, p. 512. However, he has studied the effects of such large doses of benzodiazepines by examining cases of overdose. Ex. 42, "*Pharmacokinetic Study of Lorazepam Overdosage,*" *Am. J. Psychiatry (137:11, Nov. 1980); "Benzodiazepine Overdosage: Plasma Concentrations and Clinical Outcome,*" *Psychopharmacology* (1981) 73:381-83; "Rapid Recovery From Massive Diazepam Overdose," JAMA, Oct. 20, 1978 (Vol. 240, No. 17); "Acute Overdosage with benzodiazepine derivatives," *Clinical Pharmacol. Ther. (Vol. 21, No. 4, pp. 497-514)*, Vol. 5, pp. 727-750; Vol. 6, pp. 751-53.

The findings in each study indicated that people who ingested amounts of benzodiazepines equal to or greater than what is called for in the Tennessee lethal injection protocol presented as sleepy but rousable and responsive to painful stimuli. TE Vol. XXVIII, p. 515. Patients only exhibited dangerous levels of sedation where respiration would be compromised when other drugs were ingested simultaneously with benzodiazepines.

Case	Age/Sex	Estimated ingested dose	Highest plasma concentration (ng/ml)		Deepest coma grade	Assisted ventila- tion	Duration of hospi-	Other depressant drugs	
		(mg)	Diazepam Desmethyl- diazepam		car:		taliza- tion (days)		
Diazepam	overdosage								
1	52/M	500	2,795	97	0-1	-	1	Propoxyphene/Codeine	
2	30/M	450	2.623	55	0-1	-	1	Codeine	
3	18/F	300	5,490	227	0-1	-	1	Ethanol	
4	47/F	unknown	1.058	530	0-1	-	2	Ethanol	
5	23/F	100	585	72	0 - 1	-	1	-	
6	31/F	60	922	51	0 - 1	-	1	Ethanol	
7	20/M	750	4.792	2.366	0 - 1	-	1	-	
8	32/F	700 2	3,116	194	0-1	-	1	-	
9	28/F	125	3,240	235	0-1	-	1	Ethanol	
10	21/F	unknown	1.678	292	3	+	12*	Imipramine (3 gm)	
11	21/M	unknown	8,635	679	3	+	1	Ethanol	
12	58/M	unknown	2.059	1.079	1	-	2	Amitriptyline	
13	53/F	unknown	1.727	1.443	3	÷ :	2	Propoxyphene	
14	22/F	600	6,680	162	0-1	-	L L	Percodan	
15	27/M	200	1.617	1,460	0-1	-	1	Carbital	
16	37/M	unknown	993	0	4	+	3	Ethanol/Amitriptyline	
17	25/F	500	1,089	980	4	+	1	Amobarbital	
18	37/M	unknown	892	1.966	0 — I	-	1	-	
Desmethy	diazepam or	oxazepam overdosa	ige		2				
19	32/F	Clorazepate (dose unknown)	-	1,205	0-1	-	1	_ =	
20	50/F	unknown	-	1,205	8°→1	-	t	-	
21	39/M	Oxazepam (dose unknown)	(Oxazepam:	9,540)	I	+	1	Ethanol	

Table 1. Highest mea	asured benzodiazepine	plasma concentrations	and clinical outcome
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* Seizures, aspiration pneumonia

et al. 1977: Allen et al. 1977). Severity of central nervous systems (CNS) depression was rated using the following system (Lawson and Mitchell 1972): Grade 1, drowsy but responsive to verbal stimulation: Grade 2, response to mild painful stimulation: Grade 3, minimum response to maximum painful stimulation: Grade 4, no response to maximum painful stimulation.

Ex. 42, "Benzodiazepine Overdosage: Plasma Concentrations and Clinical

Outcome," Psychopharmacology (1981) 73:381-83; Vol. 5, pp. 729-730.

THE EXTENSIVE use of benzodiazepines in clinical practice has inevitably led to their increasingly common use for deliberate selfpoisoning." Fortunately. overdose with benzodiazepines alone seldom 🤇 results in serious medical complications.' Recovery is generally rapid, and few, if any, deaths have been recorded. The reasons for this wide margin of safety and for the rapid course of clinical recovery are not well. established. Most benzodiazepines, including diazepam, are characterized by a long elimination half-life or biotransformation into pharmacologically active metabolites. making it unlikely that rapid elimination of active compounds accounts for the prompt clinical recovery.23 The following two cases allowed assessment of the pharmacokinetics of diazepam and its metabolites after large doses were ingested with suicidal intent.

REPORT OF CASES

Case 1.—A 61-year-old woman ingested an estimated 450 to 500 mg of diazepam approximately eight hours before admis-

From the Clinical Pharmacology Unit, Massachusetts General Hospital (Drs Greenblatt and Woo and Ms Allen), and the Psychopharmacology (Dr Shader) and Neuropsychopharmacology (Dr Orsulak) Research Laboratories, Massachusetts Mental Health Center, Boston.

Reprint requests to Clinical Pharmacology Unit, Massachusetts General Hospital, Boston, MA 02114 (Dr Greenblatt), sion. The patient had a diagnosis of multiple myeloma, which had been treated with antineoplastic agents. She also was receiving imipramine hydrochloride because of depression, but the clinical history did not implicate imipramine in the overdose. Admission vital signs were a blood pressure of 110/80 mm Hg and a heart rate of 75 to 80 bests per minute. Respirations were spontaneous at a rate of 20/min. The patient was responsive only to nozious stimuli. Laboratory test results and arterial blood gas determinations were normal.

The patient received naloxone hydrochloride (0.4 mg) and a 50% dextrose solution (50 ml) intravenously, with no response. She was subsequently placed under observation, with monitoring of vital signs and no specific therapy other than parenteral fluids. The patient had an episode of mild hypotension (90/50 mm Hg) 19 hours after admission; this resolved without specific treatment. The patient was fully alert and responsive 24 hours after admission and was discharged one day later with no clinical sequelae.

Case 2.-A 28-year-old man ingested 2,000 mg of diazepam approximately ten hours before admission. He had no history of previous medical disease. Admission vital signs were a blood pressure of 110/60 mm Hg and a heart rate of 68 beats per minute. Respirations were spontaneous at 16/min. The patient was responsive to verbal stimuli and was oriented as to time, place, and person. Results of laboratory tests were within normal limits.

Naloxone hydrochloride (0.4 mg) and a 50% glucose solution (50 ml) were administered intravenously. Thereafter, the pa-

1872 JAMA, Oct 20, 1978-Vol 240, No. 17

Mass

Ex. 42, "Rapid Recovery From Massive Diazepam Overdose," JAMA, Oct. 20, 1978

(Vol. 240, No. 17), Vol. 5, pp. 732

Dr. Greenblatt testified that because the blood concentrations and dose amounts for these patients was known, they can be compared to the effects of the dose of Midazolam administered in the Tennessee lethal injection protocol. TE Vol. XXVIII, pp. 519, 521. The indications are that even massive doses of benzodiazepine left persons in a sedated state where they were still responsive to, <u>and therefore not insensate to</u>, verbal and noxious stimuli. Moreover, had the overdoses caused sedation to a level of general anesthesia where a person would be insensate to noxious stimuli, the result would have been fatal. Thus their complete recovery demonstrates the inability of even massive amounts of benzodiazepines to induce that level of anesthesia. TE Vol. XXVIII, p. 521.

> E. Dr. Greenblatt testified that the injection of Midazolam in the Tennessee lethal injection protocol will not protect a person being executed from experiencing the torturous effects of the second and third chemical sin the protocol

It's the underlying mechanism of action of Midazolam, and all drugs of that class, that despite extremely high doses you cannot produce a level of sedation that is consistent with general anesthesia such that you could have noxious stimuli without being aware of them and reacting to them, such as injection of vecuronium or potassium chloride or other things like surgical procedures, like having a cut, an incision. The Midazolam simply does not do that.

Dr. Greenblatt, TE Vol. XXVIII, pp. 511-12.

Dr. Greenblatt testified that without adequate anesthetization, the vecuronium bromide and potassium chloride administered as the second and third sets of injections in the Tennessee lethal injection protocol would cause horrible pain. Vecuronium bromide is formulated in an acidic solution with benzyl alcohol that is very painful when injected. As a paralytic, it has no effect on consciousness, and so it does not render a person unaware of its effects. TE Vol. XXVIII, p. 508. "[B]asically you're suffocating and you want to breathe, but you can't because you can't work your muscles." TE Vol. XXVIII, p. 510. It will begin to take effect in less than 2 minutes, and when it does, a person will be unable to breath and unable to communicate or signal any distress. Dr. Greenblatt testified that potassium chloride, the last chemical in the protocol that stops the heart from beating, is "extremely painful" when injected, particularly in the concentration of solution called for under the protocol. TE Vol. XXVIII, p. 509. He testified to his experience in injecting potassium chloride in a clinical setting and said it had to me diluted "tremendously" and administered "very slowly. You cannot give a fast injection of highconcentration [of potassium chloride] because it's terribly painful." TE Vol. XXVIII, p. 510.

The pain on injection of vecuronium bromide and potassium chloride, and the sensation of suffocation with paralysis that vecuronium bromide would cause would all qualify as "noxious stimuli" that would overcome the limitations of the sedative properties of Midazolam. TE Vol. XXVIII, p. 510. Dr. Greenblatt testified that, in his opinion as a clinical pharmacologist and doctor of internal medicine, because of Midazolam's inability to induce general anesthesia at any dose and it's complete lack of analgesic properties, the 500mg injection called for in the Tennessee lethal injection protocol would not render a person insensate to the torturous and "extremely painful" effects of the injections of vecuronium bromide and potassium chloride called for by the protocol. TE Vol. XXVIII, p. 511.

5. Dr. Greenblatt testified that the pharmacokinetics of Midazolam create a time delay in the onset of its effects that make it certain that it will not have induced its peak sedative effect by the time vecuronium bromide and potassium chloride are injected into an inmate under the Protocol

In his testimony, Dr. Greenblatt explained that in order to make Midazolam soluble in solution for purposes of injection, its pH had to be adjusted down to 3.5, which is especially acidic. TE Vol. XXVIII, p. 495. This causes a conformational change to the drug's molecular structure that puts it into an "open-ring form" that cannot bind to the benzodiazepine receptor in brain cells. TE Vol. XXVII, p. 528. Upon injection, a human's blood naturally buffers the pH of the solution to the normal 7.4 which allows it to cross the blood-brain barrier. TE Vol. XXVIII, p. 495.In this process, Midazolam reverts back to closed ring form that enables it to bind to brain cell receptors. When clinical doses of 1-2 mL are injected, this buffering process happens rapidly. TE Vol. XXVIII, p. 528-29.

However, an injection as large as that called for in the Tennessee lethal injection protocol will take longer to buffer. TE Vol. XXVIII, p. 546. A few circulations through the body will be needed to adjust all of the Midazolam solution to a pH where it will become effective. Each circulation takes approximately 60 seconds. <u>As explained *supra*</u>, even at peak sedative effect, Midazolam cannot create a state of anesthesia that would leave a person insensate to noxious or painful stimuli.

Dr. Greenblatt's 1989 article on EEG measures of the effect of Midazolam revealed that onset of the peak effect of Midazolam when injected at clinical levels¹⁸ at approximately 15 minutes after injection based on EEG. TE Vol. XXVIII, p. 531.

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Fig. 3. Change over predrug baseline in the percentage of total EEG amplitude occurring in the 13 to 30 Hz frequency range. Each point is the mean for all subjects at the corresponding time. *Asterisks* indicate significant differences (p < 0.05) from zero change.

Ex. 44, Pharmacokinetic and electroencephalographic study of intravenous

diazepam, Midazolam, and placebo," (Clin. Pharmacol. Ther. 1989, 45:356-68), p.

789.

 $^{^{18}}$ This dose used in his study was .15mg of Midazolam per kg of subject body weight. Where the average weight may be taken as 180 pounds, this would be a 12 mg injection.

The first Bührer study that Dr. Greenblatt explained in his testimony found a 5 to 15 minute delay between injection and peak sedative effect as indicated by the EEG for a 15mg dose of Midazolam. However that time increased by more than half when the dose was increased to 25mg. The time to peak effect for the larger dose was 11 to 23 minutes. TE Vol. XXVIII, p. 526.

Table II. Electroencephalographic characteristics (onset, peak, and recovery of electroencephalographic voltage) and duration of unresponsiveness after administration of midazolam

Subject		Baseline voltage (μV)	Peak voltage (µV)						
	Dose (mg)			Onset of effect* (min)	50% of peak effect (min)	90% of peak effect (min)	Peak effect (min)	Recovery to 50% of peak effect (min)	Duration of unresponsiveness (min)
S	3.75 7.5 15.0 25.0	22 21 28 21	118 143 177 162	0.67 0.67 0.75 0.67	1.1 1.2 1.5 1.3	1.4 1.7 2.8 6.3	2.9 2.5 15.0 23.3	17 18 50 53	2 6 6 73
L	7.5 15.0	49 47	127 152	0.83 0.75	1.3 1.7	2.5 4.7	3.8 7.5	10 26	4 15
N	3.75 7.5 15.0 25.0	71 60 55 64	138 175 172 203	0.88 0.67 0.83 0.75	1.2 1.3 1.3 1.8	1.5 2.9 4.2 6.0	2.2 3.8 5.3 11.3	6 26 52 55	6 9 16

Ex. 44, Vol. 6, p. 762.

In the second Bührer study that Dr. Greenblatt explained, the time for peak sedative effect of a 25 mg dose averaged 19 minutes after injection across the subjects. It is critical to note that the subjects stopped responding to verbal stimuli after an average of only 2 minutes past the injection. <u>This is the same time frame</u> for the consciousness check in the Tennessee lethal injection protocol. Thus, inmates can be expected not to respond to their name being yelled, but would not have the maximum sedative effect of the Midazolam, which would still be less than

anesthesia sufficient to make them insensate to vecurnium bromide and potassium

chloride.

Subject	Drug	Dose (mg)	Baseline voltage (µV)	Peak effect (µV)		Time of effect*	Time of effect*			
					Onset of effect† (min)	50% of peak effect (min)	90% of peak effect (min)	Peak effect (min)	Recovery to 50% of peak effect (min)	Loss of responsivenes. (min)
s	D	15	22	121	0.58	1.2	1.8	2.8	23	R
	D	30	21	216	0.67	1.8	3.8	8.0	41	2.6
	D	50	19	192	0.92	2.0	5.0	8.3	58	4.1
	М	7.5	21	143	0.7	1.2	1.7	2.5	18	2.1
	M	15	28	177	0.8	1.5	2.8	15.0	50	3.3
	M	25	21	162	0.7	1.3	6.3	23.3	53	2.6
Ν	D	15	55	138	0.5	1.0	1.3	2.8	21	R
	D	30	74	174	0.8	1.3	4.0	7.2	63	3.1
	D	50	47	157	0.8	1.3	2.2	4.5	96	3.6
	М	7.5	60	175	0.7	1.3	2.9	3.8	26	2.2
	М	15	55	172	0.8	1.3	4.2	5.3	52	2.4
	М	25	64	203	0.8	1.8	6.0	11.3	55	2.1
Р	D	15	42	91	0.7	1.1	1.7	2.5	15	R
	D	30	27	103	0.5	1.2	3.8	5.5	37	2.6
	D	50	40	131	0.6	1.3	5.0	12.7	58	2.9
	М	25	28	130	0.7	1.3	3.4	22.5	53	2.1

Table II. Electroencephalographic characteristics (onset, peak, and recovery from electroencephalographic voltage) and duration of unresponsiveness after administration of diazepam or midazolam

Ex. 44, Vol. 6, p. 768.

There are four critical conclusions from Dr. Greenblatt's testimony and the

studies he explained:

- 1. a person can be expected to stop responding to verbal stimuli 2 minutes after being injected with a clinically appropriate dose of Midazolam;
- 2. depending on the size of the dose, the maximum sedative effect will not occur for several minutes after the injection;
- 3. the time to maximum sedative effect increases as the size of the dose increases;
- 4. even at maximum sedative effect, a person is not at a level of general anesthesia where they will be insensate to painful or noxious stimuli.

Based on these findings and his professional experience as a doctor of internal

medicine and clinical pharmacologist, Dr. Greenblatt concluded that the peak

sedative effect for the 500mg Midazolam injection in the Tennessee lethal injection

protocol would take even longer to arrive and will not have occurred by the time the

vecuronium bromide and potassium chloride are injected. TE Vol. XXVIII, pp. 533,

538. Consequently, though an inmate can be expected not to respond to the calling of his name at the time of the consciousness check, the

6. Because of the pH of Midazolam solution, the amount called for by the protocol would inflict severe damage to lung tissue and nearly certainly cause pulmonary edema

Dr. Greenblatt testified that the 3.5 pH of injectable Midazolam solution is "highly acidic." He further testified that in order to take effect, it would need to circulate in the blood for "a few" circulations to buffer to a normal 7.4 pH. Upon venous injection in the arm, the half-liter of solution called for in the Tennessee lethal injection protocol would travel first to the heart and then directly to the lungs. TE Vol XXVIII, p. 541.

The tissue in the lining of the lungs is "very delicate." This is to permit to oxygen to flow from the lungs to the blood and carbon dioxide to flow in reverse. A half-liter of pH 3.5 acid would immediately damage that thin tissue. Consequently, fluid from the blood stream would immediately begin to leak into the alveoli (airspaces) of the lungs, causing pulmonary edema. This would make air-exchange difficult, if not impossible. TE Vol. XXVIII, pp. 541-42. This can be expected to happen on the very first pass of Midazolam through the lungs as part of the circulatory process.

The sound that inmates executed using Midazolam make is not snoring or heavy breathing. It is their drowning in their own fluids as paralysis sets in from vecuronium bromide.

c. Testimony of Dr. Mark Edgar, M.D., diagnostic pathologist.

Plaintiffs' penultimate expert witness was Dr. Mark Edgar, an associate professor of pathology at Emory University. XXXIX 1380-82; Ex. 116, *Curriculum vitae*, at Vol. 11, pp. 1630-45. Dr. Edgar received his M.D. from Dalhousie University in Halifax, Nova Scotia, then received specialty training in neuropathology at Harvard Medical School. XXXIX 1380; Ex. 116. Dr. Edgar taught diagnostic surgical pathology at Cornell Medical School and also worked at Sloan Kettering Cancer Center before joining the faculty at Emory. *Id.* 1381, 88. The Chancellor admitted Dr. Edgar as an expert in the field of pathology. *Id.*, 1386.

1. Dr. Edgar reviewed the autopsies of 27 inmates executed with Midazolam.

Dr. Edgar testified that he reviewed twenty seven autopsies of inmates executed using Midazolam. XXXIX 1386, 1455. Although the word autopsy means "to see for oneself" and Dr. Edgar admitted that the "ideal situation would be for me to do these autopsies myself," he found that the state-issued autopsy reports provided to him allowed him to make some findings with respect to the data set. *Id.* 1389 ("[T]hey all have adequate gross description of every organ."). Dr. Edgar testified, "[T]he examiners in these cases would have made observations that are pertinent, and when they see something, when they're recording something, I am happy that it's present. When they don't record something, you can't always be certain it wasn't present because their focus may not have been on that." *Id.* 1387.

2. Dr. Edgar was surprised by the weights of the lungs recorded in the state autopsies; the lungs were not consistent with instantaneous death.

Dr. Edgar testified that prior to examining the records of the autopsies, he assumed that executed inmates died quickly. "I expected, when I reviewed these autopsies, that I would see something that we seldom see in a hospital autopsy, and that is that the organs would be more or less as they were when the patient entered the execution chamber. That was my expectation, that we would see, for example, pristine lungs, the kind of lungs that are seen at autopsy when someone dies instantaneously, lungs that weigh from 350 to 400 grams, lungs that we never see in a hospital autopsy where patients died gradually of multi-organ system failure, the heart slows down, their awareness slips away, fluid backs up in their lungs. I wasn't expecting that. I was expecting the heart stops quickly and death is immediate and the lungs are going to be pristine." XXXIX 1390. But upon looking at the autopsies, Dr. Edgar was struck by "the abnormalities in the lungs . . . all of the lungs were heavy. There were none of them that were what I would expect, in the 350-400 gram range. But in addition to that, they all showed – not all but the majority of them, over 85 percent of them showed pulmonary edema. And that's certainly not expected in someone who dies instantaneously. And a good number of them showed fulminant pulmonary edema, which indicates it's sudden and severe." Id., 1391-92. 3.

3. Dr. Edgar explained that pulmonary edema is the result of an injury to the lining of the lungs.

Dr. Edgar explained that "pulmonary edema is an accumulation of fluid in the airspaces of the lung, and it has a variety of causes, the final common pathway of which is always injury to the flood vessels and the lining cells of the lung,

allowing fluid and sometimes blood, to escape from the blood vessels in the airspaces." XXXIX 1393. He contrasted edema with congestion, which is an increased amount of blood in an organ or tissue; with congestion, that "blood is in the right place, though, in the blood vessels." *Id.* Pulmonary edema is marked by the blood and fluid leaking into the airspaces. *Id.*

Pulmonary edema is divided into cardiogenic and non-cardiogenic categories. "Cardiogenic pulmonary edema occurs when the heart is not pumping properly and basically blood backs up behind it into the lungs." XXXIX 1394. Non-cardiogenic pulmonary edema, on the other hand, has "a broad range of causes, including inhalation of toxic gas, injection of the toxins, drowning. A variety of physical chemical assaults to the lung can cause pulmonary edema of the non-cardiogenic type." Id. If a person were to experience cardiogenic pulmonary edema, that person would show physical symptoms prior to death: "[P]ulmonary edema, when it begins, the patients are short of breath. And they feel like they can't catch their breath, and they breathe a bit faster." Id. Dr. Edgar explained that as pulmonary edema progresses, it causes panic and terror: "As it gets worse, they may have the sense of air hunger and be gasping for air. As it gets even worse, they may have a sense of terror, panic, drowning, asphyxiation. It's a medical emergency and it's a state of extreme discomfort." Id. 1394-95. Dr. Edgar testified that in a hospital setting, pulmonary edema is treated with diuretics and morphine: "We now believe that the morphine is more helpful as a palliative measure. It calms the patients down and thereby reduces the heart rate because it reduces the terror." Id., 1395

Dr. Edgar explained that foam seen in pulmonary edema is comprised of four components: surfactant, which is a protein that lines the surface of lungs, water, air, and the energy/force of respiration. XXXIX 1399. "So surfactant mixes with water and air, and together those things, under the energy of breathing, moving air back and forth and in and out at the airspaces, produces bubbles. And it's fine bubbles. Foam or froth is the term that is used." *Id.* Dr. Edgar provided a medicolegal study of drowning which supported his position that the foam seen in acute pulmonary edema can only be produced while a subject is alive and breathing: "the froth consists of a whipped-up mixture of drowning medium, air, and secretions from bronchial mucous glands." *Id.* 1400; Ex. 120, Article—Medicolegal Study of Drowning, at Vol. 12, p. 1671.

Dr. Edgar testified that the pulmonary edema seen at autopsy would have caused the inmate distress and suffering: "If the prisoners were aware, this degree of respiratory distress would be extremely painful and alarming." XXXIX 1468 (initially read from Ex. 121, Declaration of Dr. Mark Edgar in *Ledford v. Dozier*, at Vol. 12, p. 1675, but adopted by Dr. Edgar as applying equally to his findings in the Midazolam executions). Further, his review of the autopsies indicated that the edema began some period of time before the inmates ceased to breathe—i.e. before the paralytic took effect—indicating that the Midazolam itself is the likely cause of the edema.

4. 23 out of the 27 autopsies Dr. Edgar reviewed showed signs of pulmonary edema.
Dr. Edgar reviewed the state autopsy reports from twenty-seven autopsies conducted on men executed with Midazolam, each of which was entered into evidence as an exhibit.¹⁹ XXXIX 1455; Ex. 28, 49-74, Autopsy Reports, Vol. 4, 7-8, p. 910-1132. Dr. Edgar's findings from each autopsy report were memorialized in Exhibit 118, Dr. Edgar's Demonstrative Autopsy Chart, (Vol.12, p. 1658-63), in which he underlined the findings of the state pathologists that showed the presence of pulmonary edema:

¹⁹ At the time of the trial there had been thirty-two executions using Midazolam. Ohio does not autopsy following execution (McGuire, Otte, Phillips) and two Florida men were not autopsied (Mohammad, Banks).

Name/ DOD	State	Weight	Age	R lung	L lung	Micro	PMI	Compounded MZ? / Drugs Used
Arthur, Thomas 5/26/17	AL	173 lb	75	598 g moderately congested parenchyma <u>oozing</u> <u>moderate amounts of vellow-</u> <u>tinged frothy fluid</u>	470 g moderately congested parenchyma <u>oozing</u> <u>moderate amounts of vellow-</u> tinged frothy fluid	None noted	7 h 45 min	No/ 3 drug MZ
Banks, Chadwick 11/13/14	FL	184 lb	43	No autopsy was performed.				No/ 3 drug MZ
Bolin, Oscar jr. 1/7/16	FL	200 lb	53	555 g increased firmness, decreased crepitance; heavy lungs with <u>congestion and</u> <u>edema</u>	680 g increased firmness, decreased crepitance; heavy lungs with <u>congestion and</u> <u>edema</u>	None noted	10 h 54 min	No/ 3 drug MZ
Brooks, Christopher 1/21/16	AL	156 lb	43	1020 g <u>major bronchi</u> <u>contain froth: lung oozing</u> <u>large amounts of yellow:</u> <u>tinged frothy fluid</u>	870 g <u>major bronchi contain</u> froth: lungs oozing large amounts of yellow-tinged frothy fluid	None noted	13 h 22 min	No/ 3 drug MZ
Chavez, Juan 2/12/14	FL	185 lb	46	900 g <u>frothy red fluid oozes</u> from surface on manual compression	880 g <u>frothy red fluid oozes</u> from surface on manual compression	Acute pulmonary congestion and <u>edema</u>	14 h 58 min	No/ 3 drug MZ
Correll, Jerry 10/29/15	FL	150 lb	59	610 g increased firmness, decreased crepitance; nonspecific congestion	565 g increased firmness, decreased crepitance; nonspecific congestion	None noted	13 h 24 min	No/ 3 drug MZ
Davis, Eddie 7/10/14	FL	228 lb	45	1120 g <u>ooze froth with slight</u> <u>manual compression:</u> <u>marked congestion and</u> <u>edema</u>	965 g <u>ooze froth with slight</u> <u>manual compression:</u> <u>marked congestion and</u> <u>edema</u>	None noted	14 h 17 min	No/ 3 drug MZ

Name/ DOD	State	Weight	Age	R lung	L lung	Micro	PMI	Compounded MZ? / Drugs Used
Eggers, Michael 3/15/18	AL	221 lb	50	1150 g <u>upper airways</u> <u>contain blood-tinged frothy</u> <u>edema fluid. Sections and</u> <u>intra-pulmonary airways</u> <u>show blood-tinged edema</u> <u>fluid</u>	910 g <u>upper airways contain</u> <u>blood-tinged frothy edema</u> <u>fluid. Sections and intra-</u> <u>pulmonary airways show</u> <u>blood-tinged edema fluid</u>	None noted	12h 32min	No/ 3 drug MZ
Gray, Ricky 1/18/17	VA	308 lb	39	886 g <u>upper airways foamy</u> <u>liquid</u>	715 g <u>upper airways foamy</u> <u>liquid</u>	Lung: edema and alveoli RBC: brain: acute hypoxic ischemia	11h 33min	Yes/ 3 drug MZ, where MZ + KCl both compounded
Happ, William 10/15/13	FL	179 lb	51	985 g <u>bloody froth expressed</u> on slight manual compression	825 g <u>bloody froth expressed</u> on slight manual <u>compression</u>	None noted	16h 24min	No/ 3 drug MZ
Hendrix, Robert 4/23/14	FL	281 lb	47	750 g <u>ooze bloody froth with</u> <u>slight manual compression</u>	595 g <u>ooze bloody froth with</u> slight manual compression	None noted (cerebellar mass unknown histology)	15h 24min	No/3 drug MZ
Henry, John 6/18/14	FL	176 lb	63	735 g increased firmness, decreased crepitance; <u>acute</u> <u>congestion and edema</u>	720 g increased firmness, decreased crepitance; <u>acute</u> <u>congestion and edema</u> .	None noted	13h 17min	No/ 3 drug MZ
Henry, Robert 3/20/14	FL	204 lb	55	815 g sectioned surfaces ooze blood and frothy fluid	775 g sectioned surfaces ooze blood and frothy fluid	None noted	15h 14min	No/ 3 drug MZ
Howell, Paul 3/26/14	FL	171 lb	48	760 g tracheobronchial tree pink tinged froth; frothy fluid oozes from lung surface on compression	545 g tracheobronchial tree pink tinged froth: frothy fluid oozes from lung surface on compression	Acute pulmonary edema and congestion	14h 28min	No/ 3 drug MZ

Name/ DOD	State	Weight	Age	R lung	L lung	Micro	PMI	Compounded MZ? / Drugs Used
Jones, Jack Jr. 4/24/17	AR	250 lb	52	835 <u>g mild diffuse</u> <u>edematous change</u>	735 <u>g mild diffuse</u> edematous change	Tissue saved; no further analysis	Next day	No/ 3 drug MZ
Kimbrough, Darius 11/12/13	FL	247 lb	40	860 g; slight congestion	590: slight congestion	Marked vascular congestion, <u>mild alveolar</u> <u>edema</u>	2 days	No/ 3 drug MZ
Kormondy, Johnny 1/15/15	FL	206 lb	42	840 g congested and <u>ooze</u> <u>frothy red fluid: acute</u> <u>congestion and edema</u>	620 g congested and <u>ooze</u> frothy red fluid; acute congestion and edema	None noted	19h 49min	No/ 3 drug MZ
Lee, Ledell 4/20/18	AR	227 lb	51	755 g <u>white frothy fluid</u> expressed on compression	660 g <u>white frothy fluid</u> expressed on compression	None noted	Next day	No/ 3 drug MZ
Lockett, Clayton 4/29/14	ОК	200 lb	38	740 g <u>edema</u>	580 g <u>edema</u>	<u>Pulmonary</u> <u>edema</u> , Normal brain	1d 13h 19min	No/ 3 drug MZ
McGuire, Dennis 1/16/14	ОН	Ohio do		No./2 drug: MZ and hydromorphone				
McNabb, Torrey 10/19/17	AL	234 lb	40	430 g <u>major bronchi contain</u> <u>froth:</u> moderately congested parenchyma	600 g <u>major bronchi contain</u> <u>froth:</u> moderately congested parenchyma	None noted	15h 12min	No/ 3 drug MZ
Melson, Robert 6/8/17	AL	162 lb	46	680 g mild vascular congestion, normal crepitus	540 g mild vascular congestion, normal crepitus	None noted	10h 48min	No/ 3 drug MZ

Name/ DOD	State	Weight	Age	R lung	L lung	Micro	PMI	Compounded MZ? / Drugs Used
Moody, Walter 4/19/18	AL	177 lb	83	780 g congested	980 g congested	Lungs: mild interstitial anthracosis	11h 58min	No/ 3 drug MZ
Morva, William 7/6/17	VA	163 lb	35	800 g <u>upper airway notable</u> for a moderate amount of froth	628 g <u>upper airway notable</u> for a moderate amount of froth	Lung: within normal limits; <u>scattered</u> <u>hypoxic/ischmic</u> <u>neurons</u> <u>hippocampus</u>	12h 15min	Yes/ 3 drug MZ
Muhammad, Askari (Knight, Thomas) 1/17/14	FL	<i>N/A</i>	62	No autopsy was performed.				No/ 3 drug MZ
Otte, Gary 9/13/17	ОН	Ohio does not conduct autopsies on executed inmates.						Nol 3 drug MZ
Phillips, Ronald 7/26/17	ОН	Ohio does not conduct autopsies on executed inmates.						<i>Nø</i> ∕3 drug MZ
Smith, Ronald 12/8/16	AL	248 lb	45	850 g, congested	920 g, congested	Pigmented macrophages, mucus plugs in bronchioles	13h 55min	No/ 3 drug MZ
Warner, Charles 1/15/15	ок	186 lb	47	550 g congested, <u>edematous,</u> <u>exudes moderate amount of</u> <u>clear frothy fluid</u>	550 g congested, <u>edematous,</u> <u>exudes moderate amount of</u> <u>clear frothy fluid</u>	Congestion and edema	16h 34min	No/ MZ; pancurionium bromide; potassium acetate

Name/ DOD	State	Weight	Age	R lung	L lung	Micro	PMI	Compounded MZ? / Drugs Used
Williams, Kenneth 4/27/17	AR	216 lb	38	590 g: <u>nares, oral cavity,</u> upper, lower airways serosanguinous fluid	555 g; <u>nares, oral cavity,</u> <u>upper, lower airways</u> <u>serosanguinous fluid</u>	Tissue saved; no other notation	Next day	No/ 3 drug MZ
Williams, Marcel 4/24/17	AR	421 lb	46	750 g: <u>nares, oral cavity,</u> <u>upper, lower airways</u> <u>abundant watery secretion</u>	720 g <u>nares, oral cavity,</u> <u>upper, lower airways</u> <u>abundant watery secretion</u>	Tissue saved; no other notation	Next day	No/ 3 drug MZ
Wood, Joseph 7/23/14	AZ	193	55	980 g <u>exude blood and</u> <u>marked amounts of blood</u> <u>and frothy fluid</u>	945 g <u>exude blood and</u> <u>marked amounts of blood</u> <u>and frothy fluid</u>	R and L lungs show intra- <u>alveolar</u> <u>hemorrhage,</u> <u>edema fluid</u> and pulmonary vascular congestion	16h 41min	No/ 2·drug: MZ + hydromorphone

A. 15 inmates showed signs of fulminant pulmonary edema, the sudden, severe filling of the airspace with fluid.

Dr. Edgar explained that fifteen of the twenty-seven inmates autopsied showed signs of fulminate pulmonary edema. Fulminate pulmonary edema is both "sudden and severe" and characterized by the presence of bloody or froth in the tracheal-bronchial tree. XXXIX 1395. "[I]n this context [fulminate] would mean it was – even though it showed fluid in the form of bubbles in the tracheal/bronchial tree, so not just fluid and bubbles in the lung tissue, but enough that it actually left the lungs and went up into larger airways." XXXIX 1396.

By way of example, Dr. Edgar highlighted the severity of the fulminate pulmonary edema in the case of Ricky Gray executed by Virginia with compounded Midazolam. XXXIX 1414. "[T]here are two findings. In the lungs we have, again: "The upper airways contain foamy liquid,' and a similar finding with frothy fluid on cut surfaces. In Mr. Gray's case, also there's a note that blood tinged fluid is present from the mouth." Dr. Edgar explained the significance of the blood around Mr. Gray's mouth: "I interpret that to represent froth that was blood tinged, that made its way to the mouth, and then, because the bubbles had actual dispersed, they left behind a little bit of blood and that's what they were seeing externally." *Id.* 1414. Dr. Edgar testified that the observations of the medical examiner were supported by the microscopic findings in Mr. Gray's brain, "There was a brain finding of mild, acute hypoxic-ischemic changes. That finding indicates, to put it simply, that the patient lived for some period of time with a deprivation of oxygen or blood to the brain." *Id.* 1416-17.

B. 8 additional inmates showed signs of "acute" pulmonary edema.

In the autopsies of the remaining inmates with pulmonary edema, the presence of bubbles and froth in the lungs—along with the known time course of the injury—is diagnostic of "acute pulmonary edema." XXXIX 1397. Dr. Edgar testified that "acute" as a descriptor of a diagnosis refers to a time frame: "And in this context we're talking about pulmonary edema as something that comes on over the course of minutes." *Id.* 1396-97. Dr. Edgar testified that in addition to knowing the time course of the executions and knowing that the inmates did not exhibit symptoms of cardiogenic pulmonary edema, the presence of bubbles, foam, and froth in the lung findings of the autopsy reports "indicates acute pulmonary edema." *Id.* 1397-98. Dr. Edgar explained that had any of the inmates been experiencing pulmonary edema of this severity prior to the beginning of the execution protocol, their symptoms would have been readily noticeable to a lay person: "[T]hey would be gravely ill." *Id.* 1398. Thus, it is clear that the acute pulmonary edema seen in these autopsies was caused by the lethal injection chemicals.

5. Defendant's pathologist agreed with Dr. Edgar's findings as to all but one autopsy.

Dr. Feng Li, the defendant's pathologist, testified that he disagreed with Dr. Edgar that cardiac arrest cannot cause pulmonary edema. XLVIII 108. Dr. Li testified, "If the heart stops, you will probably build fluid in the lung cause

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pulmonary congestion and edema." *Id.* Dr. Li testified that pulmonary edema was a nonspecific finding: "Not specific to Midazolam, not specific to pentobarbital, you know, in general. But, as I said, the pulmonary edema by the mechanism is divided into two general categories. Anything affecting the heartbeat, anything affecting the heart function like, you know, cardiogenic pulmonary edema as a congestive heart failure, heart attack, arrhythmia, they will cause pulmonary edema. Or some other things, you know, if it is toxic directly to the lung, to the vessel, to the heart, you know, also will cause pulmonary edema." *Id.* 112-13.

On cross examination, Dr. Li admitted that he had testified in his deposition that he agreed with Dr. Edgar's findings as to all but one of the autopsies: he disagreed with Dr. Edgar's finding as to the Kenneth Williams autopsy (Arkansas), because he wasn't willing to call serosanguinous fluid evidence of pulmonary edema. *Id.* 185.²⁰ As Dr. Edgar explained, while he "absolutely can't get inside Dr. Li's head here . . . my interpretation was probably different [from Dr. Li's] because I went past the presence of whether or not edema was mentioned explicitly and drew a

²⁰ Significantly, Dr. Li did not disagree with Dr. Edgar's finding of pulmonary edema in the Torrey McNabb autopsy (Alabama). Dr. Edgar included Mr. McNabb's findings as consistent with pulmonary edema despite the failure of the state examiner to note any edema in the lungs. Dr. Edgar testified that he did so on the basis of the examiner noting froth in the major bronchi: "Again, that indicates fulminate pulmonary edema. This is one of those cases where I paused to wonder if the lungs were examined completely and carefully, because it seems to me unlikely that there wasn't some edema fluid somewhere. But, again, I'm not 100 percent sure how important that was to these examiners conducting these autopsies for their purposes . . . [But I marked this as a positive finding for edema] because [the froth in the bronchi] could only have come from pulmonary edema. There's no other reasonable explanation for that." XXXIX 1429. Dr. Li did not contest Dr. Edgar's determination with respect to Mr. McNabb's fulminate pulmonary edema.

conclusion from the presence of fluid in and about the lungs that could only have really come from edema." XXXIX 1435. Dr. Edgar reviewed Exhibit 56 Mr. Williams' autopsy report, and explained the findings, "Kenneth Williams' upper and lower airways contained serosanguinous - - that means, thin, blood-tinged - - fluid. The pulmonary parenchyma was grayish-purplish and diffusely congested, and the right lung weighed 590 and the left 555 grams." Dr. Edgar continued, "[F]or Kennath Williams, we don't have - - we don't have a description under 'Respiratory system' that explicitly states pulmonary edema was present, but I surmised from this description [contained in the autopsy report] that the fluid made its way from the lungs in the form of froth, dissipated, and left a thing amount of blood-tinged fluid. Again, I can't conceive of a reasonable way for that to happen otherwise, so I counted that among our cases with pulmonary edema." *Id.* 1433.

> 6. Dr. Edgar's testimony conclusively refuted Dr. Li's contention that fulminate pulmonary edema can be caused by cardiac arrest and proved that it can only occur while respiration is on-going, that is before the paralytic takes effect.

Dr. Edgar refuted Dr. Li's contention that respiration is not required for the creation of froth. In his deposition and at trial, Dr. Li contended that pulmonary edema can be the result of cardiac arrest (or sudden stoppage of the heart). XLVIII 108 (Li testimony); XXXIX 1447-48 (Edgar reading Dr. Li's deposition testimony that said, "Mechanism says when the heart not working properly or stopped. The blood accumulated after will be upstream. And then the lung function will be changed and fluid will be accumulated. And then the fluid has nowhere to go"). Dr. Edgar responded to Dr. Li's testimony saying, "[W]hen I read that, I thought that

really is common sense that in order to get froth there has to be a mixing mechanism to mix the surfactant or bronchial secretions with the air and water. And in this setting, we're talking about the sort of mechanics of breathing that moves the air in and out . . . There has to be air movement or there has to be some kind of mechanical mixing in order to generate froth. The lung is not, at rest, a bubble-producing machine." XXXIX 1448. As empirical proof of that which Dr. Edgar found, as a medical doctor, to be a matter of common sense, he provided the court with a study wherein pulmonary edema was intentional induced in dogs: "And some of the dogs had one or more of the lobes of the lungs clamped so air could not move in and out of them. And the other lobes to the lungs were normally aerated with air moving in and air moving out . . . And what they found was that those clamped lungs that did not have air moving back and forth, did not have that energy, did not show froth." XXXIX 1450. He read from Exhibit 119, "The occluded lobes thus became edematous but remained non-ventilated and, hence, did not foam." Ex. 119, Article – Pulmonary Surface Activity in Induced Pulmonary Edema, Vol. 12, p. 1664-70.

- d. "There is no debate about Midazolam." XLII 1742. Dr. David Lubarsky, one of the most published anesthesiologists in the country, recognized expert in pain management, and who uses Midazolam in his practice, explained why Midazolam is incapable of preventing an inmate from feeling and experiencing pulmonary edema, the sensation of choking, suffocation, as if being buried alive, and finally the searing and excruciating pain of potassium.
 - 1. Dr. David Lubarsky is exceptionally qualified to discuss the real world use of Midazolam.

Dr. David Lubarsky is the Chief Executive Officer of UC Davis Health and Vice Chancellor for Human Health Sciences at UC Davis. XLII 1718. Dr. Lubarsky oversees the School of Medicine, School of Nursing, UC Davis Medical Center, and Primary Care Network. *Id.*; http://www.ucdmc.ucdavis.edu/leadership/index.html (last checked September 4, 2018). Prior to assuming his new position at UC Davis, Dr. Lubarsky was a tenured professor at the University of Miami where he served for 16 years in a number of roles, including chair of the Department of Anesthesiology. *Id.*; Ex. 130, *Lubarsky CV*, at Vol. 14, p. 2017. At the time that Dr. Lubarsky accepted his position at UC Davis his primary academic appointment was Chief Medical and Systems Integration Officer, University of Miami Health System and Emanuel M. Papper²¹ Professor and Chairman Department of Anesthesiology, Perioperative Medicine and Pain Management, Professor of Anesthesiology with tenure, University of Miami Leonard M. Miller School of Medicine. Ex. 130.

The University of Miami has the "largest training program in the United States ... providing about 110,000 anesthetics a year across two health systems worth about \$5 billion a year." XLII 1718. Dr. Lubarsky was personally in charge of that department. *Id.* 1719. Over the course of his tenure in Miami, Dr. Lubarsky

²¹ Emanuel M. Papper was the founding chairman of the department of anesthesiology at Columbia University. He left Columbia to become Dean of the University of Miami School of Medicine.

https://www.nytimes.com/2002/12/06/nyregion/emanuel-m-papper-87-pioneer-inanesthesiology-at-columbia.html (last checked September 3, 2018). "The Emanuel M. Papper Chair in Anesthesiology [is] a permanent tribute to Dr. Papper's goals and ideals." <u>http://anesthesiology.med.miami.edu/about-us/e.m.-papper/e.m.-papper-</u> <u>m.d.-ph.d/</u> (last checked September 3, 2018. was fully responsible for over one and half million anesthetics. *Id.* Dr. Lubarsky continues to train residents and is in the operating room providing patient care one day each week. *Id.* 1720.

Dr. Lubarksy began his professional career at Duke University. At Duke, Dr. Lubarsky became Vice Chairman and tenured professor in the Department of Anesthesiology. XLII 1721; Ex. 130. At Duke, Dr. Lubarsky worked alongside Dr. Jerry Reves and Dr. Peter Bailey.²² XLII, 1721. Dr. Reves, who co-authored the classic research article on Midazolam with Dr. Greenblatt,²³ and Dr. Lubarsky worked "very closely for a decade or so." *Id.* Dr. Reves "was an extremely profound and advanced thinker ... and did a lot of development around Midazolam[.]" *Id.* 1722.

Dr. Lubarsky is the author of eight books on anesthesiology and co-wrote the chapter on Intravenous Anesthetics in several editions of *Miller's Anesthesia*, along with Dr. Reves and Peter Glass.²⁴ *Id.* 1727. *Miller's Anesthesia*, at two-volume treatise, is considered the "definitive textbook" in anesthesiology. *Id.*²⁵ In addition

 $^{^{22}}$ Defendants' witness, Dr. Evans, relied on articles written by Dr. Reves, Bailey, and Greenblatt.

²³ See Exhibit 40, Ex. Vol. 5, J.G. Reves, M.D., *et al.*, *Midazolam: Pharmacology and Uses*, 62 Anesthesiology 310 (1985).

²⁴ Defendants' witness, Dr. Evans, admitted he misinterpreted a study by Dr. Glass. XLIV 2137-38.

²⁵ Defendants' witness, Dr. Evans, endorsed *Miller's Anesthesia* as an authoritative text. Defendants' witness, Dr. Li, had never heard of it, nor had he hear of Dr. Greenblatt, Dr. Reves, or the American Society of Anesthesiology. Dr. Lubarsky cautioned that non-experts can easily become confused if they rely solely on textbooks. "The books could be dangerous [you] might think that you understand how to deliver an anesthetic ... and miss the entire point." XLII 1733-1734.

to his books, Dr. Lubarsky has published 116 peer-reviewed journal articles, including publications in the top journals in the field of anesthesiology. *Id.* 1734-35.²⁶ Dr. Lubarsky serves on numerous editorial boards for journals in his field, has given more than 300 invited international presentations, has served as an officer in professional organizations in his field, has conducted research in the field of anesthesiology, and has received numerous professional accolades. *Id.* 1735-39; Ex. 130.

Dr. Lubarsky is also certified in pain management. Id. 1746.

"Anesthesiologists always have to know about treating acute pain, because all anesthesia is not allowing acute pain of a surgery to take place, which is again why the word sensate. So every anesthesiologist to a certain degree is expert in that." *Id.* Dr. Lubarsky explained that it is the job of the anesthesiologist to match the drug that is used to the level of pain that the procedure is expected to involve. The anesthesiologist has a number of medications at his disposal that allow him to use the least dangerous drug necessary to maximize patient safety. *Id.* 1746-48, 1754-56.

Dr. Lubarsky has used Midazolam in his practice and is familiar with its strengths and weaknesses. "[Midazolam] is one of the most studied, most

²⁶ The transcript erroneously says "16" instead of "116" this is but one of numerous errors in the transcript which is doubtless the result of the expedited nature of this appeal. This mistake is small; other mistakes are quite significant. Plaintiffs do not have the physical ability to correct all of the errors in this record prior to September 6, 2018. *See infra*, claim regarding denial of appellate due process.

understood drugs in the anesthesia [armamentarium]²⁷ of drugs, because we know a lot about its receptors, the drugs, it's an agonist, its impact on single neurons as well as [whole] organisms. There's no debate about Midazolam at all nor has there been for many years since – Dr. Greenblatt actually did a lot of the elucidating work on the drug." *Id.* 1742.

Dr. Lubarsky acknowledged that the goal of a lethal injection is entirely different from the goal of surgery. However, he explained that pain does not know the difference between the two settings and neither does the drug. In other words, the pharmacokinetics and pharmacodynamics of Midazolam do not magically metamorphosize in the execution chamber. *Id.* 1757.

2. The body's ability to sense and experience pain

Dr. Lubarsky explained how the body experiences pain and how anesthesiologists use various combinations of drugs to prevent those experiences. The terminology is inherently medical. It is not appropriate or scientific to discount science and medicine when one evaluates a process that is inextricably intertwined with science and medicine.

The American Society of Anesthesiologists publishes a summary document titled "*Continuum of Depth of Sedation: Definition of General Anesthesia and*

²⁷Dr. Lubarsky stated that armamentarium is like the anesthesiologist's tool kit. XLII 1742.

Levels of Sedation/Analgesia."²⁸ Ex. 131, at Vol. 14, p. 2069.²⁹ Dr. Lubarsky identified that document and discussed it in detail. The continuum describes four physical states of being from minimal sedation to general anesthesia. Ex. 131. The summary table focuses on responsiveness, airway, spontaneous ventilation, and cardiovascular function. *Id.* For purposes of lethal injection, responsiveness and the related concept of rousability, are the key factors. If the inmate is in a physical state where he is rousable by painful (noxious) stimuli, then he will experience everything that is happening in his body (i.e. pulmonary edema) and the effects of vecuronium bromide and potassium chloride.

Minimal sedation (anxiolysis) is the reduction of anxiety. Benzodiazepines, including Midazolam, are anxiolytics. A person in a state of minimal sedation has a normal response to verbal stimulation. Ex. 131. Moderate sedation is also known as conscious sedation. *Id.* It "is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation." *Id.* Midazolam can be used to create moderate sedation. Deep Sedation/Analgesia "is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond

²⁸ Defense witness, Dr. Li, doesn't know what the American Society of Anesthesiologists is. XLVIII 43. Nor is he familiar with the continuum of sedation. *Id.* Note: Volumes XLVIII – LI were prepared by a different court reporting company. Because of the scheduling order in this case, there was no time to serially paginate these remaining volumes.

²⁹ The pagination of the record is confusing and doubtless this brief, which is being drafted by multiple attorneys without time for proper proofreading, will be inconsistent in citation format.

purposefully following repeated or painful stimulation." *Id.* This level of sedation is the ceiling of the efficacy of Midazolam. In order to reach this level of deep sedation/analgesia, doctors always combine Midazolam (as the sedative component) with an opioid (such as fentanyl) or another analgesic because Midazolam has no analgesic properties. XLII 1810. Persons who are placed in a state of deep sedation appear unconscious. Indeed they do not respond to verbal stimuli such has having their name called. They will, however, rouse when noxious (painful) stimuli is applied.

General anesthesia "is a drug-induced loss of consciousness during which patients are not rousable, even by painful stimulation." *Id.* The state of general anesthesia is the only physical state that prevents persons from being roused (woken up) by painful stimuli. Dr. Lubarsky clearly explained that unconsciousness is only one component of general anesthesia. General anesthesia requires the person to be 1) unconscious; 2) insensate; and 3) immobile. "There is no debate on this topic. That is the definition of what general anesthesia is." XLII 1744.

A person who is sensate can feel pain, even when they are unconscious. The pain will rouse the person causing them to awaken. This is scientifically true and no witness disputed this scientific fact.

Sedation is "entirely different" from analgesia. XLII 1745. "[S]edation is an increase in the inhibitory neuro firing in the brain. It's sort of hypnosis/sleep/ sedation. Sleep is a lay term, if you will." *Id.* A person who is deeply sedated is sleeping as a result of a drug. Midazolam is classified as a sedative-hypnotic.

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Hypnotic also means sleep. Sedative also refers to the anxiolytic properties of the

medication. Analgesia "is protection from pain and protection from noxious

stimuli." XLII 1745.

The two [analgesics and sedatives] are entirely different. They're [unintelligible transcription] entirely by different receptor classes. They are dealt with by entirely different drugs. Most sedative hypnotics do not have any analgesic properties. But generally, they do not have anything to do with each other. Normally, you have to give both when you're trying to achieve an end to make the patient comfortable."

XLII 1745-46.

Dr. Lubarsky explained the difference between general anesthesia and mere

unconsciousness:

Anesthesia is three parts. Okay? Like I say, it's [not] a static measure [it] changes as the process changes.³⁰ So unconsciousness simply means you're not obviously responding to external stimuli, **but that's different from not responding to noxious stimuli, which is why the second part of general anesthesia is insensate.** Because if you're unconscious and you arouse from unconsciousness, you only look to the football field in the summer and breaking out the ammonium nitrate. They're capsules and noxious. It wakes up the unconscious athlete who fainted. That's the way that works. It's a very good example. They're not under anesthesia. They were unconscious and [now] they're not unconscious.

XLII 1771-72 (emphasis added).

3. Midazolam is inherently limited.

Midazolam has no pain relieving properties. Midazolam cannot be used as a

general anesthetic. Dr. Lubarsky explains:

[T]here are only certain drugs that are general anesthetic drugs alone. Those would be the inhalational anesthetics, which there's a defined level of the amount that you have to breathe in in order to achieve a level of a drug in your body where you are insensate.

³⁰ Counsel has corrected apparent transcription errors.

There are several IV drugs, all of which share a common principle which are Etomidate, Propofol, Barbiturates. And all of those general anesthetic drugs initially act in their sedation part, low doses, to increase GABA activity from your internal GABA in your body. And it enhances the neuron firing. But what makes them general anesthetics is at higher doses they become GABA, that is act as an agonist on the receptor directly. They do not require GABA to be present. They are GABA. So they promote a very deep level of sedation. And that's what causes the general anesthesia.

You'll notice that I did not mention Midazolam in that. But Midazolam is not a general anesthetic. There is no argument about whether Midazolam is a general anesthetic. There is nobody in the United States who does an operation with just Midazolam.

XLII 1750-51 (emphasis added).

Dr. Lubarsky went on to explain why it is that pain causes a person who is not in a state of general anesthesia to rouse (awaken). This is because there are "a known set of chemicals that work in opposition to GABA. So epinephrine, dopamine, serotonin, there's a bunch of neurotransmitters that are excited [by stimuli.]" XLII 1753. Noxious stimuli will activate these excitatory neurotransmitters. "[T]he brain gets a signal wherever it is in the body and it says I'm going to fire some exciting stuff and it's going to overcome the inhibitory neurons ... our job as anesthesiologists is to make sure that the inhibitory neurons are ... the ones that are predominantly there." *Id.*

Dr. Lubarsky testified that Midazolam is "absolutely not" the type of drug that can prevent a person from being roused by pain if it is the only drug being used. XLII 1755. "[T]his has been established in the literature." *Id.* Indeed, the scientific literature establishes that "people respond to noxious stimuli when they have just Midazolam on board. It is not a debatable point." *Id.* 1756. Dr. Lubarsky testified specifically, "It will not make someone insensate and unresponsive to noxious stimuli." XLII 1810.

Because Midazolam cannot protect against pain, Fentanyl is often used in conjunction with it. However, even the Midazolam/Fentanyl combination does not induce general anesthesia. XLII 1756.

Dr. Lubarsky addressed the ceiling effect of Midazolam as had Dr. Stevens and Greenblatt. "There's a very well established ceiling effect and it is not unique to Midazolam." XLII 1796. Dr. Lubarsky created a chart for the court to explain the difference between barbiturates such as sodium thiopental who do not have a ceiling effect and Midazolam which does. Ex. 133. ³¹

Here we have an asleep patient. And here we have a plane of surgical general anesthesia -- which is It looks something like this, again, these are well describe numbers. And look something like that.

And the point is, this is the plane of surgical anesthesia that you need to get to. No matter how much of this you inject into a human being, you will never ever get to this point because of the way that it works, which is to facilitate the internal GABA. It's just never enough. It's enough to get you to a sleep, but it is not enough to get you to a surgical plane of anesthesia. And the reason is, the graph demonstrated, is that Midazolam does not act as an agonist in high doses. The other drugs that we're talking about are GABA like at very high doses. So they move.

What happens in this Midazolam -- let's take Thiopental, for example, which works the following way. You'll give it and it will come up here. And if you give enough, it goes like that, because [thiopental] changes its mechanism of action and is a general anesthetic. And [thiopental has] been used as a general anesthetic and is approved as a general

³¹ Exhibit 133 is contained in an envelope in Ex. Vol 15 and bates numbered 2071(a) but is not part of the electronic record.

anesthetic. The FDA is not confused about this nor is anybody that practices anesthesia.

XLII 1797-98. See also Ex. 133; Ex. 16(a), at Vol. 3, p. 360.

Dr. Lubarsky explained that, "In humans, we can absolutely say that the maximum effect [of Midazolam] is somewhere south of 50 milligrams. My calculation says it's 40. The opposite³² say it's 20 to 30. It's somewhere in there." 1799. Dr. Lubarsky further emphasized that pinpointing the exact number of milligrams to define maximum effect is irrelevant. "Because while the curve goes up, its an [asymptote].³³ It's not a line. It has an ever increasing thing closes to a

³³ The transcript says "acetone," which is plainly incorrect. Counsel avers that the correct word is "asymptote." <u>http://mathworld.wolfram.com/Asymptote.html</u> (last checked September 4, 2018). *See also*, Ex. 16(a), at Vol.3, p. 360 (for depiction of an asymptote. The line for benzodiazepines relative to the ceiling is ever diminishing without ever crossing the ceiling):



 $^{^{32}}$ The word "opposite" appears to be a transcription error, but counsel cannot aver what the proper word should be.

threshold. The threshold that it comes close to and never reaches is well below that plane of anesthesia." XLII 1799-80.

Dr. Lubarsky testified that the drug company who developed Midazolam tested it for use as a general anesthetic and it failed. Dr. Reeves, Lubarsky's colleague at Duke and coauthor of Exhibit 40, was involved in that early research on Midazolam. XLII 1790-91. Midazolam is not marketed as a general anesthetic and is not approved by the FDA as a general anesthetic. XLII 1790-91. "There's not a single company or person that uses Midazolam as a single agent to so for surgery or something that has a noxious stimuli associated with it." XLII 1791.³⁴

4. The executions of Joseph Wood and Clayton Lockett demonstrate that Midazolam does not prevent an inmate from feeling pain.

Dr. Lubarksy testified that the human experimentation on Joseph Wood and Clayton Lockett demonstrates the scientific principles recognized in the field. XLII 1799. Though Mr. Wood was given 750 mg of Midazolam, he continued to be responsive and unanaesthetized: "it's very clear looking at the Joseph Wood, unfortunate human experience, that that dose was 50 milligrams. They kept giving

³⁴ Midazolam was once used to *induce* anesthesia but has fallen out of favor. "It's not used because as a single agent it doesn't work. So when you go and try to, say put a breathing tube in someone that they respond dramatically. And you can't do a minor procedures really under just Midazolam. So you're having to add other drugs in anyway. So you might as well start with other drugs." XLII 1792.

Induction is not the same as maintenance and "merely means that you have achieved a level of inhibition such that the person is unlikely to respond to *verbal* stimuli ... or non-noxious stimulations such as a breathing mask on them." *Id.* (emphasis added). Such stimulus is not the same as the noxious stimulation of pulmonary edema, Vecuronium Bromide, or Potassium Chloride.

50 over and over and over again and nothing ever changed. Every time they gave 50, they never got more effect than the first 50 milligrams . . .the repetitive dosing of 50 milligrams of Midazolam, 15 different injections, clearly established that Midazolam had no greated effect all the way up to and including a 750 milligram aboe and beyond the 50 milligrams. Joseph Wood continued to breath[s], struggle, and snort through each of those and there was no increasing effect to diminish that. And he did not suffer a cardiovascular arrest by increasing doeses. He did not get more sedated." *Id.*, 1799, 1816-17. Dr. Lubarsky clarified that that which happened to Mr. Wood was not because the drugs were administered over a period of time:

Each drug has a very specific mathematical model of exactly how that happens, as Midazolam does. And I'm not an expert in it and I can't write the equation for it. But we do know that the half life changes from approximately 27 to 33 minutes beginning when the body gets Midazolam to an average of about 30 milligrams or so. It changes closer to a hundred minutes. That's why they don't recommend bigger doses. So after Joseph Wood, for instance, got the second dose of Midazolam, the half life was probably closer to 70 or 100 minutes is my guess. There are curves in that same textbook chapter that we wrote that fully describes this for different drugs, but for Midazolam that's about correct. So what we can say, because I also heard this, is that each dose was not over the negative prior to the next dose. And since there was no greater effect, the only human experiment that exists in this dose range to show there is a ceiling effect in therapy and receptors as in animal studies.

XLII 1805-06. Dr. Lubarksy testified that the differences between the Arizona protocol used to kill Mr. Wood and the Tennessee protocol at issue at trial would not have affected the efficacy of the Midazolam: "I would only state that [the execution of Mr. Wood] overstates by far the efficacy of Midazolam, because we know that the combination of the narcotics and Midazolam are much, much more potent than either on alone." *Id.* 1819-20. However, the addition of the paralytic in Tennessee would have prevented Mr. Wood from conveying his distress. *Id.* 1819.

Dr. Lubarsky further testified that, despite whatever may have happened to Mr. Lockett's IV, Mr. Lockett received more than a therapeutic dose of Midazolam. XLII 1837. Dr. Lubarsky's review of Exhibit 47, The Oklahoma Department of Safety Report on Exeuction of Clayton Lockett, revealed that though Mr. Lockett's IV dislodged at some point during the execution, Mr. Lockett received Midazolam into his intramuscular space. *Id.* 1838; Ex. 47, at Vol. 6, p. 836 et. seq. Dr. Lubarsky testified that Mr. Lockett received the Midazolam in his muscle in sufficient time to receive its peak effect long before he was dead: 'It had more than enough time to take effect." *Id.* 1841.

5. The Lethal Injection Chemicals (LIC) cause noxious stimuli that will rouse the inmate from sedation.

A. Vecuronium Bromide causes air hunger and panic which is a noxious stimulus.

Dr. Lubarsky is familiar with vecuronium bromide and its use. XLII 1774. Vecuronium bromide does not effect the mechanism of action of Midazolam. XLII 1817. Vecuronium bromide does not protect the inmate from sensing noxious stimuli. Rather, "it paralyzes you and prevents anyone from seeing any sign of distress that you might voice or move or try to express." XLII 1821. Vecuronium Bromide acts as a stimulus and increases the risk of pain. *Id.*

Dr. Lubarsky testified that the administration of Vecuronium Bromide to a person who was not in a plane of general anesthesia is:

Basically, it's like burying someone alive. They lose the ability to communicate their distress. They lose the ability to breathe. They still have the air hunger. It's as if you're basically locked in a box and someone now has basically covered your mouth and you can't [breathe] and your lungs and your brain are screaming.

XLII 1774. The administration of Vecuronium Bromide is a noxious stimuli capable of arousing an inmate under the protocol "because it initiates that whole fight or flight syndrome and the adrenaline surge and overcoming what appears to be a sleeping state." XLII 1775. Thus, the Vecuronium Bromide stimulates the excitatory neurons and "as we all know, Midazolam is incapable of keeping someone in an anesthetized, hypnotic, or sedated state in the face of noxious stimuli, which is why it is not used as a general anesthetic." *Id.*

B. Potassium Chloride, a small amount of which is known to "cause a patient to scream out in pain," is a noxious stimulus.

Dr. Lubarsky is familiar with Potassium Chloride and has observed that the administration of extremely small amounts of the drug "cause a patient to scream out in pain." XLII 1776. Administration of the massive amount of Potassium Chloride called for in the protocol will be "akin to being burnt alive." XLII 1776.

[I]t's a very caustic chemical. One of the reasons it's so caustic is it not only it basically causes all your cell membranes to go crazy. It sends serious pains throughout. And it is an extremely painful thing. It's like every nerve fiber in your body along the path and the trail of that Potassium Chloride would be delivered.

XLII 1777. Dr. Lubarsky emphasized, "It's one of the most painful drugs you can administer if you're wrong. I don't know any other drug, to be quite honest, that is more painful that the administration of Potassium Chloride." XLII 1780. Dr. Lubarsky testified the administration of Potassium Chloride is a noxious stimuli which would rouse an inmate sedated with Midazolam to awareness. XLII 1780-81.

C. Pulmonary edema is a noxious stimulus.

Dr. Lubarsky testified that he agreed with Dr. Greenblatt and Dr. Edgar's opinion that Midazolam appears to be caustic to the pulmonary lining resulting in pulmonary edema. XLII 1813. Dr. Lubarsky has attended patients with pulmonary edema. Dr. Lubarsky opined that pulmonary edema is a noxious stimuli that would rouse a deeply sedated inmate. "You feel like you can't draw breath. You get anxious, terrified. You're incredibly uncomfortable with pulmonary edema, which is what we're saying. And it's torturous." XLII 1822.

7. The "Consciousness Check" in the Tennessee lethal injection protocol is a completely ineffective assessment of whether the inmate is sensate, aware, or rousable.

A. The consciousness check in inherently inadequate to assess level of sensation and awareness.

The July 5, 2018 protocol specifies that two minutes after the second syringe of Midazolam is pushed, "the Warden shall assess the consciousness of the condemned inmate by brushing the back of his hand over the condemned inmate's eyelashes, calling the inmates name loudly two times, and grabbing the trapezius muscle of the shoulder with the thumb and two fingers and twisting." Ex. 2, July 5, 2016 Protocol, at Vol. 2, p. 172.³⁵

 $^{^{35}}$ The word "loudly" was added on July 5, 2018, along with the trapezius pinch. See Ex. 3 (redline version) at Vol. 2.

None of these actions is sufficient to assess for the inmate's ability to perceive noxious stimuli or his rousability. Dr. Lubarsky explains that the eyelash brush "tells you that you have induced sleep, but it's not in the plane of surgical anesthesia by any stretch of the imagination." XLII 1922. Similarly calling the inmates name loudly is insufficient because "loss of response to verbal stimuli is one of the earliest signs of moderate ... sedation. It's not an indicator whatsoever of unconsciousness." XLII 1922. A trapezius pinch is likewise inadequate. "That's not how we measure for a surgical anesthetic. The normal things, surgeons take a saw, something like a sharp clamp. And usually if there's any question, we [clamp] in the area of the proposed incision to make sure you don't start the cut before the patient is actually appropriately anesthetized." XLII 1923-24.

B. The placement of the gurney straps affirmatively interferes with the Warden's ability to observe signs of sensation and awareness.

Dr. Lubarsky further testified that the protocol itself affirmatively interferes with the Warden's and Executioner's ability to observe signs of sensation and awareness. During his testimony, Dr. Lubarsky was shown exhibits 84 and 88. XLII 1769. Exhibit 84 is a schematic of drawing of the gurney and the strap configuration. Exhibit 88 is a photograph of the straps which are used to secure the inmate's upper body to the gurney.

Ex. 84, Computer Diagram of Gurney, at	Exhibit 88, Photograph of the Chest
Vol. 9, p. 1186	Restraints of the Gurney, at Vol. 9,
	p. 1190



Dr. Lubarsky testified that the configuration of the straps, which are bolted to the gurney, would interfere with an observer's ability to determine if the inmate was in a state of general anesthesia (unconscious, insensate, immobile), "because you're restricting minor movements which are signs that people are not fully asleep." XLII 1769. Moreover, "the way that the [inmate] is strapped down" makes the trapezius pinch "extremely difficult to do ... in an appropriate fashion ... You need to get to the trapezius muscle to even perform that in an appropriate manner." XLIII 1923.

8. Mr. Irick's hands were taped to the gurney, preventing witnesses from observing finger and hand movement; Dr. Lubarsky testified such taping was an impediment used by Florida officials to mask signs of awareness.

At trial, Dr. Lubarsky specifically warned about the practice of taping the inmates' hands during an execution with reference to Florida executions. Describing Florida Department of Correction efforts to obscure signs of consciousness, Dr. Lubarsky testified that "the covering of the hands and ... other things that have been done to obscure any response to the consciousness check[.]" XLIII 1926. Moreover, Dr. Lubarsky testified that "subtle things occur, grimacing, minor hand movements, minor ankle or foot [movements]. These are the way the body is telling you this is wrong." XLII 1767. Dr. Lubarsky stated that if he observed a small twitches of the hand he would "[i]mmediately deliver anesthetic." XLIII 1767.

With full knowledge and notice that the practice of covering the hands of the inmate would obscure the inmate's ability to signal sensation and awareness, Defendants taped Mr. Irick's hands to the gurney. "Irick's hands were strapped to the gurney using a brown tape." Dave Boucher, *Billy Ray Irick execution brings no resolution to lethal injection debate*, Tennessean, p. A1 (August 10, 2018).

Following the execution, official media witnesses described what they observed in a live press conference which was live-streamed by multiple news outlets. Dr. Lubarsky reviewed the press conference and news accounts of the execution. In addition to concluding that the media witnesses described movement consistent with Mr. Irick being sensate and aware during his execution, see below, Dr. Lubarsky also explains in his September 2, 2018 sworn declaration, "During my testimony I discussed physical signs that indicate that a person is not in a plane of

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surgical anesthesia, which include hand movement. A trained observer knows that if a patient moves his fingers or hands that is a clear indicator that they are not anesthetized. The taping of Mr. Irick's hands affirmatively prevented the Warden from observing an important indicator that Mr. Irick was not anesthetized." September 2, 2018 Declaration of Dr. David Lubarsky, Attachment B to Motion to Expand the Record.

Given that: 1) there was testimony during the trial regarding other inmates who moved their fingers and hands as proof that these inmates were not properly anesthetized; 2) Dr. Lubarsky's explicit testimony that restraining the hands would cover up important indicators of sensation and awareness; and 3) the fact that taping of the hands is unnecessary given the wrist restraints, there is no other conclusion to be drawn except that the taping of the hands was intended to prevent witnesses from observing signs of awareness and sensation. This fact alone is a reason for this Court to pause, vacate execution dates, and permit a more studied and deliberate appellate process.

9. Dr. Lubarsky affirms that lay witness observations in other Midazolam-based executions indicate that the executed inmates were sensate and aware, including in the case of Billy Ray Irick.

Prior to Dr. Lubarsky's testimony, the Court heard from witnesses to Midazolam-based executions from every jurisdiction which has used Midazolam. Two of them, Arizona and Florida, have since abandoned Midazolam altogether. Every jurisdiction that has carried out an execution has documented instances of

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the inmate exhibiting signs that he was not properly anesthetized. Tennessee now joins their ranks.

Dr. Lubarsky analyzed the movements these witnesses observed and provided his expert opinion as to the significance of each:

- eyes opening after the consciousness check (Brooks-Alabama, Alang and Leslie Smith XXX 718, 729; Smith-Alabama, Hahn, XXX 780; Howell-Florida, Rudenstine, XXXI 804-7): "that says they're conscious." XLIII 1848;
- grimacing (McNabb-Alabama, Freeman, XXX 760): "that's a sign that they're reacting to the [external] stimuli." XLIII 1848;
- barking (Smith-Alabama, Hahn, XXXI 776-78 "barking cough, almost like a seal"; Arizona-Woods ("snorting"), Hall XXV 265; Williams-Arkansas, Motylinski ("coughing and choking"), XXXI 824): is a "common description of respiratory distress with pulmonary edema" XLIII 1848;
- raising the arm after the consciousness check (McNabb-Alabama, Freeman, XXX 758; Smith-Alabama, Hahn, XXX 780): "They're awake." XLIII 1849;
- fingers fluttering (Moody-Alabama, Hahn, XXXI 791): "they're trying to let you know that they're awake." XLIII 1849;
- lifting head off the table (Wood-Arizona, Baich XXVII 390): "They're awake."
 XLIII 1849;
- clenched fist (Melson-Alabama, Leslie Smith, XXX 738-9; Smith-Alabama, Hahn, XXX 780: "They are awake." XLIII 1850;

- turning their head (McNabb-Alabama, Freeman, XXX 760;Gray-Florida, Peiffer, XXXI 845): "They are awake." XLIII 1851;
- licking their lips (Smith-Alabama, Hahn, XXXI 776-77): "They are probably awake. XLIII 1851;
- writhing (Otte-Ohio, Wright XXX 696; Lockett-Oklahoma, Sanderford XXXI 861 "thrashing": "They're experiencing pain and discomfort and they're probably awake." XLIII 1851;
- Mouthing words (Phillips-Ohio, Wright XXX 688; Lockett-Oklahoma, Sanderford XXXI 860-1): "Absolutely awake." XLIII 1851;
- lachrymation, i.e. tearing (Wood-Arizona, Baich XXVII 401; Otte-Ohio, Wright XXX 699 "tears streaming down his face."): "You are close to being awake or awake" XLIII 1852.³⁶

Subsequent to the trial, Billy Ray Irick was executed. Official media

witnesses offered their observations immediately thereafter. See

https://www.tennessean.com/story/news/crime/2018/08/09/billy-ray-irick-tennesseeexecution-lethal-injection/830253002/ (last checked September 4, 2018). These observations included that Mr. Irick "gulped for an extended period of time" was "choking," "gasping," "coughing," and "his stomach moved up and down."

³⁶ Defense witness Dr. Li testified that lachrymation (tearing) is similar to involuntary urination which he says occurs in general anesthesia. Dr. Lubarsky flatly stated that this is not true. XLIII 1852. "Involuntary urination is really muscle relaxation. It has nothing to do with the sympathetic activation associated with tearing. So I am –don't know why he would say that." XLIII 1853.

Significantly, Mr. Irick was observed to move his head and strain against the straps after the consciousness check and prior to the vecuronium bromide (paralyzing drug) taking effect.

In his article, "The Execution of Billy Ray Irick," Steven Hale (a journalist and official media observer) wrote, "Irick did appear to react physical to the second drug. He jolted and produced what sounded like a coughing or choking noise. He moved his head slightly and appeared to briefly strain his forearms against the restraints." <u>https://www.nashvillescene.com/news/pith-in-the-</u>

wind/article/21017550/the-execution-of-billy-ray-irick (last checked September 4,

2018.37

Dr. Lubarsky has reviewed all of the media accounts and concludes:

The official media witnesses describe physical behavior of Mr. Irick after the drugs were administered that I recognize to be signs that Mr. Irick was not in a plane of surgical anesthesia during his execution. This is important because an inmate who is not placed in a plane of surgical anesthesia is not protected from the subsequent torturous effects of the lethal injection process.

September 2, 2018 Declaration of Dr. David Lubarsky, p. 1. Dr. Lubarsky concludes:

The failure to place Mr. Irick in a plane of surgical anesthesia means that he was sensate when the chemicals were introduced into his system. As Dr. Greenblatt, Dr. Stevens, and I explained in detail, this means that when Mr. Irick experienced noxious stimuli, he was roused into awareness because at most he was only sedated.

The noxious stimuli include the pulmonary edema caused by the pH of Midazolam when injected as well as the suffocation from the vecuronium

³⁷ Irick's execution was carried out at 7:48 p.m. on August 9, 2014. Hale's article was published at 2:00 PM on August 20, 2018 according to the website –less than nineteen hours after the execution. From the video of the press conference, it does appear that Mr. Hale took written notes of his observations.

bromide and the excruciating burning pain caused by the potassium chloride.

Based on the review of the media accounts, I conclude to a reasonable degree of medical certainty that Mr. Irick was aware and sensate during his execution and would have experienced the feeling of choking, drowning in his own fluids, suffocating, being buried alive, and the burning sensation caused by the injection of the potassium chloride.

Id. 2 (emphasis added).

II. Defendants' expert proof was completely discredited.

a. Dr. Evans repudiated the basic tenets of his testimony that is the basis of the Supreme Court's opinion in *Glossip v. Gross*, 135 S.Ct. 2726 (2015). The foundation of *Glossip* has crumbled.

The State's first witness was Roswell Lee Evans, Pharm.D. Dr. Evans is a retired Dean of the Auburn School of Pharmacy.XLV 2032. Though he has lived in Alabama for the past 24 years, he is not licensed in Alabama. XLV 2061. He is only licensed in the State of Georgia, but he has not practiced there since 1970. *Id.* 2034; Ex. 141, *Evans CV*, at Vol. 16, p. 2268-69. Dr. Evans testified on behalf of the State of Oklahoma in *Glossip v. Gross*, 135 S. Ct. 2726 (2015). Dr. Evans testimony in *Glossip* was presented in a preliminary injunction setting. *Id.* The Oklahoma district court found him to be well qualified and reliable. "Dr. Evans' central point, which the District Court credited, that a properly administered 500–milligram dose of midazolam will render the recipient unable to feel pain." *Glossip v. Gross*, 135 S. Ct. 2726, 2743–44 (2015). Here, Dr. Evans' central point was upended.

Dr. Evans' qualifications were vigorously challenged by Plaintiffs' counsel in the chancery court. XLV 2059-2067; XIII 1795-1809 (Plaintiffs' Trial Brief). The Chancery Court found his credentials to not be as substantial as Plaintiffs' experts. XVII 2251, n7 ("The Defendants' two experts, while qualified, did not have the research knowledge and imminent publications that Plaintiffs' experts did.") In contract, the Chancery Court held, "The Inmates presented the testimony of four well-qualified and imminent experts. The Court finds that these experts established that midazolam does not elicit strong analgesic effects and the inmate being executed may be able to feel pain from the administration of the second and third drugs." XVII 2251. Dr. Evans conceeded that Plaintiffs' experts "described ... very well" how Midazolam works and how it affects the human body. XLV 2070.

1. Dr. Evans is neither well qualified or reliable.

Dr. Evans is a Pharm.D. He is not a Ph.D. When he received his Pharm.D, in 1972, the degree only required 18 months of post-graduate education. XLV 2059. Midazolam wasn't on the market in 1972. *Id.* The last time Evans was in an operating room (other than as a patient) was in 1972, as a graduate student. *Id.* Evans has never been present when Midazolam was administered. *Id.* He has no experience in prescribing Midazolam, indeed he is not allowed to prescribe medications. *Id.* 2060. Evans has never researched, published, or presented on the subject of Midazolam. He did present lectures regarding Xanax (generic name alprazolam) at places such as "The Ozark Society" and the "Black Hills Winter Seminar" in the 1980's and he did write an article about Xanax in 1992. *Id.* 2062-2064. Xanax is administered orally. *Id.* 2064. Evans is not a pharmacologist. XLV 2058.

Since 1994, the majority of Evans' professional time (85%) has been devoted to administrative tasks. XLV 2121. He spent very little time teaching (at most two hours

a week). *Id.* 2122. Prior to being hired to testify for the state of Florida in 2014, Evans had not studied midazolam for lethal injection, nor had he researched it. *Id.*

On cross examination, Dr. Evans was repeatedly impeached with examples of his prior inconsistent statements. XLV 2121-2198.³⁸ There is not time to provide a play-by-play of all of the times that Dr. Evans has flipped his opinion on the effects of various drugs. What is important, is that the *Glossip* opinion is based on a finding in the context of a preliminary injunction hearing—that the district court did not

³⁸ For example, Evans testified in his deposition that he had not provided testimony by declaration of deposition since his trial testimony in Tennessee in West v. Schofield. 2126. This is completely false. Evans provided two declarations and a video-taped deposition in the Tommy Arthur (the transcript erroneously refers to this case as the Tom Sarsa) case in Alabama. In his deposition in Arthur, Evans admitted that he has misrepresented the findings of Dr. Peter Glass' study regarding the utility of the BIS monitor for measuring consciousness in individuals who were sedated with midazolam. XLV 2137. Dr. Glass concluded that the BIS monitor is an excellent tool. Dr. Evans' represented that the study showed that it was not. Even though while on the stand he admitted his misrepresentation of the Glass study in *Arthur*, he repeated that same misrepresentation in his declaration provided pre-trial in Abdur'Rahman. Evans' omission of the Arthur case in his Rule 26 disclosure appears intentional. His list of testimony goes back to 1985. Arthur is the only case he was involved in (that we know of) between his testimony in Tennessee in July, 2015, and his testimony in Tennessee in July, 2018. XLV 2126-2142 (given more time, counsel would be able to provide pin cites for each sentence). Dr. Glass, as has been mentioned, is a close colleague of Dr. Lubarsky. A BIS monitor is one safeguard that TDOC could use, but has chosen not to.

Dr. Evans was also questioned regarding his flip-flopping answers under oath. He was questioned regarding an opinion given for the State of Montana regarding his opinion that Pentobarbital is an "ultra-fast acting drug" (where such a characterization was necessary for Pentobarbital to be used in executions). When asked about that opinion in Tennessee (in the previous *West* litigation), Dr. Evans repudiated his answer in Montana, testifying that while he may have given the answer (with which he was being impeached) in Montana, but that "That's not how it's classified." XLV 2197.

commit clear error in relying on Evans for two propositions: 1) the ability of Midazolam to protect the inmate from feeling pain; and 2) the ceiling effect. Plaintiffs' well qualified and eminent experts established that Midazolam's mechanism of action does allow Midazolam to protect against pain and that it has a ceiling effect short of general anesthesia which is what is required to protect against pain. Dr. Evans agreed with Plaintiffs' experts on these two propositions. The foundation of *Glossip* has crumbled and, accordingly, its logic must fall.

2. Dr. Evans admits Midazolam is not an analgesic.

On cross-examination Dr. Evans was asked, "Midazolam is not an analgesic is it?" He replied, "It is not." XLV 2148. Evans admitted that in other proceedings he testified that Midazolam does not have any pain-relieving properties. *Id.* 2150. Evans then sought to qualify his answer by stating "There is some pretty hypothetical information that very high doses of this drug may have analgesic effects." *Id.* 2151. The Court struck that answer. *Id.* 2152. Evans admitted that *Miller's Anesthesia* is an authoritative text and that it teaches that "benzodiazepines lack analgesic properties and **must be used with NSAID drugs to provide sufficient analgesics**." XLV 2157 (emphasis added). Evans admitted that Midazolam is not capable of rendering an inmate in a state of surgical anesthesia.

Evans admitted that Dr. Greenblatt is the one of the leading scholars in the area of benzodiazepines in the country. XLV 2168. Dr. Greenblatt's research is the research which establishes that midazolam has a ceiling effect. Ex. 40. Evans does not criticize Dr. Greenblatt's research and methodology. Indeed Evans defers to
Greenblatt. XLV 2168. The only study regarding the ceiling effect offered by Evans is the Hall Study. XLV 2165. The Hall Study, which was conducted on dogs, is not relied on or cited by any of Plaintiffs' experts. XLV 2166. Confoundingly, given that Evans cited it for the opposite proposition, Dr. Evans admits that the Hall Study suggests midazolam has a ceiling effect. XLV 2168.

3. Evans' suggestion that a toxic dose of Midazolam could cause coma, lacks scientific support.

Though Evans tried to suggest that massive doses of midazolam cause respiratory depression which may result in coma, he had no scientific study to back up the assertion and the studies he relied on did not support his supposition. Instead, the study by Dr. Lubarsky's colleague and co-author, Dr. Bailey refute Evans' conclusion. Ex. 145. That study concluded that Midazolam did not produce any change from baseline in oxygen or ventilation. XLV 2169-70. Moreover, there was no difference in ventilatory response between the administration of fentanyl alone, or fentanyl with midazolam. XLV 2170. In fact the research that Evans produced suggests is that there is a problem with fentanyl (which is given with midazolam for deep sedation), not midazolam. See XLV 2121-2198. Indeed Evans' resource, Goodman and Gilman's *The Pharmacological Basis of Therapeutics* (13th ed. 2018) states, "these drugs can cause apnea during anesthesia or given with opioids. And patients severely intoxicated with Benzodiazepines usually require assistance **only** when they have also ingested another suppressant drug." XLV 2202. The text further states, "Midazolam has minimal effects on respiration and oxygen saturation even in doses of up to one milligram per kilogram." Id. 2173.

Evans was unable to produce a single scientific study to support his speculation about a massive dose of midazolam causing a coma. All Evans presented was a single case study of a 63 year old man who died after being administered a therapeutic dose of midazolam (10 milligrams). XLV 2174; Ex. 146, *Article* at Vol. 16, p. 2344. The authors of the case study stated that it was the first report of a death from midazolam. XLV 2174.³⁹ Evans presented no other evidence of death by midazolam overdose. Nor did he refute the scientific data from Dr. Greenblatt which establish that benzodiazepines, even in the amounts given in the protocol, do not result in coma or death. *See*, Ex. 42, *Greenblatt Article—Acute Overdoes with Benzodiazepines*, at Vols. 5-6, p. 727-753 (showing that overdoses of benzodiazepines do not result in death).

In the end, Evans admitted that his testimony in *Glossip* was that a toxic dose of midazolam was essentially 7.1 grams. XLV 2145. Evans now says that that calculation was too high, but he admits that he did not correct his testimony by filing a supplemental declaration with the court.

Even if one were to accept Evans' baseless speculation that there is a dose of Midazolam that is so high it will result in a coma, Evans' testimony is that it would take **twenty minutes** for the person to stop breathing which would be the trigger for respiratory depression. XLV 2148, 2174. In the meantime, the inmate would feel the effects of the other two drugs, including the potassium. He would experience the sensations of being buried alive, unable to call out for help, and then of every nerve

³⁹ The man died two days after a routine procedure.

fiber in his body being set on fire by the potassium. The inmate would experience that prolonged torture before the putative toxic effects of the midazolam would hypothetically take hold, even according to Evans' speculation.

b. Defendants' pathologist was not knowledgeable about the relevant issues, lacked credibility, and could not identify any sources or scientific support for his opinions.

Defendants' last witness was Dr. Feng Li. Dr. Li is a forensic pathologist. He is not a pharmacologist. XLVIII 42. He is not a member of any organization that deals with pharmacology. XLVIII 43. He is not an anesthesiologist. XLVIII 42. He is not familiar with the American Society of Anesthesiology. XLVIII 43. He has never administered midazolam. XLVIII 43-44. He has not seen midazolam administered. He graduated from medical school in China in 1983. XLVIII, 42; Ex. 149, *Li CV*, at Vol. 19 2752.⁴⁰

Dr. Li has never conducted research on pharmaceuticals. XLVIII 44; Ex. 149. Dr. Li has never published an article about any pharmaceutical. XLVIII 44; Ex. 149. Dr. Li has never presented a lecture about pharmaceuticals. XLVIII 44; Ex. 149. Dr. Li does not have an H-Index –in fact he does not know what an H-Index is. XLVIII 45.

Dr. Li has spent his entire professional career as a medical examiner. Ex. 149, at Vol. 19 2752. Dr. Li has never conducted an autopsy on person who

⁴⁰ Thought Dr. Li identified Ex. 149 as his current CV on direct examination. On cross-examination he stated that it was not current. XLVIII 45. Defendants did not provide the Court with an updated CV. According to Dr. Li, any additions to his CV are not relevant to the issues before the Court.

overdosed from midazolam. XLVIII 46. Dr. Li testified that he cannot tell from an autopsy whether the decedent was aware of pain prior to their death. XLVIII 47.

Dr. Li was questioned extensively about the research upon which he relied in forming the opinions stated in his report. Though he claimed to have knowledge of toxicology, he admitted in his deposition that he was not an expert in toxicology. Dr. Li did not know that Sufentanil is an opioid. XLVIII 140. Dr. Li testified that 10 milligrams of Midazolam is more than a therapeutic dose, when all of the testimony preceding him and the scientific research in evidence demonstrated the falsity of that statement. XLVIII 141-142.⁴¹

Dr. Li did not know who Dr. Greenblatt was, though his scant 4 page report cited articles that relied on Dr. Greenblatt and Dr. Reves' research.⁴² Dr. Li did not read the seminal article on Midazolam, Ex. 40, until the night before his testimony. XLVIII 138. He did not review Dr. Greenblatt's scientific research which concluded that benzodiazepine overdoses are extremely unlikely, even at the levels used in the lethal injection protocol, without the presence of other CNS depressants such as fentantyl. Ex. 42 (collective).

Dr. Li claimed to rely on phantom sources. He stated that he did not include all of his sources in his report, and when challenged to name any additional

⁴¹ Further vitiating his credibility, Dr. Li maintains that an injection of potassium chloride without anesthesia would not be painful. XLVIII 48.

⁴² On cross-examination it was clear that the articles cited by Dr. Li did not support his position on direct examination.

authority for his testimony, he was unable to name them. XLVIII 48 ("I don't want to list everything I have or I know."); XLVIII 121 ("some sources are listed, some **sources I don't list** as a result of too many references to put in. So as I said, today, and in the past, I cannot list everything I studied or researched on. I can only put **certain most important** as I said, I mean, in the report.")(emphasis added); XLVIII 122 ("I cannot explain everything I have."); XLVIII 125 ("I cannot list everything I have."); XLVIII 156 ("I don't want to list them all."); XLVIII 160 ("I mean I don't list it here."); XLVIII 169 ("I cannot list everything I have or everything I know in this declaration.").

Dr. Li admitted that he did not disclose that his list of sources relied upon in his four page report was incomplete. XLVIII 169. Dr. Li agreed that there were no page limits or time limitations placed on him in preparing his report. XLVIII 170. After being impeached with each of his listed sources and those authored by Plaintiffs' expert witnesses, Dr. Li simply replied that his opinions were based on "common knowledge." XLVIII 129; XLVIII 159-60 ("Q: Common knowledge but you don't have a source? A: I have a source but, I mean, I don't list it here.").

The Chancery court did not credit or rely on anything that Dr. Li had to offer.

III. Eye-witnesses to executions from every state that has used Midazolam testified on behalf of Plaintiffs; witnesses in all states observed movements and behaviors following administration of Midazolam and the performance of consciousness checks.

Plaintiffs called eleven eye-witnesses to execution. They were able to share first-hand reports from every state that has used Midazolam as part of an execution protocol: Alabama, Arizona, Arkansas, Florida, Ohio, Oklahoma and Virginia. As

will be described, below, they uniformly testified that condemned inmates showed signs of awareness or pain following consciousness checks, and occasionally evidence of suffering prior to the check, as well. Plaintiff's offered this testimony in support of their Eighth Amendment claim as well as their claims involving procedural due process and access to the courts.

Plaintiffs, through these eleven witnesses, were able to present evidence never heard in such detail or breadth by any court, previously.⁴³ Collectively, the eye-witnesses demonstrated that Midazolam cannot render an inmate insensate to pain, and that pain and suffering appears to be inherent in a three-drug, Midazolam-based, lethal injection execution.

a. Arizona: Joseph Wood was given 750 mg of Midazolam, yet showed signs of awareness and pain for nearly two hours; he gasped, gulped and pressed against his restraints until being declared dead—albeit, the EKG reveals he was still alive.

The execution of Joseph Wood by the state of Arizona demonstrated significant limitations on Midazolam's ability, in the real world, to render an inmate insensate, immobile and unresponsive. Moreover, because Mr. Wood was executed by a protocol that did not include a paralytic, witnesses were able to see Mr. Wood's respond to painful stimuli.

Like our protocol, the Arizona protocol relied on Midazolam to render Mr. Wood unaware of noxious stimuli (but, unlike our protocol, it relied on

⁴³ Later, in Argument, appellants will discuss the limited proof that has been presented during applications for temporary injunctions, which has then led to the major published opinions on the efficacy of Midazolam.

hydromorphone to stop respiration and cause death). XXVII 323-23, 367. Plaintiff's offered the testimony of three of Mr. Wood's lawyers: Dale Baich, Robin Konrad, and Julie Hall. Both Mr. Baich and Ms. Hall were eyewitnesses to the execution while Ms. Konrad was Mr. Baich's and Ms. Hall's conduit to the courts.

> Dale Baich has witnessed thirteen executions, Joseph Woods' execution was the first one he ever tried to stop; he observed Mr. Woods gasping for breath and straining against restraints for nearly two hours.

Mr. Baich testified that he is an attorney licensed in Arizona and has served as the supervisor of the Capital Habeas Unit (CHU) of the Office of the Federal Public Defender for the District of Arizona for the past eighteen years. XXVII 327. In that capacity, he has witnessed thirteen executions. *Id.* 334. Mr. Wood's execution was the only execution in which Mr. Baich attempted to contact the courts to stop the proceedings. *Id.* 335. Mr. Baich not only witnessed Mr. Woods' execution, he also obtained and reviewed the Arizona Department of Correction execution binder that is the official record of the department of the execution. *Id.* 355; Ex. 27, *Joseph Wood Execution Binder*, at Vol. 4, p.488.

Mr. Baich described Joseph Wood's response to the lethal injection of a total of 750 mg of Midazolam and 750 mg of hydromorphone. XXVII 405. Mr. Baich was seated on the top row of the witness gallery with an unimpeded view of Mr. Wood. Mr. Baich (along with Ms. Hall, who was seated in front of him) watched as department of correction officials set the lines in Mr. Wood's arms—a process of about ten minutes. *Id.* 380. Mr. Baich testified that after the lines were set, Mr. Wood blinked his eyes and puffed out his cheeks and made movements with his

tongue and then three minutes later a man in surgical garb performed the first consciousness check. *Id.* 386-87; Ex. 27, *Joseph Wood Execution Binder*, at Bates 107 (noting that at 13:57 "Housing Unit 9 Section Leader advises witnesses the inmate has been sedated").

Mr. Baich saw Mr. Wood's breathing become more shallow, Mr. Wood's face lost color and his lips moved slightly, then it appeared he stopped breathing. Id. 390. After it appeared that Mr. Woods had stopped breathing at 2:05pm, "all of a sudden, his mouth opened wide, his head jerked back, he pushed up against the restraints, and then his mouth closed and he went back on the table. And from where I was witting I saw the witnesses in front of me sort of sit up and jump when they saw that happen." Id. 391. Mr. Wood's movements occurred 12 minutes after the official logs reflected that the lethal chemicals had been administered. Id. Mr. Wood repeated this sudden movement two minutes later. Id. 392. "Again, the witnesses were startled and jumped a bit. And then about a minute later Mr. Wood] just started gasping and gulping. And as time went on I was counting anywhere from five to fifteen gulps and gasps every minute." Id. Mr. Wood laid "there gasping and gulping and struggling to breathe" for almost two hours. Id. 393; see also Id. 404-412 (reviewing Ex. 27, Joseph Wood Execution Binder, at pp. 107- $109)^{44}$

⁴⁴ Exhibit 27 was filed separately and out-of-sequence and does not have the same Bates numbering as other Exhibits. However, a long alphanumeric system is stamped at the bottom of each page, which ends in a three digit numeral that appears to be sequential. Citations are to this.

At 2:50 Mr. Baich decided to contact the federal court to attempt to stop the execution. XXVII 394. He wrote a note directing Julie Hall to leave and call his office, specifically Robin Konrad, who would know what to do. Ex. 26, *Handwritten Note Given from Mr. Baich to Ms. Hall*, at Vol. 4, p.486; *see also* Ex. 27 at p. 104 (noting officers "escorting 1 from IM witness to external staging (Julie Hall – female attorney).

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Some ten minutes later, Mr. Baich sent another lawyer, Kevin Lerch, to find Ms. Hall to provide her information that nothing had changed in the death chamber: Mr. Wood continued to gasp and gulp and try to breathe. XXVII 399; Ex. 29, *Copy of Handwritten Note given to Mr. Lerch from Mr. Baich*, Vol.4, p. 504; see also, Ex. 27, *Joseph Wood Execution Binder* at Bates 104.



Mr. Baich testified that some twelve to fifteen minutes before Mr. Wood died, Mr. Baich saw "a tear by his right eye, a little tear." XXVII 401.

Mr. Baich testified that the warden deviated from the written protocol by allowing fifteen administrations of the two-drug protocol (it was intended to be 50 mg Midazolam and 50 mg of hydromorphone, not 750 mg of each). XXVII 403. Mr. Baich reviewed the administrations of the lethal chemicals recorded in the official execution book, noting that though the official logs reflect varying amounts of time between administrations of the lethal chemicals, the official account repeatedly noted "the inmate remains sedated" the entire time that Mr. Woods was gasping and gulping. XXVII 409-12. Mr. Baich testified that the EKG strips included in the execution book reflect that Mr. Wood took his last breath at 15:09:40 but then resumed breathing at 15:10:07 and that the EKG strips show continued activity after Mr. Woods was declared dead. *Id.* 415; Ex. 27, *Joseph Wood Execution Binder* at pp. 118 and 331.



execution and subsequently reading Mr. Keifer's article: Reporter Describes Arizona Execution: 2 hours, 640 gasps. Id. 417. Mr. Keifer's account of the execution aligned consistent with his recollections. XXVII 417. Mr. Baich testified that he knew some specifically remembered both seeing Michael Keifer of the Arizona Republic at the Following Mr. Wood's death, Mr. Baich read news articles that were with Mr. Baich's memory and contemporaneous notes of the execution. *Id.* of the reporters who witnessed the execution by name. Id. 377. Mr. Baich

now allowed the use of cellphones, and (2) Arizona has agreed to Mr. Baich discussed the legal accommodations made by Arizona in the wake of the Woods' execution: (1) lawyer-witnesses are never again use Midazolam, benzodiazepines or paralytics in executions. સં

Mr. Baich testified the state of Arizona has made accommodations

subsequent to the Wood execution; Arizona now permits attorney-witnesses to use

cellular telephones. XXVII 400.

Additionally, during further litigation the Arizona death row inmates proffered a two-drug protocol involving the use of Midazolam and potassium chloride as the *Glossip* alternative. *Id.* 419; Ex. 34, *First Amendment Coalition of Arizona v. Ryan*, Vol. 4, p. 528. This litigation settled with Arizona's agreement to never use Midazolam, any other benzodiazepine, or any paralytic, in any future executions. *Id.* 420-23; Ex. 30, *June 21, 2017 Stipulated Settlement Agreement*, at Vol. 4 p. 505; Ex. 32, *December 19, 2016 Stipulated Settlement Agreement*, at Vol. 4, p. 520.

3. Julie Hall corroborated the testimony of Mr. Baich and shared additional details; she also testified about the difficulties in reaching a court during a botched two-hour long execution, when the attorneys are denied access to a telephone.

Julie Hall, an attorney licensed in Arizona, tried to secure process for Joseph Wood during his Midazolam execution on July 23, 2014. Ms. Hall, a private practitioner with twenty-two years' experience in capital litigation, represented Mr. Wood for nine years. XXV 227. Prior to the administration of Midazolam and hydromorphone, Mr. Wood was physically healthy—enough so that he was able to play basketball prior to his execution. *Id.* Ms. Hall visited with Mr. Wood on the day of his death, starting around 6:45. *Id.* 243. She described for the court the path taken into the prison to the death watch and to the death chamber and also the path used for egress from the death chamber back to the administration building where she had left an investigator with her cell phone. *Id.* 244-45; 251.

Ms. Hall testified to her observations of the Wood execution, providing details that mirrored the testimony of Mr. Baich. Ms. Hall testified that at 1:52 there was

an announcement that the execution had begun. XXV 260. About five minutes later, a man came into the room and approached Mr. Wood, after which there was an announcement over the intercom to the witnesses. *Id.* 261. Three minutes later, Ms. Hall noted a quiver in Mr. Wood's cheek which she was unsure whether was normal or not. *Id.* 262. Two minutes after she noted the quiver, Mr. Wood began to gasp for air. *Id.* Ms. Hall noted that when the intercom was on for the announcements, she could hear Mr. Woods' breathing, "And it wounded like snorting." *Id.* 265.

At 2:50 after Mr. Wood had been gasping and snorting for over fifty minutes, Mr. Baich passed Ms. Hall a note that caused her to leave the witness room to contact the court. XXV 266; Ex. 26, *Handwritten Note Given from Mr. Baich to Ms. Hall*, Vol. 4, p.486. Ms. Hall "walked out of the death house and immediately the first officer I saw and told him that I needed a phone." *Id.* 266. Instead of providing her a phone, that officer, "walked me all the way from back there in the death house all the way out to the front administration building, which meant going through the sally port security area again, and then back into the administration building, up the stairs to the room where [the investigator] was waiting." *Id.* Ms. Hall wanted to access the courts, "because something as going very, very wrong, and it looked like Mr. Wood was suffering." *Id.*

Ms. Hall's efforts to secure access to the courts were unsuccessful. The walk from the death house to a place where Ms. Hall had access to a phone took nine minutes. *Id.* 267. When she finally had access to a phone, Ms. Hall called the Office of the Federal Public Defender for the District of Arizona: "I let them know he's still

alive. I don't [know] what's wrong. Something's going wrong. He's gasping, he's gulping, he's snorting, and that they needed to call the court." *Id.* At 3:39. Ms. Hall was placed on a call with the Justices of the Arizona Supreme Court and attempted to convey the situation: "And it was frantic. It was frantic. It was hard for me to hear them, and I'm not sure how well they could hear me." *Id.* 269 – 70. The Arizona Supreme Court instructed Ms. Hall, "Julie, Julie get back in there" to obtain more information on Mr. Wood's condition. *Id.* 272. But "the officer was refusing and saying, 'Nobody gets back in. Once you leave that's it." *Id.* Ms. Hall later learned that Mr. Wood "was already dead by the time I started talking to the Arizona Supreme Court." *Id.* 273-74.

4. Robin Konrad, a law school professor, testified about the challenges in conveying information to a court when is denied eye-witness access to the execution chamber.

Robin Konrad, a Howard School of Law professor who was formerly an attorney with the Capital Habeas Unit of the Arizona Office of the Federal Public Defender, testified regarding her efforts to access the federal courts on Mr. Wood's behalf. After Ms. Hall alerted Ms. Konrad to the problem with the execution, Ms. Konrad emailed motions to the federal and state courts. XXV 298. Ms. Konrad then represented Mr. Wood in a telephonic hearing with Judge Wake of the Federal District Court for the District of Arizona beginning at 3:27. *Id.* 300. Ms. Konrad moved the federal court for a stay of execution such that life saving measures would be initiated. *Id.* 303. During the hearing, Ms. Konrad learned from the state's attorney that Mr. Wood had died. *Id.* 303. She later learned that Mr. Wood died at 3:53. *Id.* 309.

Ms. Konrad testified that the conditions under which she was forced to litigate for Mr. Wood impeded his access to the courts. "I felt that I did not – was not able to fully answer the Court's questions because I didn't have information about what was going on with my client that was timely. I was relying on what the state's attorney was telling the Court with regard to information he was receiving directly from his client who was present at the execution." *Id.* 306-07. That is, unlike the state's attorney, Mr. Konrad was not permitted to have a witness in the chamber who could contemporaneously share information. *Id.*

5. Summary of Arizona testimony regarding Mr. Woods' execution: an otherwise healthy man took nearly two-hours to die an apparently arduous death; no witnesses from Arizona disputed Plaintiff's proof.

Dale Baich and Julie Hall collectively described how an otherwise healthy man took nearly two-hours to die, after application of 750 mg of Midazolam and 750 mg of Hydromorphone. XXV 243-274; XXVII 390-415. His death was preceded by gasping, gulping and lunging against restraints. *Id.* When officials finally declared the time of death he was still alive according to the EKG. Ex. 26. Mr. Baich, Ms. Hall and Ms. Konrad explained the difficulties in accessing a court, due to Arizona's denial of telephonic access. XXV 298-304. No witnesses were called by Defendants to rebut their testimony in any way.

b. Ohio: Midazolam was not able to render Ronald Phillips or Gary Otte immobile, insensate and unaware: Mr. Phillips gulped like a fish and Mr. Otte produced active tears. Carol Wright, supervisory assistant federal public defender, testified regarding her observations during the executions of Ronald Phillips and Gary Otte in Ohio. XXX 657. Those executions involved a protocol of Midazolam, Rocuronium bromide (a paralytic), and potassium chloride. *Id.* 664. Ms. Wright represented Mr. Phillips solely on his litigation related to lethal injection. *Id.* 679. Ms. Wright described Mr. Phillips execution as proceeding in a predictable manner, with no reason for alarm until after the warden had given the signal for the administration of the drugs to begin. *Id.* 688. "[T]he only thing that I noticed with Mr. Phillips, we could see him breathing a little faster, a little more dramatically, than he was and we could see movement in his mouth, like, just kind of a movement with his mouth . . . almost like a little a fish maybe gulping, kind of, or words being mumbled." *Id.* 688. Ms. Wright watched the execution until Mr. Phillips finally expired, she did not attempt to seek judicial intervention. *Id.* 691.

Ms. Wright also testified regarding the execution of Gary Otte in September 2017. Ms. Wright represented Mr. Otte from November 2016 until his death. Ms. Wright testified that after Mr. Otte's last words, he sang a hymn and then a prayer and then the warden crossed his arms signaling for the execution to begin. *Id.* 696. Ms. Wright observed that "within fifty seconds" of the crossing of the warden's arms, "Mr. Otte's stomach violently moving up and down." *Id.* Based on her training with experts during years of litigation in lethal injection, Ms. Wright believed that Mr. Otte's airways were obstructed and determined she should contact the court. *Id.* 698. When she initially attempted to leave the room, "They blocked the door. They

said, 'sit down.' I said, 'I need to call the Court,' I sat down." *Id.* Ms. Wright then observed "tears coming out of [Mr. Otte's] left eye, streaming down his face, and a clenched left fist." *Id.* She again attempted to leave the death chamber: "I got up again and went to the door and said, 'Dear Lord." *Id. 699.* The guard blocking the door then was permitted Ms. Wright to leave, and she called her colleagues from the phone right next to the door to the witness room. *Id.* Ms. Wright was able to monitor that which occurred in the death chamber through a window into the witness room from the hallway with the phone. *Id.* She related to the federal court that she was able to see into the execution chamber and that Mr. Otte's movement "had stopped and his fists had uncurled a bit." *Id.* 702. The court denied Ms. Wright's motion as it appeared that the paralytic had already been administered. *Id.*

Ms. Wright was the only witness who testified about the executions of Mr. Phillips and Mr. Otte. Ms. Wright testified that though both men were overweight, neither had known serious health problems prior to the administration of the Midazolam. XXX, 683, 691. Defendants did not call any witness to rebut or contradict her testimony.

c. Executions in the state of Alabama: Mr. Brooks opened his eyes after the consciousness check; Mr. Melson moved his arm; Mr. McNabb moved his head and arm; Mr. Smith opened his eyes and moved his arm; Mr. Moody moved a finger; every inmate moved after the consciousness check.

Testimony was presented regarding the executions of five men in Alabama: Christopher Brooks, Robert Melson, Terry McNabb, Ronald Smith and Walter Moody. All five were executed using a three-drug, Midazolam-based, lethal injection protocol.

Investigator Terri Alang and attorney Leslie Smith of the Federal Defenders Program for the Middle District of Alabama testified about the execution of their client, Christopher Brooks, who opened his eyes after the consciousness check. Ms. Alang, a licensed attorney who works as an investigator, read a declaration she wrote within five days of the Brooks execution into the record pursuant to Tennessee Rules of Evidence Rule 803.⁴⁵ XXX 718. After the warden read the execution warrant, Mr. Brooks said his last words, culminating with "I hope this brings closure to everyone. I will take each of you with me in my heart. I love you. I love you all. I love you. I love you all. I will see you soon. Good-bye. I love you. I love you. I love you. That is all." Id. 722. After that "Chris's eyes closed and his mouth gaped open. Chris's breathing at this point was very rapid, his chest heaved up and down." Id. 722-23. A few minutes later an officer conducted a consciousness check: "I noticed no reaction on Chris's part . . . Chris's eyes went back to the closed position and his mouth continued to remain open. His breathing had slowed quite a bit . . . I did not look at the clock again until 6:24 p.m. At this time I noticed that Chris's eyes appeared to reopen. It might have happened in the few minutes before, but I cannot say for sure, because 6:24 is when I looked at the clock. His eyes were

⁴⁵ Ms. Alang is currently receiving medical treatment for demyelination in her brain, which has negative impacts on memory. Her declaration was written pursuant to office policy requiring on memorialization made within five days of the event she investigated/observed and was signed in the presence of a witness prior to the onset of neurological impairments. XXX 716-17.

definitely closed right after the consciousness check. Being closest to the door in the front row, I had a clear view of his right eye and arm. His right eye appeared more open than the left, to the point I thought he was looking out." *Id.* 723-24.

Ms. Smith, the supervising attorney of the capital habeas unit of the Federal Defenders for the Middle District of Alabama, corroborated Ms. Alang's observations of Mr. Brooks. XXX 729. Ms. Smith, a Lieutenant Colonel in the United States Army Reserve JAG Corp who has served in combat zones, testified that she has witnessed the execution of two clients, Christopher Brooks and Robert Melson. *Id.* 731. Like Ms. Alang, Ms. Smith specifically noticed that after the consciousness check, Mr. Brooks's eyes were closed. *Id.* 735. But, like Ms. Alang, Ms. Smith noticed that "at some point after Mr. Brooks's eyes closed, after being manipulated during the consciousness check, the eye that I saw that was closest to me, which I think was the left one, opened." *Id.* 736. Ms. Smith was "surprised to see his eye reopen after the consciousness check." *Id.* She also "noticed that his respiration appeared to be labored, that he was breathing heavily at first, until it appeared that respiration stopped, or at least was no longer visible to me." *Id.*

Ms. Smith also witnessed the execution of Robert Melson where she, again, observed unexpected movement after the consciousness check. XXX 738. She testified that "after the consciousness check had been performed, a few minutes later, I saw visible movement of Mr. Melson's arm . . . it was a clenching of the hand. And this time it would have been the right hand or arm that I saw moving after the consciousness check." *Id.* 738-39. She recalled that "as it happened with

Mr. Brooks's execution, the respiration was rapid at the beginning. He seemed to have very labored breathing because the chest movements were exaggerated." *Id.*

Christine Freeman, Executive Director for the Public Defender for the Federal Court in the Middle District of Alabama, testified regarding the execution of Torey McNabb in October 2017. XXX 748. Ms. Freeman sat in the front row and had unimpeded view of Mr. McNabb through the glass. Id. 752. Mr. McNabb was on the gurney when she entered, restrained with belts across his chest, around his legs, and perhaps at the upper arm, though his lower arms remained free. Id. 753. Before the first consciousness check, Mr. McNabb's "arms were out and were shaking, and there was just—at some point, they started to do that. It was change from his original position because he originally had posed himself with both middle fingers extended towards the audience. So his arms start shaking. We can see him breathing pretty deeply." Id. 756-57. After that, a consciousness check, including a pinch to Mr. McNabb's upper left arm was performed and Mr. McNabb reacted: "his arm kind of twitched, you know, his left arm did. It was twitching as if 'get that off me." Id. 758. After a passage of time, a second consciousness check was performed, "and he still seemed to be moving." Id. 759. Ms. Freeman demonstrated the movement, moving her hands at the wrists in a side-to-side motion. Id. In addition to the movement of his hands, following the second consciousness check, "his mouth opened and shut quite a bit as well." *Id.* The movement of McNabb's mouth was almost like a fish. Id. After some more time, Mr. McNabb's "right arm just completely [went] up like this (indicating), just extended straight up vertically.

Maybe the elbow was bent a little bit, but the arm, his right arm, went way above his body and above his head. Then he turned his head toward us, to the left. And you could just see this grimace on his face. It was pretty dramatic . . . generally the client is facing straight ahead, They can turn their neck a little bit, of course, but if they're unconscious you wouldn't expect that. But he turned his head almost all the way to the left, and we could see his face fully, which was grimacing. His brow was furrowed, his lips were kind of tightened. I mean, it was a grimace." *Id.* 760. After that, there was no more movement "and eventually the guard came over and pulled the curtain shut." *Id.* 761.

Spencer Hahn testified regarding the executions of Ronald Smith and Walter Moody. Mr. Hahn is an assistant federal public defender with the Federal Defenders of the Middle District of Alabama. XXXI 766. He testified that he only met Mr. Smith two days before Mr. Smith's execution. *Id*.768. Mr. Hahn believes that the lethal chemicals began flowing around 10:30 pm, based upon seeing the tubing "sort of kick, like something had been pushed through it. And then a few, maybe thirty seconds later, I saw Mr. Smith kind of sit up his chest, run his tongue all the way around both lips, and put his head back and kind of rest for a second, and then started breathing very heavily, gasping and coughing." *Id*. 776-77. Mr. Smith's coughing "was about every ten seconds. There was sort of a barking cough, almost like a seal. The rest of the time was labored, very deep breathing attempts." *Id*. The coughing noise was loud enough to clear the barrier of the glass and concrete block between the execution chamber and the witness room, such that Mr. Hahn heard it without benefit of a microphone. *Id.* 778.

Mr. Hahn testified regarding the ineffectiveness of Alabama's consciousness checks. "[I]n Alabama they wait approximately five minutes after they inject the Midazolam before the conduct what they call a consciousness assessment . . . In this case, he shouted 'Inmate Smith' three times. It was loud enough that I would hear it through the glass. It was somewhat surreal in that Mr. Smith was still conscious and moving, and they were acting as if they were trying to wake him up." XXXI 779. Mr. Smith responded to a pinch of his arm, "When that pinch occurred, Mr. Smith moved his arm in, as if toward his body." Id. After that, Mr. Hahn "heard some raised voices from the commissioner's observation room that sounded uncertain and a little panicky." Id. 780. After the second dose of Midazolam, "Mr. Smith had a similar reaction. The breathing issues slowed down a bit, he kind of leaned up a bit, then he sort of rested for a minute, just like the first one. And then he started up again with the heavy breathing, the coughing, the moving of the arms, and the clenching and the unclenching of the fists." Id. After five minutes, a second consciousness check was performed. Id. 781. "This one was nearly identical to the first . . . The difference here was that this time, instead of brushing the eyelid up, the guard attempted to brush the eyelid as if he were trying to close it, and it popped back open again. At that point, he came aback around and pinched the back of the left arm. And the way it differed this time was, his right arm then moved and he clenched his fist, but his left arm did not move." Id. Mr. Hahn "thought they were

going to call off the execution because I know that they have a protocol that involves a second dose of Midazolam. I'm not aware they have one that involves a third dose. There was no third consciousness check. But shortly thereafter, Mr. Smith's breathing started to slow and he stopped moving." *Id.* 782.

Mr. Moody appeared to already be dead when the curtains to the execution chamber opened on April 19, 2018. XXXI 788. Mr. Moody did not respond to the warden's inquiry about last words or otherwise move until after the Midazolam began to flow. Mr. Hahn could not even discern that Mr. Moody was breathing. *Id.* 789. After Mr. Hahn "saw some sort of frothy liquid coming through" the IV tubing, Mr. Moody "started to breathe very heavily and in a manner similar to Ron [Smith]. And so that was the first real movement that I saw in Mr. Moody." *Id.* 790. Mr. Moody "was breathing in through his nose, out through his mouth. It was noticeably different than his pre-drug breathing." *Id.* After the consciousness check, Mr. Moody moved his left pinkie a couple of times. *Id.* 791. Mr. Hahn saw more "stuff" coming through the tubing "and shortly thereafter, Mr. Moody stopped moving altogether. And he turned gray and fairly ashen, and I assume at that point he was deceased." *Id.* 791.

Ms. Alang, Ms. Smith, Ms. Freeman and Mr. Hahn were the only witnesses who testified about the executions in Alabama. Ms. Freeman, and Mr. Hahn testified that the executed men were healthy prior to the injection of Midazolam. XXX-XXXI, 762, 769, 785. Defendants did not call any witness to rebut or contradict any of the testimony described above.

d. The execution of Paul Howell by the State of Florida: his arms twitched upon injection of Midazolam, and his eyes opened with each subsequent injection of lethal injection drugs.

Sonya Rudenstine is a defense lawyer based in Gainesville, Florida. July 11, 2018 Tr., XXXI 794. After graduating from New York University School of Law, she started her legal career as a death penalty clerk for the New Jersey Supreme Court. *Id.* at 795. Then after a series of positions, including as a law school professor, she opened her own law practice in 2006. *Id.* at 796. In that capacity, she represented Paul Howell, who was executed by the State of Florida. *Id.* at 796-97.

Ms. Rudenstine witnessed Mr. Howell's execution. XXXI 796. He was killed with 500 mg of Midazolam, 100 mg of Vecuronium, and 240 millequivalents of potassium chloride. *Id.* at 797. Ms. Rudenstine was not allowed to have any writing implements, or access to a phone, during the execution—however she watched the clock, committed what she witnessed to memory, and wrote it down immediately after the execution. *Id.* at 799-800. At trial Ms. Rudenstine compared her recollections with the events described in the State of Florida's timeline of the execution. *Id.* at 805-06; Ex. 22, *Timeline Howell Execution*, at Vol. 3, pp. 413-16.

At 6:18 or 6:19, Mr. Howell's left arm began to twitch (this was the arm with the lethal injection catheter), and continued to twitch for "a fairly lengthy period of time." XXXI 803-04. His arm twitched concurrently with the injection of Midazolam. *Id.* at 806. Then Mr. Howell's eyes closed. *Id.* at 804.

At 6:22 a consciousness check was performed, and then Vecuronium was started. *Id.* at 807, Ex. 22, p. 416. At 6:23 following the consciousness check and the commencement of Vecuronium, Mr. Howell's eyes opened, and remained open for a minute. XXXI 807. It looked to Ms. Rudenstine as if he were conscious. *Id.* at 804-05.

At 6:26 the Vecuronium finished, and potassium chloride was begun, at this same time, Mr. Howell's eyes opened a second time. XXXI 804-05, 807-08; Ex. 22, 416. His eyes remained open until he was declared dead. XXXI 804-05.

Ms. Rudenstine was the only witness who testified about the execution of Mr. Howell. She testified that though Mr. Howell suffered from mental health problems he did not have any physical health problems prior to his execution. XXXI 798. Defendants did not call any witness to rebut or contradict her testimony.

e. The execution of Kenneth Williams by the State of Arkansas: he coughed, moaned and gasped, while violently straining against his straps when the only drug in his system was Midazolam.

Eric Motylinski is a federal public defender from Philadelphia, Pennsylvania. July 11, 2018 Tr., XXXI 816-17. Prior to becoming a public defender he worked in a variety of positions, including as a staff attorney for the District Court of Appeals, and as a clerk for a trial court judge in Philadelphia. *Id*.at 817. He was appointed to represent Kenneth Williams sixteen-days prior to his scheduled execution, an execution which he witnessed. *Id.* at 817-18.

Mr. Williams was executed with 500 mg of Midazolam, followed by a fiveminute wait, then 100 mg of Vecuronium, and 240 milliequivalents of potassium chloride. XXXI 818-19. As Mr. Williams had sickle cell anemia, which could cause difficulty in locating a vein, he agreed to have catheters inserted prior to his execution, and this was done successfully. *Id.* at 820-21. Mr. Motylinski was permitted access to a pen and paper, and the ability to use a phone immediately outside of the execution chamber. *Id.* at 821.

At 10:50 p.m., Mr. Williams read his last words, and after those were finished he began speaking in tongues. XXXI 823; Ex. 23, Arkansas Timeline Williams *Execution*, at Vol. 4, pp. 461-62. While he was speaking in tongues, a voice over a loudspeaker announced that the execution was ready to proceed. XXXI 823. According to Arkansas time records, lethal injection chemicals were started at 10:52 p.m. Ex. 23, p. 461. According to Mr. Motylinski, Mr. Williams continued speaking in tongues, but his voice "became slow and halting" until he stopped speaking at 10:53. XXXI 824. From 10:53 to 10:54, Mr. Williams' chest was "pumping, and I could see his head kind of moving back and forth, and I could also see his cheek muscles moving as if he was clenching and unclenching his jaw." Id. At 10:55, he began "moaning...choking and coughing and heaving." Id. Mr. Motylinski could hear this through the walls, even though the microphone had been turned off. Id. at 824-25. Also at 10:55, Mr. Williams' chest was "rising up from the gurney repeatedly, rhythmically, and violently, kind of hitting up against the straps." *Id.* at 825.

At 10:56, Mr. Williams' reaction was "less extreme," but his breathing was labored. XXXI 825. At 10:57, Mr. Motylinski left the room to call the court. *Id.* At this time a consciousness check was recorded as being performed. Ex. 23, 461. At

11:01, Mr. Motylinski returned, and Mr. Williams was quiet and not moving. XXXI 825-26. He was pronounced dead at 11:05. *Id.* at 826; Ex. 23, 461.

Based on the timing—the five minute wait, and a consciousness check at 10:57 p.m.—all symptoms that Mr. Motylinski witnessed (the coughing, moaning, and violent straining) occurred when the only lethal injection drug in Mr. Williams' system was Midazolam. Ex.23, 461.

Mr. Motylinski reviewed the State of Arkansas' records of the execution,

which he said "substantially minimize what I saw." XXXI 827; Ex. 23, pp. 460-61.

He explained:

[I]t says there was no coughing sound, but I heard a coughing sound and a choking sound. And ten seconds does not—although there were no seconds on the clock, you know, I was able to track the minutes, and seconds don't account for the raising and lowering of the chest. That happened for a longer period than that.

It doesn't describe, you know, the clenching and unclenching of his jaw or the movement of his head. It doesn't, you know, it just doesn't describe the violence and the force of the convulsions that, you know, he was experiencing against the straps. This is sanitized almost to the point of being unrecognizable, in comparison to what I saw.

XXXI 828; Ex. 23, pp. 460-61.

Mr. Motylinski was the only witness who testified about the execution of Mr. Williams. He testified that Mr. Williams had sickle cell anemia which affected the officials' ability to locate a vein for the IV, but was otherwise healthy prior to the administration of Midazolam. XXXI 820. Defendants did not call any witness to rebut or contradict his testimony. No witness from Arkansas addressed Mr. Motylinski's criticisms of their "sanitized" report.

f. The execution of Ricky Gray in the state of Virginia: Mr. Gray turned his head from side to side after the consciousness check.

Elizabeth Peiffer, a senior staff attorney at the Virginia Capital Representation Resource Center, testified regarding the execution of her client, Ricky Gray. XXXI 831. Ms. Peiffer, who had previously witnessed the execution of a client by use of compounded pentobarbital, witnessed Mr. Gray's execution by compounded Midazolam, Rocuronium bromide, and potassium chloride on January 18, 2017. *Id.* 835-36. Ms. Peiffer did not see any signs of consciousness in her client who received the pentobarbital. *Id.* 834. However, it was very different with the Midazolam, and she saw signs of consciousness after the consciousness check. *Id.*

Ms. Peiffer recounted her efforts to document what occurred during the Gray execution. Witnesses were not allowed to wear watches into the viewing room, but "there was a large clock on the wall." XXXI 840. Ms. Peiffer had pen and paper with her in the viewing room and took contemporaneous notes during the execution. At trial she used those notes to refresh her memory. *Id.* 841-42.

Mr. Gray walked into the execution chamber and was strapped to the gurney, after which, at 8:54, the viewing room curtains were closed for the insertion of the IVs. *Id.* 841. The curtain re-opened at 9:27, and Mr. Gray was asked if he wished to have any last words. He declined. *Id.* 842. After that, the execution began. At 9:30 "there was a sound like a cry, and there was breathing that I saw, heavier breathing and a snoring sound . . . Mr. Gray was somewhat overweight and I could see his stomach moving visible, more visible than it had been moving before." *Id.* 843-44. At 9:31, Ms. Peiffer noted continued labored breathing, then at 9:32 the

Department of Corrections performed a consciousness check by pinching Mr. Gray's toe. *Id.* 844-45. After the consciousness check, Ms. Peiffer saw Mr. Gray continue to labor to breathe and then at 9:33, he turned his head from side to side. *Id.* 845. "His head was at about a midline position, and he moved it to one side and then to the other." Id. After Mr. Gray moved his head from side to side, "the movement stopped" and Ms. Peiffer did not see any more movements or breathing from Mr. Gray. *Id.* 846. At 9:42, Mr. Gray was pronounced dead. *Id.*

Ms. Peiffer was the only witness who testified about the execution of Mr. Gray. She testified that prior to the administration of Midazolam, Mr. Gray was a healthy thirty-nine year old man. XXXI 837. Defendants did not call any witness to rebut or contradict her testimony.

g. The execution of Clayton Lockett in the state of Oklahoma: Mr. Lockett writhed and bucked on the gurney, moaning and mouthing words until he died of a heart attack.

Dean Sanderford, an assistant federal public defender in the Tenth Circuit testified regarding the execution of Clayton Lockett in Oklahoma. XXXI 852. Mr. Sanderford previously worked at Public Defender Service in Washington D.C. and served as a judicial law clerk to Judge King on the Fourth Circuit Court of Appeals. *Id.* 852-53. On April 29, 2014, Mr. Sanderford, who had not previously witnessed an execution, witnessed Mr. Lockett's, because "he asked me to." *Id.* 853.

Upon arrival at the prison, Mr. Sanderford was escorted to the viewing chamber. *Id.* 854. The curtain to the execution chamber was closed. *Id.* Nothing happened for a long time: "The execution was scheduled to start at 5:00, and the curtain stayed closed. It stayed closed. You know, everyone was kind of wondering what was going on. There was no information or anything like that." Id. 855; see also Ex. 36, Execution Logs for Clayton Lockett and Email, Vol. 4, p. 619 (noting that shades raised in chamber at 6:23). When the curtain opened, Mr. Lockett was on a gurney in the execution chamber, completely covered with a sheet: "we could only see his head." Id. 856. The Warden announced that the execution was to begin. Id. "Not much happened at first. Mr. Lockett was staring at the ceiling and looked toward us. But after a couple of minutes, his eyes started to kind of glaze over and his eyelids started to droop and pop open every now and then, but he was – the first drug was clearly starting to take effect." Id. Mr. Sanderford recounted that a doctor performed first one and then a second consciousness check on Mr. Lockett. Id. 858-59; Ex. 36, Execution Logs for Clayton Lockett and Email, Vol. 4, p.619 (noting second consciousness check at 6:33). After the second check, there was an announcement that Mr. Lockett was unconscious. Id. 859. Mr. Sanderford was aware from litigation that the next step in the Oklahoma protocol would be the administration of a paralytic. Id.

After the second consciousness check, the execution of Mr. Lockett went horribly awry:

[A]fter a couple of minutes, maybe three minutes, his body started to kind of move. It was subtle at first, but it looked like his body was just kind of coming up off the gurney a little bit. As time passed, those movements became more pronounced and violent. We assumed under the sheet he was strapped down, and it looked as if he was straining against the straps, like his back was arching, his chest looked like he was trying to rise up off the table. His eyes started to flutter open and he was mumbling. I know there were some people who thought they could make out words. I personally could not. But he was – there were definitely sounds coming out of him like he was trying to speak . . . it sounded like someone trying to speak, like mumbling kind of, in a sort of urgent way. But, you know, I don't know how else to describe it; almost like someone who was intoxicated.

XXXI 860 - 61. The official Oklahoma Department of Public Safety Report described

Mr. Lockett's movements after the administration of the drugs:

The description of Lockett's movements and sounds varied among the witnesses. The movements descriptions ranged from quivering to thrashing, but most agreed that Lockett's head did rise off the table. There were differing recollections regarding whether Lockett's eyes opened after he was deemed unconscious. The sound descriptions varied from mumbling to Lockett making statements.

Ex. 47, OK Dept. of Safety – Execution of Clayton Lockett, Vol. 6, p. 863.

Mr. Lockett's thrashing became more pronounced as time passed. "[O]ver the next, I guess, couple of minutes, once this started – maybe three, four minutes, it's hard to say exactly, it just got more and more pronounced, more and more violent. You could sense panic in the execution chamber. You would see it on the warden's face. There was a guard in the room with us who was crying." XXXI 861.

The warden ordered the curtains to the viewing room be closed. "And all the sudden, the warden said, 'Shut the curtains, shut the curtains." And they shut the curtains so we couldn't see anymore." XXXI 861. The Director of the Department of Corrections later announced that the execution had been cancelled. *Id.* 862. "At that point, took some of the guards, law enforcement, who were in the viewing room with us, said, you know, 'We need to get the attorneys out, get the attorneys out.' And

somebody came and escorted us out of the prison." *Id.* Mr. Sanderford learned that Mr. Lockett had died from watching CNN, while in the parking lot of the prison. *Id.*

The Oklahoma Department of Safety investigation determined that Mr. Lockett was injected with the full, intended dose of Midazolam prior to the administration of Vecuronium bromide and potassium chloride. Ex. 47, Vol. 6, p. 856-57. Though the Department of Public Safety report reflects that "an IV failure complicated the ability [of the report] to determine the effectiveness of the drugs" (Ex. 47, at Vol. 6, p. 862) the report also shows that "the IC access was completed by a physician licensed as a medical doctor. The physician graduated medical school over 15 years ago, currently worked in emergency medicine and was certified in family medicine . . . This was his second execution with the first being four to give years earlier. Ex. 47, at Vol. 6, p. 853. The Report also reflects "the concentration of Midazolam located in Lockett's blood was greater than the therapeutic level necessary to render an average person unconscious." XXXI 867; Ex. 47, OK Dept. of Safety – Execution of Clayton Lockett, at Vol. 6, p. 852. Yet Mr. Lockett was clearly not unaware and insensate during his execution.

The Oklahoma Department of Safety determined that though officials in conjunction with the Governor determined the execution should be stopped, "Lockett died prior to the order for a stay being relayed to the personnel inside the execution chamber." Ex. 47, *OK Dept. of Safety – Execution of Clayton Lockett*, Vol. 6, p. 861. The report faulted the Oklahoma protocol for its "limited provisions for contingencies once the execution process began," finding "[t]here was conversation

inside the [execution] chamber about administering life-saving measured to Lockett, including transporting him to the emergency room, but no order was given." *Id.* 860-61.⁴⁶

Mr. Sanderford was the only witness who testified about the execution of Mr. Lockett. Mr. Lockett's health prior to execution was well documented and presented in Exhibits 36, *Execution Logs of Inmate Clayton Lockett*, at Vol. 4, p. 572 and Exhibit 47, *Oklahoma Department of Safety – Execution of Clayton D. Lockett*, at Vol. 6, p. 830-68. Defendants did not call any witness to rebut or contradict his testimony or proof.

IV. TDOC turned a blind eye to the substantial risk of severe pain that the Tennessee lethal injection protocol creates.

The proof established that Commissioner Tony Parker and Deputy Commissioner Debbie Inglis acted with willful ignorance in accepting the Midazolam protocol(s). Ms. Inglis has worked on the state's execution protocols since at least 2007 when she was part of a committee that researched the state's lethal injection method from the ground up and made a recommendation that the then-commissioner rejected. She has advised TDOC on four separate lawsuits

⁴⁶ The Report also found a need for more clear terminology and communication amongst the Department of Correction, the Office of the Attorney General and the Governor's office: "It was apparent during this investigation that specific terminology should be clearly defined so they are understood by all personnel involved in the execution process. This will allow DOC, OAG and Governor's Office personnel to have a common understanding of how each term affects the execution process and the actions that should take place if such terms are used. Defined terms should include, but are not limited to 'stop,' 'stay,' and 'halt." Ex. 47, OK Dept. of Safety – Execution of Clayton Lockett, Vol. 6, p. 866.

challenging different protocols, two of which found Tennessee's method to be unconstitutional. Yet Commissioner Parker learned of none of this from his deputy commissioner. He preferred instead to seek consultation from other corrections officials who have used Midazolam in executions.

Parker's and Inglis's testimony makes clear that they were aware there was a substantial risk of severe pain and suffering to Plaintiffs that both of them actively tried to distance themselves from.

a. Ms. Inglis is TDOC's institutional memory on matters of execution protocol who knew everything, but said nothing.

Debbie Inglis was hired as general counsel in 1994 and added "deputy commissioner for administration" to her title in 2017. XL 1555-56, 1564. With the exception of one person, she has worked on lethal injection longer than anyone else at TDOC. She is very familiar with all the risks and all of the legal issues.

In 2007, then-governor Bredesen granted reprieves to four Tennessee inmates scheduled to be executed because the execution protocols contained "deficiencies in the written procedures intended to ensure that all legal executions will continue to be carried out appropriately." Ex. 107, *Copy of Executive Order by the Governor*, at Vol. 11, p. 1532-33. The manual mixed up references for procedures for execution by electrocution with those for execution by lethal injection. This included instructions to hook up all electrical apparatus after an inmate was strapped to a gurney and to check that the IV apparatus was out of the reach of the person being executed after he was strapped into the electric chair. XL 1566.

A commission was convened to study lethal injection from scratch, and Inglis was a member. The group consulted with, among others, anesthesiologists and a physician. XL 1570. Based on its research, the group put forward the idea for a 1drug protocol using a barbiturate (eg., sodium thiopental or pentobarbital), as Plaintiffs urged here. In the course of the group's deliberations, Inglis, herself, provided an article that discussed

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 [] 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, is only one of the many controversial aspects of this drug combination."

Ex. 108, Harbison v. Little, 411 F.Supp.2d 872, at Vol. 11, p. 1537 (brackets added).

Hence, Inglis was personally aware since 2007 that (1) potassium chloride is a painfully torturous chemical; (2) a person being executed will experience and suffer that painful torture if he is not rendered fully unconscious and insensate; and (3) that a paralytic gives an appearance of serenity that masks the torture that is actually occurring. TE XL, p. 1580 (Inglis acknowledges that a person has to be unconscious before proceeding with the paralytic and potassium chloride components of a 3-drug execution); p. 1585 (Inglis recalls testifying in *Harbison* that "the second and third drugs, without adequate anesthesia would result in a horrible, painful and terrifying death."). Inglis was not only aware of the risk of pain inherent in a 3-drug lethal injection protocol from having participated in the 2007 execution working group. In her capacity as attorney for TDOC, she was also aware that Tennessee's lethal injection protocol was found unconstitutional by both a federal court in *Harbison v. Little*, 411 F.Supp.2d 872 (M.D.TN. 2007), and a Tennessee Chancery Court in *West v. Ray*, No. 10-1675-I (Davidson Cty. Chancery Ct., Nov. 22, 2010). Ex. 108, *Harbison v. Little*, at Vol. 11, p. 1534; Ex. 109, *West v. Ray*, No. 10-1675-I, at Vol. 11, p. 1567. In both instances, the courts ruled that the protocol created a risk that a person being executed would not be adequately anesthetized <u>not</u> to experience the suffocation caused by the paralytic or the chemical burn caused by the potassium chloride.

So when the pharmacy with which TDOC contracted with to provide chemicals for killing inmates advised TDOC that "[b]eing a benzodiazepine, [Midazolam] does not elicit strong analgesic effects. The subjects may be able to feel pain from the administration of the second and third drugs," Inglis already knew the actual and legal risks that were implicated. Ex. 114, *Email dated September 7, 2017*, at Vol. 11, p. 1628. And yet, she did nothing.

She did not contact the pharmacy. She did not contact any medical professionals to get further information or insight. There were no meetings. TE, Vol. XL, pp. 1627, 1631-32. From her perspective as general counsel and deputy commissioner for administration, it was "in the commissioner's court." She had delegated the matter or identifying and working a chemical supplier for lethal
injection to a member of her staff, and saw herself as "in the middle" – between that staff-member and the commissioner. TE, Vol. XL, pp. 1627, 1631-32. So Inglis left the matter of the risk of unconstitutional pain and suffering there, between those two. TE, Vol. XL, p. 1635.

b. When the pharmacy that Commissioner Parker retained to find chemicals for executions informed him that TDOC's choice of chemicals risked severe pain to persons killed, Parker skipped over scientists and medical professionals to consult with prison administrators who had used Midazolam.

Tony Parker was appointed commissioner of TDOC in 2016. XXXIV 1101. He has spent 35 years – his entire professional career – as a TDOC employee. XXXIV 1102. In that time he has served as a warden, regional administrator, assistant commissioner of prisons. XXXIV 1103-05. He never held a position at Riverbend Maximum Security Institution, where death row is housed and executions are carried out, nor did he participate in or receive training to conduct an execution. XXXIV 1104.

It is the Commissioner's responsibility to decide what the Tennessee lethal injection protocol will be. XXXVI 1159. He testified that he wants to know enough information to "satisfy [himself] that the [Tennessee] protocol is adequate and constitutional." XXXVI 1161. This includes knowing judgments courts have made about previous protocols. To this end Debbie Inglis, and her staff play a big part in the protocol process, Parker relies on her. XXXVI 1152, 1162. Indeed, he testified that Ms. Inglis "has been part of an execution where Midazolam was used." XXXVI 1172.

The proof tended to suggest that Ms. Inglis does not know that the Commissioner relies on her to keep him informed. Despite whatever efforts she has made to bring the Commissioner up to speed, the proof demonstrated that he knows very little of the history of judicial review of Tennessee's execution protocols. He did not know that a federal court had found the 3-drug protocol unconstitutional because of the risk of inadequate anesthetization. XXXVI 1190. He did not know that Governor Bredesen had issued execution date reprieves and rescinded the Tennessee execution protocol because of incoherencies and errors. XXXVI 1180. He did not know that the Davidson County Chancery Court found the 3-drug protocol to be unconstitutional in 2010, after it had been used to execute two people. XXXVI 1204. Parker did not know any of the risks of suffering that had been attributed to using a paralytic throughout Tennessee lethal injection litigation. Parker was similarly unaware of that same issue in this litigation. He did not know that, or why, Defendants' answer to the amended complaint denied that vecuronium bromide and potassium chloride, without adequate anesthetization, would cause severe pain and suffering. XXXVI 1196-97.

Nevertheless, Parker knew that the pharmacy with which he eventually signed a contract and obligated the State of Tennessee to pay, believed that the protocol that he chose, which incorporated Midazolam, posed a risk of pain and suffering to the people TDOC puts to death. Parker saw the email from the pharmacy and understood its implications for Tennessee executions. XXXVI 1227-28; Ex. 114, *Email dated September 7, 2017*, at Vol. 11, p. 1628.

Parker testified that he did not discuss the content of the email with the pharmacy that sent it because he did not know him. XXXVI 1228. Parker's own staff recommended that pharmacy, and Parker trusted it, as a source for lethal injection chemicals, information about their availability, and eventually their knowledge of how to specially compound the chemicals. It is inconceivable why Parker did not trust their assessment of the risks presented by the chemical combination that he chose, <u>or even their recommendation of how to mitigate those risks</u>.

Instead, Parker relied on the word of other corrections officials who had experience in executions that incorporated Midazolam. XXXVI 1230, 32. These were people with no professional biochemical knowledge of Midazolam and its physiological effects in an execution. Presumably, they were able to assure Commissioner Parker that in executions where they had seen Midazolam used, the person ended up dead. However, almost every jurisdiction that uses Midazolam with which Parker could have consulted also uses a paralytic. Parker acknowledged that a paralytic, like vecuronium bromide or pavulon, would block any indications of distress or suffering from a person being executed. Therefore, it was extremely unlikely that any of the corrections administrators whom Parker consulted could have seen any problems in a Midazolam execution.

Parker got the information he wanted from those other corrections officials. Based on his consultations with them, he believes that Midazolam will render a person unable to feel pain and unaware of the suffocation and chemical burn caused

by vecuronium bromide and potassium chloride in the Tennessee lethal injection protocol. XXXVI 1235-36. Though Plaintiffs were able to produce a pharmacologist, a medical doctor and clinical pharmacologist with 35 years of experience researching Midazolam, and the head of a department of anesthesiology for a university hospital who unanimously agreed that medical science demonstrates that Midazolam is incapable of rendering a person insensate to that degree of noxious stimulus, Commissioner Parker's prison administrator colleagues convinced him that it can. XXXVI 123.

This is the chain of authority for the means by which Tennessee puts people to death: Commissioner Parker relied on Deputy Commissioner Inglis in selecting a lethal injection protocol. Deputy Commissioner Inglis delegated the task to one of her staff. The staff person worked with a pharmacy that Commissioner Parker eventually contracted. The pharmacy that Commissioner Parker contracted told Deputy Commissioner Inglis's delegee that a Midazolam protocol made it likely that executed persons would suffer. The staff person gave that information to Commissioner Parker, who in turn asked corrections administrators from other states their opinions.

Defendants' cannot evade the reality of the substantial risk of severe pain that the Tennessee protocol creates by dumping that knowledge on someone else's desk – a subordinate or a delegee or a contracted agent – any more than they can negate the science that proves that risk with reports that inmates injected with a

paralytic exhibited no signs of suffering after they were sedated with Midazolam. Defendants know the risk. It is real, and it is unconstitutional.

c Where TDOC passed up opportunities to obtain the active pharmaceutical ingredient for pentobarbital, that it may be "unavailable" for purposes of this litigation is a circumstance of their own making.

That Defendants do not have pentobarbital is a circumstance of their own making. In 2014, TDOC signed a contract with a pharmacy that could and did obtain the active pharmaceutical ingredient for pentobarbital. XL 1601. That API was available to use in executions when this Court upheld the previous 1-drug protocol that called for pentobarbital. As well, TDOC could have stockpiled the API at its pharmacy at the DeBerry special needs facility. Both Commissioner Parker and Deputy Commissioner Inglis testified to this. XXXVI 1211; XL 1615.

Once the API that TDOC acquired during the course of the *West v. Schofield* litigation expired, Defendants renewed their search for pentobarbital. They found 10 pharmacies that had pentobarbital available; the only issue was the sufficiency of the amount that those pharmacies could provide. XXXVI 1348-49. Ex. 105, *PowerPoint Presentation*, at Vol. 11, p. 1477. TDOC's own research found access to pentobarbital.

Defendants' claim that pentobarbital is not available is based on their own manipulation of resources and should not be credited by this Court.

d. Testimony of Warden Tony Mays

Tony Mays is Warden of Riverbend Maximum Security Institution. The Tennessee Lethal Injection Manual makes it his responsibility, among others, to select execution team members, select a person to serve as Executioner, to order the Executioner to proceed with the execution, and to perform the "consciousness check" on an inmate during the course of an execution. Ex. 2, 7/5/18 Lethal Injection *Procedures Manual*, at Vol. 1, p. 119; Vol. 2, p. 172. Mays characterized the lethal injection manual as a document that "gets into every part that is involved in the lethal execution stemming from certain individuals that play a part in it from day one until the final moment." XXIII 942. Mays testified that the Manual is the only instruction that he has for overseeing and carrying out an execution by lethal injection. XXXIII 942.

However, Mays's testimony demonstrates that there are critical parts of executions that the manual does not "get into." Furthermore, Mays's testimony reveals that Defendants – and TDOC – rather than deliberately developing a protocol that would comport with the Eighth Amendment and protect inmates from torturous execution, worked on the fly to cobble together a protocol. Defendants relied on Plaintiffs' litigation to identify constitutional infirmities and continued to nip and tuck up to and after the hearing in this case began. The Lethal Injection Manual might as well be a stack of sticky-notes.

Mays first received the July 5, 2018, version of the Manual on the morning of the same day that it was issued. XXXIII 994. He did not receive advance notice of any of the changes – reassigning responsibility for acquiring the lethal injection chemical from him to the commissioner, elimination of the 1-drug protocol, storage and preparation of compounded lethal injection chemicals, adding the trapezius

pinch to the "consciousness assessment," – nor was he consulted on any of them. XXXIII 988, 995. Neither was the reasoning for any of these changes explained to him. XXXIII 988.

1 Mays is responsible for selecting and training execution staff and supervising executions.

The Manual charges Warden Mays to hold a class annually where the Manual is "reviewed and clearly understood" by all execution team members. It is also the Warden's responsibility to supervise the Execution Team's simulation of an execution day including all execution procedures for at least 1 hour per month. Ex. 2, 7/5/18 Manual, at Vol. 2, p. 138. The Manual requires that "All training that occurs is documented. The documentation includes the times and dates of the training, the participants, and the training content." Ex. 2, 7/5/18 Manual, at Vol. 2, p. 138. Mays testified that the lethal injection manual is the only source of instruction that he has available for training those TDOC staff who carry out executions by lethal injection. XXXIII 942-43.

Failure to abide by these requirements constitutes a deviation from the Manual. TDOC's failure to adhere to the requirements of the Manual is evidence that the Protocol creates a substantial risk of serious harm for the very reason that there can be no presumption that its procedures will be carried out.

2. The Manual is Mays's only source of instruction for executions, so where it does not say what to do if an inmate shows signs of suffering, and Mays has no training for such a scenario, his plan for that situation is simple: keep going with the execution. Mays testified that the lethal injection manual "gets into every part that is involved in the lethal execution." XXIII 942. This may be true, as long as an execution proceeds exactly according to the Manual. There is no provision, and hence no training (because the Manual is the guide for all training), for what actions should be taken if an inmate appears to be suffering as has occurred in other jurisdictions that use Midazolam as a sedative for executions.

The Manual anticipates four problems occurring in an execution: that the IV line cannot be inserted into a vein; that the IV apparatus by which the lethal injection chemical is delivered into a person does not work; that the person being put to death responds to the "consciousness assessment" that the Warden performs after the Midazolam has been injected; or that the person is not dead when the physician checks at the conclusion of all of the injections. Ex. 2, *7/5/18 Manual*, at Vol. 3, p. 175. If a person being put to death responds to the "consciousness assessment" measures, the warden will instruct the Executioner to administer a second set of syringes full of Midazolam.

Plaintiffs' experts were unanimous that a second set will render an inmate any more insensate than the first set precisely because Midazolam is biochemically incapable of rendering a person insensate to noxious stimuli such as burning or suffocation. Plaintiffs' experts also agreed that any additional sedative – versus <u>anesthetic</u> – effect from a second round of Midazolam injections would be delayed because of the pharmacokinetics of the drug which would require multiple

circulations through the circulatory system in order to buffer the pH to a level where the drug's molecular structure would become operative.

When the warden was asked if he had heard of any of the Midazolam executions where the person being executed writhed, coughed, opened his eyes, and strained against the gurney restraints like the ones in Arkansas, Florida, and Alabama of which Plaintiffs presented evidence, Mays stated that he had not. XXXIV 1069-72. He testified that the only instruction he had for if such circumstances occurred in a Tennessee execution was what is in the Manual.

There are no instructions in the Manual for what to do if a person being put to death exhibits signs of suffering or painful reaction to the lethal drugs. Thus, the warden would be left to figure out what to do. Mays testified that if he saw such signs of suffering or torture after he had performed the consciousness check and instructed the Executioner to proceed, he would simply let the execution go forward without regard for signs of the inmate's suffering. XXXIV 1074-75, 1079. Commissioner Parker and Deputy Commissioner Inglis affirmed that what to do in such a situation is the warden's decision. XXXVI 1248-49; Vol. XL, p. 1646.

For this reason, the bare terms of the Protocol, by the <u>omission</u> of information – what the warden should do if an a person being executed shows signs that he is sensate and responding to noxious effects of the second and third chemicals – create a risk that a person being executed will endure that pain. The warden does not have any instruction on what to do, and so his plan is simply to watch an inmate suffer as he dies.

3. Mays contradicted his testimony that everything regarding lethal injection executions proceeds according to the protocol.

Mays testified that the Protocol is the only instruction he has for carrying out executions and that he follows it to the letter. His testimony, however, revealed multiple instances where he – or more senior officials in TDOC – deviate from or violate the procedures set forth in the Manual.

4. Mays and TDOC violated the Manual's requirements regarding documentation of training, forcing Plaintiffs and the public to just "take their word for it" that the people carry out killings on behalf of the State have been trained.

The Manual requires that "All training that occurs is documented. The documentation includes the times and dates of the training, the participants, and the training content." Ex. 2, 7/5/18 Manual, at Vol. 2, p. 138. TDOC Deputy Commissioner and General Counsel Debbie Inglis also testified that all of the training that occurs in connection with executions is to be documented. X 1574. Yet Defendants either have not followed that requirement or failed to produce documentation of several critical trainings that they asserted occurred, which would have been responsive to Plaintiff's discovery requests.

A. There is no documentation of Mays's alleged last-minute training on how to assess a person being executed for consciousness before the lethal chemicals are injected.

In his deposition on June 4, 2018, Mays indicated that he had not received any training on how to perform the consciousness assessment in the then-current manual. That assessment consisted of shaking the person being executed and calling his name. The July 5, 2018, Manual added a requirement that the warden assess the consciousness of the person being put to death by "grabbing the trapezius muscle of the shoulder with the thumb and two fingers and twisting." Ex. 2, 7/5/18 *Manual*, at Vol. 2, p. 172. This is a specialized procedure that requires instruction to know what to look for on the body as responsive movement to indicate that a person is sensate, and would be interfered with by the lethal injection gurney straps. XLIII 1922-24. Mays testified at trial that on July 5, the same day that he was given the new Protocol with no warning or explanation for its changes and one month before Billy Irick was to be executed, a physician trained him how to perform the trapezius pinch. May could not provide any documentation of the training, which is required by the Manual. The Chancellor would not allow Plaintiffs' counsel to inquire into the qualifications of the person.

Mays thus testified falsely when he said that his only instruction for carrying out an execution was what is written in the manual, and he failed to follow the requirement that his training be documented.

B. Mays does not know whether the executioner has been trained as the Protocol requires.

The Executioner is responsible for injecting the chemicals into the IV apparatus that will deliver them into the body of a person being put to death. Ex. 2, 7/5/18 Lethal Injection Manual, at Vol. 2, p. 172. If it is not done properly, it can cause infiltration or dislodge the IV catheter, as occurred in the horribly flawed execution of Clayton Lockett. Ex. 47, Oklahoma Department of Public Safety Executive Summary Case No. 14--18951, at Vol. 7, p. 830 et seq. Thus, this training is <u>critical</u> to an execution. Presumably for this reason, the Manual requires

that "The Executioner receives initial and periodic instruction from a qualified medical professional." Ex. 2, *7/5/18 Lethal Injection Manual*, at Vol. 1. p. 138.

Warden Mays testified that he did not know whether either of the people whom he had selected to fill the role of executioner had received any such training. Mays, who is not a qualified medical professional, had not trained them. XXXIV 1054. He had not seen any documentation of their receiving such training. He only knew that they had participated in practice executions using saline solution.

But even Defendants' counsel acknowledged that there is a difference between practicing with saline and knowing how to properly inject lethal injection chemicals. When Plaintiffs' counsel questioned Warden Mays about how long it takes to actually inject a syringe of lethal injection solution into the IV apparatus, Defendants' counsel objected saying the practice was with saline and therefore the Warden's answer was not probative. XXXIV 1052. The distinction in solutions – their flow through the IV apparatus and the catheter into a person's vein – is critical. The attorney general recognized this, but Defendants' do not.

They have failed to provide the training to the executioner that is required by the Manual. Their failure to do so is proof that the Manual does not provide for an execution that comports with the Eighth Amendment.

C. Mays does not have the instructions from the pharmacy on how to handle, store, prepare, and administer the lethal injection chemicals that are essential to practicing an execution.

Warden Mays testified that he instructs the execution team to practice according to the terms of the Manual, and that it is the only guide they have for

carrying out an execution. XXXIII 943, 967. But the Manual is incomplete and where it has gaps in information, the execution team cannot practice what they will be expected to do when putting a person to death.

The Manual requires members of the execution team to prepare the lethal injection chemicals "in accordance with the directions of the Pharmacy with which the Department has a Pharmacy Services Agreement." Ex. 2, 7/5/18 Lethal Injection Manual, at Vol. 1, p. 145. But Mays testified he had not seen these instructions and did not have any information that anyone on the execution team had seen them. XXXIII 1020-21, 1023; XXXIV 1040-42. Thus, the execution team practiced without full instructions on how to prepare the lethal injection chemical. By the warden's testimony, executions go the way practice goes.

The omissions from the Manual prove its inadequacy to provide for an execution that comports with the protections of the Eighth Amendment. Defendants' failure to comply with the terms of the Protocol that they themselves developed is proof that they cannot be presumed to carry out an execution according to its terms, and therefore those terms should not be credited.

5. The Manual does not instruct, and Mays cannot explain why, the timing of the syringe injections changed after the 7/5/18 Manual was issued.

On multiple occasions in the spring of this year, after the January 2018 protocol was issued, Mays supervised practice execution sessions with the execution team. The team practiced the electrocution protocol and both lethal injection protocols. The last practice of the 1-drug pentobarbital protocol for which TDOC provided records occurred in January 2018, two weeks after the 2-protocol manual was issued. Ex. 96, Vol. 9, p. 1218.

When the team practiced the three-drug lethal injection execution protocol, each syringe was injected 1 minute apart. Ex. 96, *RMSI execution practice records,* at Vol. 9, p. 1232; Ex. 97, *RMSI execution practice records,* at Vol. 9, pp. 1301, 1303; Ex. 98, *RMSI execution practice records,* at Vol. 9, p. 1320. XXXIII 967, 971-72. This order was not instructed in the January 2018 Manual.

Mays testified that he and a second person led a class for the execution team to review the manual as required by the protocol on July 5, 2018, the same day that the general counsel delivered the new Manual to him. TE, Vol XXXIII, p. 993; Ex. 2, Tennessee Lethal Injection Manual, p. 138. The execution team also practiced a lethal injection execution on that day. Ex.99, 7/5/18 Lethal Injection Chemical Administration Record, p. 1329. However, Mays testified that he, himself, did not instruct the practice execution. TE, Vol XXXIII, p. 1015. At that training, additional time was added between the injections. What had been an 8-minute process became a 14 minute process. A minute was added between syringes two and three (Midazolam #2 and saline #1); between syringes four and five (vecuronium bromide #1 and #2); between syringes six and seven (saline #2 and potassium chloride #1); and between syringes eight and nine (potassium chloride #2) and saline #3). Ex. 99, RMSI 7/5/18 execution practice records, at Vol. 9, p. 1329. Warden Mays testified that he did not know why the extra time was added, and that it is not instructed in the lethal injection manual. TE, Vol. XXXIII, p. 1014.

Warden Mays was not involved in, apprised of the reason for, and could not explain the alteration in the injection schedule. He did not even supervise the training under the new manual. The reason is that his TDOC superiors had concerns and doubts about what an execution with their protocol would look like. So they took control of the training. This altered injection schedule occurred after Defendants' counsel had taken the depositions of all three of Plaintiffs' experts – Drs. Stevens, Greenblatt, and Lubarsky – each of whom explained the scientific reasons that Midazolam cannot and will not protect an inmate from the torturous feelings of suffocation and burning that vecuronium bromide and potassium chloride will cause. Plainly, TDOC officials were attempting to alter the timing of the effects of the chemicals. The Midazolam was given an extra minute before the injection of saline to take effect in addition to the 2-minute wait added to the Manual – three extra minutes to get closer to peak sedative effect, which is still insufficient to protect a person being put to death. The paralytic was also given two extra minutes to work – increasing the likelihood that the person executed would be completely immobilized and any signs of suffering would be repressed.

TDOC made critical revisions to the Manual and the manner in which executions are carried out just five weeks before Billy Irick was scheduled to be killed. These efforts to tweak "on-the-fly" and create a shadow Protocol for lethal injection reflects Defendants' awareness that the written Protocol's reliance on Midazolam creates a substantial risk of severe pain and suffering to inmates who will be killed.

6. Mays acknowledged that he has not followed the procedures set forth in the Manual by failing to dispose of expired lethal injection chemicals and document training.

The lethal injection manual requires that "as [lethal injection] chemmicals reach their expriation dates, they are disposed of by hazardous waste pcik-up." Ex. 2, 7/5/2018 Lethal Injection Manual, at Vol. 1, p. 143. Warden Mays testified that he had not abided by this instruction because at the time of the hearing in this case, July 2018, he still had lethal injection chemicals on hand at RMSI that had expired in May 2018. He admitted that this was a violation of the procedures in the manual and contrary to his testimony that he follows the manual to the letter. XXXIII 984-85.

Warden Mays testified that he did not know whether either of the people whom he had selected to fill the role of executioner had received any such training. Mays, who is not a qualified medical professional, had not trained them. XXXIV 1054. He had not seen any documentation of their receiving such training. He only knew that they had participated in practice executions using saline solution.

The Warden's failure to abide by the procedures in the manual demonstrates that those procedures will not assure Plaintiff's execution that is without a substantial risk of severe pain and suffering.

e. The protocol contains the same kind of errors that caused Governor Bredesen to halt executions and order a protocol review.

Mays testified that the Manual is his only instruction for training his employees and carrying out an execution. Yet by his own testimony, it is replete with omissions and inconsistencies that of the kind that caused Governor Bredesen

to issue reprieves to inmates scheduled to be executed so that the Manual could be made revised into a coherent document.

On page 35 of the Manual, there are instructions for the "Procurement, Storage, Accountability, and Transfer" of compounded lethal injection chemicals ("LIC"). Ex. 2, 7/5/15 Lethal Injection Manual, at Vol. 1, p. 141. The manual instructs that, "When the LIC is received . . . [it] is placed in an unmovable heavy gauge steel container" in the RMSI armory. Warden Mays testified that there is such a container for storage purposes. XXXIII 1028.

On the very next page, the manual instructs that after an execution, any LIC that is "unused and not compromised in any way" should be returned to the armory "and secured in the refrigerator." Ex. 2, *7/5/15 Lethal Injection Manual*, at Vol. 1, p. 142. The warden did not know where the LIC should be stored.

The manual also states that "Compounded preparations shall be transferred, stored, and maintained in accordance with the directions of the Pharmacy with which the Department has a Pharmacy Services Agreement." Ex. 2, 7/5/15 Lethal Injection Manual, at Vol. 1, p. 141. But the warden did not have those directions and thus did not know how to manage the LIC. XXXIII 1037. The Warden also testified that his staff who were on the execution team had not received instructions from anyone else. XXXIII 1041-42.

Deputy Commissioner Inglis testified that the instruction from the pharmacy had been verbally relayed to staff who participate in executions. XL 1667-68. This conflicts with Commissioner Parker's testimony that there are no protocols that are

not written down. XXXVI 1185-86. Inglis had previously testified in 2007 in *Harbison v. Little* that it was especially important to write everything down in the manual because those procedures are not part of the TDOC staff's routine responsibilities and they do not have the vocational background to make independent judgments. XL 1571.

Defendants' testimony and accounts for the state of the manual indicate that it cannot provide instructions, or serve as a basis for training, to carry out an execution that does not create a substantial risk of severe pain and suffering. The Commissioner believes that everything that is needed is written down. The Deputy Commissioner believes some things can be relayed verbally to specific members of the execution team. The Warden does not know how to handle the lethal injection chemicals, does not know which – if any – of his staff have received instructions that he is unaware of, and does not know when he will receive instructions from the pharmacy.

f. Documentation received by Plaintiffs' counsel subsequent to this Court's order indicates a further conflict between TDOC actions and the manual.

On September 3, 2018, Plaintiff's counsel received from TDOC documents requested pursuant to the Tennessee Public Records Act. See Attachment A to Motion to Expand the Record. These documents contain records of actions by TDOC personnel in connection with the execution of Billy Ray Irick on August 9, 2018. Mr. Irick was a plaintiff in this litigation. These documents reveal additional omissions and inconsistencies in the manual, as well as deviations from the procedures prescribed in the manual. One document appears to be instructions from the pharmacy for storing and preparing the Midazolam for injection. The first instruction on this document is "Remove 4 vials of Midazolam from the freezer and place in refrigerator 24 hours prior to use as to allow to thaw." It is unclear whether TDOC or RMSI personnel could or did store the chemical in the proper manner because <u>there is no indication</u> <u>in the manual that a freezer is available at RMSI to store frozen lethal injection</u> <u>chemical</u>. Any assurance by Defendants that they will follow the storage instructions from the pharmacist is meaningless if there are not physical facilities to adhere to those instructions. This is a source of risk of severe pain and suffering on the face of the protocol.

Amongst those documents there is also a "Chemical Preparation Time Sheet." This is one of the records that the manual requires to be filled out as part of the process of documenting the completion of procedures in carrying out an execution. Ex. 2, 7/5/2018 Lethal Injection Manual, at Vol. 1, p. 121 (The Lethal Injection Recorder's duties include completing the Lethal Injection Checklist). The Chemical Preparation Time Sheet for the day of Mr. Irick's execution produced by TDOC indicates that the primary set of syringes of Midazolam was prepared at 7:28, <u>one</u> <u>minute before Irick's execution began</u>. The rest of the syringes – vecuronium bromide, potassium chloride, and saline – were prepared between 5 and 5:30 pm, earlier that day. This is the proper procedure in the manual. Ex. 2, 7/5/2018 Lethal Injection Manual, at Vol. 1, p. 145. To have prepared the Midazolam syringes just seconds before the execution was to begin violated the manual and contradicted the Warden's testimony that his staff adhere to the manual and would carry out an execution the very same way they practice. The unreliability of the warden and plain falsity of his testimony indicates that the text of the protocol in meaningless when it is actually time to put a person to death, and therefore it creates a substantial risk of severe pain and suffering.

Also included in the documents produced to Plaintiffs' counsel by TDOC is the chemical preparation sheet for the second, back-up set of syringes. This set of syringes is in place in case there is a problem with the injection of the first set into the IV apparatus or an inmate responds to the consciousness assessment after the first injection of Midazolam. Ex. 2, *7/5/2018 Lethal Injection Manual*, at Vol. 2, p. 175 ("Contingency Issues"). The record produced by TDOC indicates that the Midazolam syringes for the second, back-up set were never prepared. If Mr. Irick had responded to the consciousness assessment or there had been problems with the IV apparatus, the execution team would not have been prepared to carry out the contingency procedures in the manual. Defendants' failure to follow the procedures in the manual indicates that the protocol is meaningless for purposes of Defendants' carrying out an execution and therefore creates a substantial risk of severe pain and suffering for Plaintiffs.

These circumstances are virtually identical to those that were cause for a reprieve from the governor in 2007. There are critical instructions missing from the current lethal injection manual. There is no indication that RMSI has adequate facilities for storage of the LIC according to the instructions provided by the

pharmacy with which TDOC has a pharmacy services contract. Records from Mr. Irick's execution indicate that the words on the face of the manual are irrelevant when it is time for Tennessee to put a person to death.

The Tennessee lethal injection protocol, by content, omission, and failed application creates a substantial risk of severe pain and suffering for Plaintiffs.

ARGUMENT

- I. Plaintiffs' proof establishes that the July 5, 2018 three-drug lethal injection protocol violates the Eighth and Fourteenth Amendments to the United States Constitution and Article I, § 16 of the Tennessee Constitution.
 - a. Binding precedent establishes that if the first drug in a three-drug protocol fails to protect the inmate from the severe pain caused by the second and third drugs, then that protocol is unconstitutional. Plaintiffs have proven that Midazolam fails to protect inmates from pain.

1. The holdings in *Baze*, *West*, and *Abdur'Rahman*

In 2008, Chief Justice John Roberts, writing for the plurality in *Baze v. Rees*, 553 U.S. 35 (2008), held: "It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, **constitutionally unacceptable** risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride." *Id.* at 53 (emphasis added)

In 2010, this Court held, "Proper administration of an adequate amount of sodium thiopental is **essential to the constitutionality** of Tennessee's three-drug protocol." *State v. West,* No. M1987-000130-SC-DPE-DD 2010, Order, p. 2. (Tenn.

November 29, 2010) (emphasis added) (Attach.1).⁴⁷ Five years earlier in an asapplied challenge to the use of a paralytic in the lethal injection protocol, this Court observed:

[I]t was undisputed that the injection of Pavulon and potassium chloride would alone cause extreme pain and suffering, all of the medical experts who testified before the Chancellor agreed that a dosage of five grams of sodium Pentothal as required under Tennessee's lethal injection protocol causes nearly immediate unconsciousness and eventually death. Dr. Levy testified that such a dose would cause an inmate to be unconscious in about five seconds and that the inmate would never regain consciousness and would feel no pain prior to dying. Dr. Heath similarly testified that a lesser dosage of two grams of sodium Pentothal would cause unconsciousness in all but "very rare" cases and that a dosage of five grams would "almost certainly cause death."

Abdur'Rahman v. Bredesen, 181 S.W.3d 292, 307-08 (Tenn. 2005).

As a result of the three mechanisms of action of barbiturates, a properly delivered dose of sodium thiopental will render an inmate completely insensate to pain, and unarousable by noxious stimuli. *Dr. Stevens testimony re; barbiturates,* XXIV 104-111; Ex. 14, *Mechanism of Action at the GABA receptor*, at Vol. 3, 358. Unlike Midazolam, barbiturates do not have any ceiling effect, and with increasing doses will bring a person to the plane of general anesthesia, and, ultimately, stop breathing and cause death. *Id.* at 115 and 125. Thus, the barbiturate sodium

⁴⁷ The chancery court in the 2010 *West* decision held that Tennessee's lethal injection protocol (which utilized sodium thiopental as the first drug) "was unconstitutional because it 'allows ... death by suffocation while the prisoner is conscious." *West*, 2010 Chancery Court Order, Ex. 106, p. 2. At the time, Tennessee performed no consciousness checks. Subsequently, TDOC adopted consciousness checks sufficient for a protocol using sodium thiopental, but insufficient for Midazolam as discussed in detail below. *See* testimony of Dr. Lubarsky, discussed *supra*.

thiopental could meet the requirements of *Baze* and *West*, because it could prevent the inmate from experiencing the "constitutionally unacceptable" effects of the paralytic and potassium chloride.⁴⁸ *Glossip* did not alter, abandon, or change that analysis.

2. Expert testimony establishes that Midazolam cannot and will not render inmates insensate to pain; they will experience severe pain and suffering produced by the second two drugs; this scientific truth is ratified by eye-witness observations.

The chancery court found

The inmates presented the testimony of four well-qualified and [eminent] experts. The Court finds that these experts established that Midazolam does not elicit strong analgesic effects and the inmates being executed may be able to feel pain from the administration of the second and third drugs.

XVI 2251. The Court also found that the defendants' two proffered expert witnesses

"did not have the research knowledge or [eminent] publications that Plaintiffs'

experts did." XVI 2251, n.7.

The Court found that Plaintiffs' eleven (11) eye-witnesses testified that in the

Midazolam-based executions they observed, "there were signs such as grimaces,

clenched fists, furrowed brows, and moans indicative that the inmates were feeling

pain after the Midazolam had been injected and when the vecuronium bromide was

injected." XVI 2258 (emphasis added). Defendants did not present a single witness

to dispute this evidence. Established by omission from the record. The eye-

witnesses' powerful and descriptive testimony, which has been recited at length in

⁴⁸ Previous challenges to sodium thiopental focused on the ability of prison guards to properly deliver sodium thiopental so that it would perform as intended.

the Statement of Facts, is un-contradicted and accepted. *See also* XXV 279-300; XXVI 301-09; XXVII 321-428, 439-462; XXVIII 463-68; XXX 657-755; XXXI 756-870. Their testimony makes this case different from *Glossip*.⁴⁹

Unlike *Glossip*, the Chancery Court did not reject a single aspect of Plaintiffs' expert or eye-witness testimony. Unlike *Glossip*, ⁵⁰ the Chancery Court did not credit (or meaningfully acknowledge) the defense witnesses, Dr. Li⁵¹ or Dr. Evans, and their limited claims regarding the efficacy of Midazolam.⁵²

A. Mechanism of action, and the fundamental science that establishes why Midazolam cannot protect an inmate from pain and suffering.

Midazolam's effect on the body is limited by its single mechanism of action.

Dr. Stevens testimony, XXIV 106-10, 113-14; Dr. Greenblatt testimony, XXVIII 511-

⁴⁹ The petitioners in *Glossip* "provided little probative evidence … and the speculative evidence that they did present to the District Court does not come close to establishing that its factual findings were clearly erroneous." *Glossip*, 135 S. Ct. at 2743. In stark contrast, here Plaintiffs presented the testimony of world-class experts, including the man who did the research on Midazolam in order for it to obtain FDA approval. In further contrast to *Glossip*, **Dr. Evans endorsed the testimony and credibility of Plaintiffs' experts, XLV 2070**, whereas in *Glossip* his since-disavowed (and now-discredited) opinions provided the scientific basis for the Court's conclusions.

⁵⁰ *Glossip* found that the district court did not commit clear error in finding Dr. Evans "well-qualified." In the years since *Glossip*, Dr. Evans has been subject to closer examination. It appears that "the emperor has no clothes."

⁵¹ An OCR search of the Chancellor's order for "Dr. Li" "Feng" and "medical examiner" which produced zero hits, conclusively establishes that Dr. Li's testimony was discounted entirely.

⁵² The Chancery Court did credit Dr. Evans' testimony regarding Plaintiffs' facial challenge to compounding, which is a separate issue, and, uniquely, one where the views of a qualified pharmacist could be helpful.

12; Ex. 14. An understanding of a drug's mechanism of action is foundational to understanding its properties, including any ability to render an inmate insensate to pain. *Stevens*, XXIV 80-81, 84, 86, 161, 164.

Midazolam's mechanism of action only acts on certain neuroreceptor sites where GABA binds.⁵³⁵⁴ XXIV, 106-110; Ex. 13, *GABA Receptor*, at Vol. 3, 355; Ex. 14. It does not and cannot act on opioid receptors, which regulate pain.⁵⁵ XXIV 81, 84, 86. Midazolam does not and cannot act on, or block, excitatory neurotransmitters.⁵⁶ XXIV 110, 156, 161; Ex. 10, *Neurotransmitters, Receptors and Effects on Neurons*, at Vol. 3, 354. Excitatory neurotransmitters overcome the inhibitory effect of Midazolam when activated by noxious stimuli. *Id.*

As a result of this limited mechanism of action, Midazolam has a "ceiling effect," and regardless of the dose administered will never bring an inmate to the plane of general anesthesia or render them insensate to pain. *Stevens*, XXIV 123-25, 130-35, 161, 164; *Greenblatt*, XXVIII 496-98, 513; *Lubarksy*, XLII 1796-99; Ex. 16(a); *Ceiling effect of Midazolam*, at Vol. 3, p. 360.

⁵³ See Ex. 4, Ex. Vol. 3, for a helpful glossary of terms.

⁵⁴ Barbiturates effectively become GABA and are therefore much more powerful than benzodiazepines.

⁵⁵ Opiods have an inhibitory effect on neurons, and thus have a powerful analgesic (pain reducing) effect. In sufficient quantity opioids (such as fentanyl reduce respiration and lead to death. Ex. 4, at Vol. 3 350.

⁵⁶ Barbiturates can.

The testimony of Plaintiffs' experts was ratified by the Defendants' pharmacy expert, Dr. Evans:

Q. Would you describe for the Court how Midazolam works and how it affects the human body?

A. Sure. It's been described by experts for the Plaintiffs very well....

XLV 2070.

What all of the experts agree upon establishes the crucial fault of Midazolam. It is a sedative-hypnotic, a drug designed to put someone to sleep (hypnosis). XXIV 83, 112-13. An inmate given Midazolam should fall asleep (and appear unconscious), but once noxious stimuli (pain or suffering) activate the excitatory system, this will overcome the inhibitory effect of Midazolam and rouse the inmate, who will then awaken to experience unfathomable pain and suffering (and in many cases, they will awaken at the same time that vecuronium is paralyzing their face, arms, body, and lungs). *Stevens,* XXIV 161-64, 218; *Greenblatt*, XXVIII 510-12, 515.

B. The second two drugs will cause an inmate to feel as if they are buried alive, and then set afire; Midazolam will not protect them from this severe pain and suffering.

The expert proof was uncontested that the second two drugs would cause severe pain, mental anguish and needless suffering, if an inmate was not rendered insensate and unaware. XXV 161-62; XXVIII 508-10; XLII 1774-77. The suffering inflicted by vecuronium on someone who is aware was described as "[i]t's as if you're locked in a box and someone has now covered your mouth and you can't breathe and

your lungs and brain are screaming." XLII 1774. However, as vecuronium's primary role is to paralyze the inmate, starting at the face, an inmate will lose all ability to communicate the pain and terror that they experience. XXV 153-56. Meanwhile, potassium chloride causes a person to feel as if they are "being burnt alive." XLII 1776.

This is not hyperbole, unfortunately. Real world anesthesiologists have seen what happens to patients when those two drugs are used and anesthesia fails. In the former they can only report their sensations later (as they are paralyzed and feel that they are "dead"), but with even with small doses of potassium, "they scream out in pain." *Id.* at 1774-76.

Midazolam's sole intended purpose in the July 5, 2018 protocol is to render an inmate insensate and unaware of the pain and suffering otherwise caused by the second and third drugs. The proof in the record—established by every expert who testified on this issue —is that Midazolam is not an analgesic and *cannot* protect an inmate from this pain. *Stevens*, XXIV 161-64; *Greenblatt*, XXVIII 510-12; *Testimony of Dr. Lubarsky*, XLII 1810; *Testimony of Defendant Expert Dr. Evans* XLV 2070, 2148, 2157. As already explained above, it cannot bring an inmate to the plane of general anesthesia, so they will be roused by the pain they experience. XXIV 123-25, 130-35, 161, 164; XXVIII 496-98, 513; XLII 1796-99.

Dr. David Greenblatt, who participated in the research that later led to FDA approval for Midazolam's use as a sedative-hypnotic established that Midazolam's absence of analgesic properties is not seriously debated within the scientific/medical

community. XXVIII 512-13. In fact, as the expert witnesses for both sides testified, the leading textbook in this area, *Miller's Anesthesia* states clearly that drugs like Midazolam "lack analgesic properties and must be used with other anesthetic drugs to provide sufficient analgesia." Miller, R., *et al.* eds., *Miller's Anesthesia*, Vol. 1, p. 842 (8th ed. 2015); *Evans,* XLV 2157.⁵⁷ Dr. Lubarsky plainly stated, "there simply is no debate" about Midazolam's limitations. XLII 1742. Instead, the real-world use of Midazolam in pain-producing procedures is *always* accompanied with a painrelieving opioid such as fentanyl. XLII 1810.

Thus, it is clear, Midazolam will not bring an inmate to the plane of general anesthesia, it will not render an inmate insensate to pain, and an inmate who is executed with Tennessee's three-drug protocol will experience severe pain, mental anguish and needless suffering. They will experience the suffocation of vecuronium and the burning alive of potassium chloride. The basis of these truths is not simply expert "opinion" but solid science based on fundamental scientific principles, corroborated by real world observations.

3. Plaintiffs presented new, never before heard proof, that Midazolam, alone, causes severe pain and suffering as the inmate drowns in his own blood and bodily fluids.

Plaintiffs established, by a preponderance of the evidence, that the administration of 500 mg of Midazolam, alone, causes severe pain and needless

⁵⁷ Plaintiffs' expert Dr. David Lubarsky co-wrote the chapter on the use of intravenous anesthetics for a number of years. His work is acknowledged in the most current edition.

suffering. Autopsies reveal that no less than 23 out of 27 inmates executed using a Midazolam-based lethal injection protocol suffered pulmonary edema.⁵⁸ *Testimony* of Dr. Edgar, XXXIX 1395-98; Ex. 118, Dr. Edgar's Chart, at Vol. 12, pp. 1658-63. A person who suffers pulmonary edema has fluid and blood leaking into the airspaces of their lungs, ultimately filling the airspaces with liquid. XXXIX 1468; *Greenblatt*, XXVIII 541-42; *Lubarsky*, XLII 1813. The sensation of drowning in blood and fluid is a noxious stimuli which will of rouse inmates sedated with Midazolam. *Stevens* XXV 161-62; *Lubarsky*, XLII 1822. The finding of pulmonary edema is similar to findings with persons who have drowned or suffered poison gas attacks. *Edgar*, XXXIX 1394.

Dr. Stevens explained that Midazolam will not dissolve in neutral solution; rather, to be used in injections it must be dissolved in a strong acid, with a pH of close to 3.0 – while human blood is slightly more neutral with a pH of 7.4.⁵⁹ XXIV 136-40. Dr. Greenblatt testified that the most probable cause of the pulmonary edema is the acidic quality of the two (or four) massive doses of Midazolam that will not be buffered until after they have passed through the lungs. XXVIII 541-42. As a result, the lining of the lungs break down and the airspaces will fill with fluid and

⁵⁸ Plaintiffs' expert Dr. Edgar reviewed the autopsies conducted by other pathologists. What those doctors missed, failed to record, or did not even look for, cannot be known. Nonetheless, 23 out of 27 autopsy reports established that the inmate had acute pulmonary edema.

⁵⁹ The pH scale is logarithmic, with each "step" away from 7.0 representing a 10-fold increase in acidity. Thus, a pH of 3, which is 4 steps from neutral, indicates a 10,000 fold increase in acidity.

blood, and the inmate will feel as if he is being drowned. *Edgar*, XXXIX 1394-95; *Lubarsky*, XLII 1813, 1822.

The eye-witnesses to the underlying executions provided strong corroboration that the pulmonary edema was caused by Midazolam, and not due to some preexisting health condition. They collectively described the inmates they watched die as being healthy prior to the administration of Midazolam, without any prior respiratory distress. XXV 232-33 (Woods), XXX 683 (Phillips), XXX 691 (Otte), XXXI 762, 769, 785 (all five Alabama inmates), XXXI 798 (Howell), XXXI 820 (Williams), XXXI 837 (Gray); *see also* Ex. 36, *Execution Logs of Clayton Lockett*, at Vol. 4, p. 572; Ex. 47, *Execution of Clayton Lockett*, at Vol. 6, pp. 830-68.

The eye-witnesses also described barking, gasping for breath, coughing, heaving and labored breathing after the injection of the Midazolam (and prior to paralysis), consistent with the inmates suffering respiratory distress. XXV 265-66 and XXVII 391-93, 404-412 (Woods, gasping and gulping for nearly two hours), XXX 688 (Phillips, gulping like a fish), XXX 698 (Otte, stomach violently moving up and down); XXX 722 (Brooks, rapid breathing, chest heaving); XXX 738-39 (Melson, labored breathing, exaggerated chest movements); XXX 759 (McNabb, breathing like a fish); XXXI 776-77 (Smith, barking cough like a seal, labored and deep breathing); XXXI 790 (Moody, very heavy breathing, noticeably different than prior to injection); XXXI 824-25 (Williams, chest was pumping, choking, coughing and heaving); XXXI 841-41 (Gray, heavier breathing and snoring sound).

Thus the unchallenged expert testimony was corroborated by eye-witness observations. This proof established by a preponderance of the evidence that inmates who are injected with 100 ml of acid, containing 500 mg of Midazolam, will suffer severe pain and mental anguish as blood and bodily fluids fill their lungs due to pulmonary edema. It was clearly established that the only possible cause of the pulmonary edema was the acidic Midazolam.

The Chancellor's order failed to address this additional cause of severe pain and needless suffering, which no court—including the Supreme Court in *Glossip* has ever heard before. ⁶⁰ No findings of fact or conclusions of law were reached on this issue. XVI 2229-2288, *established by omission*.

b. *Glossip*, which was decided in a preliminary injunction posture, is not binding here.

1. Preliminary Injunction rulings are not binding precedent and have limited persuasive value.

The Court in *Glossip* was careful to highlight the procedural posture of the case, the denial of preliminary injunction. "[W]e review the District Court's factual findings under the deferential 'clear error' standard. This standard does not entitle us to overturn a finding 'simply because [we are] convinced that [we] would have decided the case differently." *Glossip*, 135 S. Ct. at 2739 (quoting *Anderson v.*

⁶⁰ Distinguishing this case from *Glossip* for the first time we have a dataset of results from real world human experiments with Midazolam. At the time of *Glossip* there simply had not been enough Midazolam-based executions to create this dataset. Nor had any pathologist examined the data of the Midazolam-based executions until Dr. Mark Edgar did so in this case.

Bessemer City, 470 U.S. 564, 573 (1985)). That is, *Glossip* involved a highly deferential standard of review.

2. Each and every premise on which *Glossip's* observations about Midazolam were based have now been discredited.

The evidence presented in the chancery court challenging Tennessee's method of execution is directly contrary to the record that supported the Supreme Court's decision in *Glossip*. The record in *Glossip* was from an evidentiary hearing on a motion for preliminary injunction (in contrast to the full trial here) and contained a finding, based upon pharmacist Lee Evans' testimony that Midazolam "would make it a virtual certainty that any individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from the application of the second and third drugs." *Glossip*, 135 S. Ct. at 2736. Dr. Evans no longer takes such an extreme position, XLV 2148-50, 2162,⁶¹ and the record in the chancery court is diametrically to the contrary.

The proof now establishes (and Dr. Evans now concedes) what the chancery court concluded here: "[M]idazolam does not elicit strong analgesic effects and plaintiffs may feel pain from the administration of the second and third drugs." XVI 2251 (7/26/18 final order). The testimony of Drs. Stevens, Greenblatt, and Lubarsky, detailed above, makes this truth abundantly clear. Indeed, as shown above, their

⁶¹ Q. Dr. Evans, you have testified that Midazolam is not capable of rendering plaintiffs in a state of surgical anesthesia, correct?

A. Correct.

XLV 2162.

testimony establishes beyond any doubt that inmates will suffer severe pain, mental anguish and needless suffering under the three-drug protocol.

Further, in addition to the finding based on Dr. Evans' now-discredited testimony, the *Glossip* court cited to 12 other Midazolam executions that "**appear[ed]** to have been conducted without any significant problems." *Glossip*, 135 S. Ct. at 2745-46 (emphasis added). The Tennessee plaintiffs presented testimony from eleven witnesses to a dozen Midazolam-based executions—at least one from every jurisdiction that has used Midazolam—who uniformly observed indications that inmates were sensate, aware and responsive during the administration of the second two drugs. XXV 279-300; XXVI 301-09; XXVII 321-428, 439-462; XXVIII 463-68; XXX 657-755; XXXI 756-870. Crucially, 24 of the 27 autopsied inmates executed with Midazolam showed clear signs of pulmonary edema, a fact that the *Glossip* court could not have been aware of (as the vast majority of those executions had yet to take place). The "appearance of no significant problems" in *Glossip* has been dispelled, in large part because we now have the "experimental data" from a large dataset of flawed executions.⁶²

> 3. The Chancellor placed undue weight on the factual findings of other courts, while failing to engage in fulsome factual analysis of the record before her.

⁶² It is also apparent from the record that the official reports of executions such as the Court relied upon in *Glossip* "substantially minimize what I saw." XXXI 827 (Motylinski testimony).

The Chancery Court recognized that Plaintiffs presented the testimony of four "well-qualified and [eminent] experts." XVI 2251. Their qualifications were described in detail and contrasted with the lesser qualifications of the Defendants' experts. *Id.* The Chancellor broadly accepted their conclusion that Midazolam does not "elicit strong analgesic effects and the inmate may be able to feel pain from the administration of the second and third drugs." *Id.* Whether this pain was "severe" was not addressed. *Id.* Yet, as is clear from the Statement of Facts, and throughout this Brief, Plaintiffs' experts testified to significantly more than what the Chancellor summarized, and their conclusions were significantly more direct: inmates will suffer torturous deaths if killed using the three-drug protocol (and have suffered such deaths all around the country, while dying under the veil of paralytic drugs such as vecuronium).

The crucial substance of this expert testimony was conspicuously omitted from the chancer court's *Memorandum of Findings of Fact and Conclusions of Law*, XVI 2229-79. Rather, immediately after acknowledging Plaintiffs' experts' credentials and eminence, and giving a mild characterization of their proof, XVI 2251, the Chancellor abandoned any further discussion of their scientific opinions and the bases therefor. Instead, the Chancellor moved on to discuss other courts' holdings regarding the constitutionality of Midazolam-centered lethal injection protocols; *e.g.* "Midazolam's use in executions has never been held by the United States Supreme Court to be unconstitutional or pose an unacceptable risk of pain." XVI 2253. The court cited to *Gray v. McAuliffe*, No. 3:16CV982-HEH, 2017 WL

102970, at *11 (E.D. Va., Jan. 10, 2017) for the proposition that the "Supreme Court and 'numerous other courts' have concluded that Midazolam is an adequate substitute for Pentobarbital in a three-drug protocol."

As has been discussed at length throughout this brief, the proof that was presented at THIS trial (unlike in those "other courts") was overwhelming: Midazolam's one-limited mechanism of action does not enable it to adequately substitute for the three much more potent mechanisms possessed by Pentobarbital; executions reliant on Midazolam will cause severe pain and mental anguish. Thus, the Chancellor's dependence on the factual findings of 'numerous courts' was a somewhat frightening abdication of her responsibilities to address the proof presented in this critical case (one that this Honorable Court had most clearly indicated needed a full trial and developed factual findings).

4. The undeveloped record from preliminary injunction hearings should not be given precedence over the in-depth testimony presented over a two plus week trial.

Tennessee's two-plus-week trial was the first in the nation. All prior Midazolam litigation has been resolved at the preliminary injunction stage. *Glossip*, 135 S. Ct. at 2731 (application for preliminary injunction); *In re Ohio Execution Protocol*, 860 F.3d 881 (6th Cir. 2017), *cert. denied sub nom. Otte v. Morgan*, 137 S. Ct. 2238 (2017) (preliminary injunction vacated); *Grayson v. Warden*, 672 F. App'x 956, 962 (11th Cir. 2016) (preliminary injunction); *Gray v. McAuliffe*, No. 3:16CV982-HEH, 2017 WL 102970, at *1 (E.D. Va., Jan. 10, 2017) (preliminary injunction).

It should go without saying that preliminary injunction cases inevitably involve "limited development of the record" and are "not guided by focused presentation of legal arguments." O'Bannon v. Town Court Nursing Ctr., 447 U.S. 773, 802 fn. 10 (1980) (Blackmun, J. concurring). The Sixth Circuit has observed that applying the law of the case doctrine is "tricky" when examining decisions involving preliminary injunctions, because such rulings "are generally tentative decisions." Howe v. City of Akron, 801 F.3d 718, 740 (6th Cir. 2015) (citing Gooch v. Life Investors Ins. Co. of Am., 672 F.3d 402, 433 (6th Cir. 2012) and Bieneman v. City of Chi., 838 F.2d 962, 964 (7th Cir. 1988). According to the Sixth Circuit, deference to prior decisions should only apply when the ruling was "based on a fully developed factual record and a decisionmaking process that included full briefing and argument without unusual time constraints." Howe, 801 F.3d at 740 (quoting Sherley v. Sebelius, 689 F.3d 776, 782 (D.C. Cir. 2012)). Although "law of the case doctrine" has no application to our situation, the Sixth Circuit's concerns highlight why the decisions of other courts made on more limited records, under greater time pressures,⁶³ in injunction proceedings should be of no significance.

For instance, in *In re Ohio Execution Protocol*, the Plaintiffs were able to present two experts, but they did not have the advantage of the nation's leading researcher on Midazolam, Dr. David Greenblatt, nor the pathologist perspective

⁶³ Plaintiffs' counsel do not want to minimize the time pressures from this case. However, it is clear that, despite the urgency of the schedule, there was sufficient time to develop the expert proof and eye-witness testimony in a manner that has never been done anywhere else in the country.
provided by Dr. Edgar. Moreover, respectfully, counsel for plaintiffs in *in re Ohio* simply did not have the time to prepare or present the type of high-level science that Dr. Stevens and Dr. Lubarsky provided in this case. *E.g. In re Ohio*, 860 F.3d at 887-88 (summarizing Dr. Stevens' limited testimony in that case, and comparing it to the testimony of the defense experts, as if they were simply two equally valid competing opinions of equally credentialed experts). Crucially, at the time of *In re Ohio*, there had only been nine prior Midazolam executions, and, according to the plaintiff's second expert, Dr. Bergese, at that time "the quality of the data is not there." *Id.* at 888. Plainly, as has been set-forth throughout this brief, the "quality of the data" is now present, and it unequivocally establishes that Midazolam cannot render an inmate insensate and that an execution relying on Midazolam will inflict severe pain, mental anguish and needless suffering.

5. Throughout modern history, Courts have reached incorrect scientific conclusions based on scientific opinions that were subsequently shown to be unreliable junk.

The scientific process can be messy, and errors are committed along the way to finding the truth. Our law is full of examples where older, and incorrect, scientific paradigms were ultimately overturned by superior science. But, along the way, for periods of time, the Courts relied on bad science to the prejudice of litigants. Some examples of this include our State's evolutionary understanding of eye-witness identifications, and the recent history of Dr. Andrew Wakefield and his now-debunked hypothesis that vaccines cause autism. For most of Tennessee's jurisprudential history, it was accepted that eyewitness testimony "has no scientific or technical underpinnings which would be outside the common understanding of the jury," and thus expert testimony was not permitted. *State v. Coley*, 32 S.W.3d 831, 833-34 (Tenn. 2000). The dissent in *Coley* observed that the court was "foreclose[ing] judicial recognition of future scientific advances." *Coley*, 32 S.W.3d at 839 (Holder, J., dissenting). Indeed, by 2007, this Honorable Court recognized that there "have been advances in the field of eyewitness identification," and *Coley* was overruled. *State v. Copeland*, 226 S.W.3d 287, 299-300 (Tenn. 2007). Today, the validity of such expert testimony is fully accepted. *Id*.⁶⁴

Similarly, science and the law now recognize that there is no plausible connection between the MMR (measles, mumps and rubella) vaccine and autismspectrum disorders. *E.g. Hazlehurst ex rel. Hazlehurst v. Sec'y, Dep't of Health & Human Servs*., 88 Fed. Cl. 473, 478 (2009), *aff'd sub nom. Hazlehurst v. Sec'y of Health & Human Servs.*, 604 F.3d 1343 (Fed. Cir. 2010) (upholding finding that Dr. Wakefield, the proponent of the autism-MMR linkage hypothesis had been "widely discredited by the scientific community" and that the underlying studies were "scientifically flawed and unreliable"); *Cedillo v. Sec'y of Health & Human Servs.*,

⁶⁴ Other examples of evolving scientific standards in the law that come to mind, but that counsel does not have time to fully brief include: recovered memories (and the Wenatchee Satanic Witch Trials in Washington State), shaken baby syndrome, and the (in)fallibility of fingerprint and/or tool mark identification.

617 F.3d 1328, 1349 (Fed. Cir. 2010) (upholding finding of special master that there was no "persuasive evidence" that vaccine caused autism).

However, this was not always the case, and for well-over a decade there were "qualified and well-respected individuals" who testified in court that MMR would cause autism. *E.g. Dixon v. Sec'y of Dep't of Health & Human Servs.,* No. 01-605V, 2003 WL 23218020, at *4 (Fed. Cl. Nov. 25, 2003), *aff'd*, 61 Fed. Cl. 1 (2004). Indeed, Andrew Wakefield, now recognized as a charlatan, was originally cited approvingly by the courts. *Dixon*, at *10.

The evolution of judicial understandings of both eyewitness identification and vaccines illuminates why the Chancellor erred in relying on the factual findings of other courts, instead of engaging with the evidence that was presented in her courtroom.⁶⁵

6. It should go without saying that litigation involving parties with no privity has no preclusive effect under the applicable doctrines of *res judicata* and collateral estoppel.

The Chancellor did not conclusively state whether an inmate would suffer severe pain or mental anguish. XVI 2229-2259 *established by omission*. Rather, her sole conclusion on this essential factual determination was: "The Court finds that these experts established that Midazolam does not elicit strong analgesic effects

⁶⁵ More tritely, counsel could point to the ills that would have befallen civilization had scientific certitudes about the origins of disease (caused by "miasmas"), the efficacy of blood-letting (which killed George Washington), or Aristotelian physics (overturned by Newton, Einstein, Bohr and Hawkings—and under which, we would not have satellites, nuclear energy or cell phones) not been rejected by later generations.

and the inmate being executed may be able to feel pain from the administration of the second and third drugs." *Id.* at 2251. She then moved on to discuss the conclusions of the "numerous other courts" that Midazolam-based executions are not unconstitutional. To the extent that she was attempting to import either factual findings or legal conclusions from those other cases, such was gross error under Tennessee law.

Any attempt to import findings of fact from other courts would be governed by the doctrine of collateral estoppel, or issue preclusion. *Mullins v. State*, 294 S.W.3d 529, 534-35 (Tenn. 2009). Tennessee uses a five-part test to see whether collateral estoppel applies, and for no less than three reasons it could not apply, here. *Bowen ex rel. Doe v. Arnold*, 502 S.W.3d 102, 107 (Tenn. 2016); *Beaty v. McGraw*, 15 S.W.3d 819, 824 (Tenn. Ct. App. 1998). The three fatal flaws are (1) the judgments upon which the Chancellor relied have not become final (they were all in preliminary injunction stage), (2) present Plaintiffs are not in privity with the plaintiffs in those other states, and (3) present Plaintiffs did not have "a full and fair opportunity in the earlier suit to litigate the issue now sought to be precluded." *Bowen*, 502 S.W.3d at 107; *Beaty*, 15 S.W.3d at 824. Moreover, the other two concerns, whether the (a) issues are identical, and (b) whether they were decided on the merits will not apply to many if not all of the "numerous other cases."⁶⁶ Ultimately, for the Chancellor to apply collateral estoppel, she would have to find,

⁶⁶ To the extent that a decision was based on different alternatives than Tennessee, and to the extent that the relevant court did not substantively address "severe pain and mental anguish" then the other two considerations would also not be met.

above and beyond all five-factors, that "the same issue was, in fact, determined in a prior suit between the same parties and that the issue's determination was necessary to the judgment." *State v. Scarbrough*, 181 S.W.3d 650, 655 (Tenn. 2005). As we have different parties and different issues, it was legally improper for the Chancellor to rely on factual findings from "numerous other courts."

Similarly, to the extent that the Chancellor was attempting to import the legal conclusion that Midazolam-based protocols are not cruel and unusual, this would be governed by *res judicata* or "claim preclusion," which also is completely inapplicable. *Jackson v. Smith*, 387 S.W.3d 486, 491 (Tenn. 2012). "*Res judicata* bars a second suit between the same parties or their privies on the same claim with respect to all issues which were, or could have been, litigated in the former suit. *Jackson*, 387 S.W.3d at 491. Again, the parties must be the same, the claims must be the same, and the judgment must be final; none of which is true, here. *Id.*

Thus, for all of these reasons, it was terribly inappropriate for the Chancellor to ground her factual determination in the decisions of "numerous other courts" instead of based on the well-developed record before her.

> 7. *Glossip* emphasized the numerous safeguards in place in Oklahoma, including continuous monitoring of the inmate using an EEG. Those safeguards are not present here. In fact, Tennessee's protocol contains additional risks to the inmate apparently not present in Oklahoma.

Important to the District Court's decision in *Glossip*, upon which the Court relied, is the fact that Oklahoma implemented numerous procedural safeguards.

The protocol also includes procedural safeguards to help ensure that an inmate remains insensate to any pain caused by the administration of

the paralytic agent and potassium chloride. Those safeguards include ... numerous procedures for monitoring the offender's consciousness, including the use of an electrocardiograph and direct observation, and ... detailed provisions with respect to the training and preparation of the execution team.

Glossip, 135 S. Ct. at 2735.⁶⁷ Later in the Court's opinion, it stressed, that

Oklahoma's protocol included safeguards including that staff "must continuously

monitor the offender's level of consciousness." Glossip, 135 S. Ct. at 2742.

Critically, these safeguards are absent in Tennessee. Moreover, the TDOC protocol knowingly and affirmatively prevents the Warden and Executioner from observing signs that the inmate is aware and feeling the effects of the drug because the straps prevent the inmate from moving,⁶⁸ the inmates hands are taped to prevent movement,⁶⁹the prison does not use an EEG, EKG, or BIS monitor.⁷⁰

⁶⁷ Oklahoma has only executed one inmate with these safeguards allegedly in place. That inmate cried out in pain. <u>http://www.dailymail.co.uk/news/article-2536976/I-feel-body-burning-Man-executed-lethal-injection-Oklahoma-beating-convenience-store-worker-death-1995.html</u> (last checked September 5, 2018.) No inmate has been executed in Oklahoma since the *Glossip* decision. The original case remains pending in the district court. Moreover, since *Glossip*, Arizona has agreed to never again use Midazolam or a paralytic in an execution. Exs. 30-33, Ex. Vol. 4 505-528. Florida has abandoned the use of Midazolam, as well.

 $^{^{68}}$ Billy Irick did, nonetheless, move his head after being declared unconscious – a clear sign that he was feeling the drugs. *See* September 2, 2018 declaration of Dr. David Lubarsky.

⁶⁹ See, *supra*, discussion of Dr. Lubarsky's trial testimony regarding the importance of observing hand and finger movement as a critical sign that the inmate is trying to signal that he is in pain.

⁷⁰ XXXVI 1255, Testimony of Warden Mays.

Warden Mays testified that there is not any way of maintaining or measuring brain activity in the lethal injection protocol. XXXVI 1255. Further, a physician does not provide training as to how to conduct a consciousness check. XXXVI 1254.

With these critical safeguards missing and Tennessee's willful action to inhibit observation of sensation and awareness, Tennessee's protocol is readily distinguishable from the Oklahoma protocol in *Glossip*.

c. The Chancery Court's finding that up to 18 minutes of suffering is not constitutionally intolerable has no basis in law, and is contrary to *Baze, West* and *Abdur'Rahman.*

Having found that Plaintiffs established that Midazolam will not protect the inmates from pain and that Plaintiffs presented proof that individuals who have been executed with Midazolam have experienced pain, the Chancellor rested her opinion on her belief that 10-18 minutes of suffering is not constitutionally intolerable. XVI 2254-57. There is no basis in the law for this proposition, and no case was cited in support. Indeed, neither this Honorable Court, nor the United States Supreme Court have ever issued an opinion suggesting that 10-18 minutes of suffering is constitutional.

It is true that the United States Supreme Court has found that inmates are not entitled to a pain-free execution. But it is also true that the Supreme Court and this Court have found that if the first drug in a three-drug protocol fails to protect an inmate from the pain and suffering of the second and third drugs, then the protocol is constitutionally intolerable. The Chancellor ignored *Baze, West, and Abdur'Rahman* and relied on a temporal standard that has no legal origin.

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Plaintiffs proved that the use of Midazolam in the Tennessee protocol violates the Eighth Amendment in that "there is a substantial, constitutionally unacceptable risk of suffocation from the administration of [the paralytic] and pain from the injection of potassium chloride." *Baze*, 535 U.S. at 53. In addition, Midazolam alone will cause pulmonary edema and cause severe, unnecessary pain. Finally, Dr. Lubarsky's unrebutted testimony is that the protocol's consciousness check is (a) inadequate and (b) impossible to carry out given the way the inmate is strapped to the gurney. Moreover, the way that the inmate is restrained to the gurney prevents the warden and others from observing signs of awareness and sensation.

Where this Court's review of the Chancellor's application of law to the fact is *de novo*, her decision should be reversed.⁷¹

- d. Plaintiffs met their burden under *Glossip* to identify a known, feasible, and readily available alternative method of lethal injection in spite of the peculiarities of Tennessee law.⁷²
 - 1. The uncontroverted proof is that Pentobarbital was available to the State of Tennessee at the time Commissioner Parker chose to adopt the three-drug Midazolam protocol; the uncontroverted proof is that the Pentobarbital that was available for purchase

⁷¹ The Chancellor's conclusions regarding the acceptability of 10-18 minutes of human suffering will be returned to, when discussing the U.S. Supreme Court's prohibition on torture, below.

⁷² It should be noted that Tennessee law does not allow consideration of other constitutional means of execution until lethal injection is declared unavailable or unconstitutional AND electrocution is also declared unconstitutional. T.C.A. § 40-23-114(e) (Supp. 2014). Plaintiffs are prohibited by case law from challenging the constitutionality of electrocution until lethal injection is found to be unconstitutional or unavailable. *West v. Schofield*, 468 S.W. 3d (Tenn. 2015).

in 2017 would still be good for use in executions in 2019 and into 2020; the uncontroverted proof is that a single-drug Pentobarbital protocol was feasible and readily available and that the State of Tennessee chose not to utilize it.

This Honorable Court issued *West v. Schofield* on March 28, 2017, which permitted the State of Tennessee to carry out executions using one-drug Pentobarbital. *West v. Schofield*, 519 S.W.3d 550 (Tenn. 2017). With Pentobarbital permitted, the responsibility for securing this drug was delegated down two tiers (or more) of responsibility, from Commissioner Parker, past Deputy Commissioner Inglis, to an anonymous individual known as the "Drug Procurer." XXXVI 1145; XXXVII 1336; XL 1605. The sole responsibility to secure the lethal injection chemicals (LICs) was vested in this "Drug Procurer," and no one else in the department worked on that project. XL 1608-9. All communications with potential suppliers were made by the "Drug Procurer." XL 1619-20. Commissioner Parker did not communicate with a single pharmacist or drug supplier. XXXVII 1313. Whereas, Deputy Commissioner Inglis only claimed to have spoken with the original (*circa-*2014), supplier of Pentobarbital, "Source A." XL 1614-15.

All records related to the "Drug Procurer's" search for Pentobarbital were produced by the Tennessee Department of Corrections; in total these heavily redacted documents totaled 48 pages (including a 17 page PowerPoint summary of the search). XL 1617-18; Ex. 105, *Documents Produced by Department of Correction*, at Vol. 10, p. 1468; Ex. 126, *June 20, 2018 email from Drug Procurer to Potential Pentobarbital Seller*, at Vol. 14, pp. 1969. Based on these records, over the spring and summer of 2017, the "Drug Procurer" found approximately ten pharmacies that were willing and able to sell Pentobarbital but they (individually) did not have "sufficient quantities of the needed form of Pentobarbital and no source to obtain sufficient quantities;" additionally there were roughly seventy suppliers who were willing, but did not have any supply on hand. XXXVII 1338-39; Ex. 105, *Documents Produced by Department of Correction*, at Vol. 10, p. 1477. This proof that there were willing and able sellers was originally offered as substantive proof, paradoxically, not by Plaintiffs, but by Defendants after a heated debate on its admissibility. XXXVII 1323-38.

The crucial portion of the relevant exhibit appears as follows:

Collectively, contact was made with close to 100 potential sources, including the 3 major U.S. chemical wholesalers. None of these worked for one or more of the following reasons:

- Company did not have an inventory of Pentobarbital apprx. 70%
- Company did not have sufficient quantities of the needed form of Pentobarbital and no source to obtain sufficient quantities – apprx. 10%
- Company unwilling to supply Pentobarbital if it was to be used in lethal injection – apprx. 20%



Ex. 105, *Documents Produced by Department of Correction*, at Vol. 10, p. 1477.

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As the "Drug Procurer" was protected from deposition, testimony, or identification, *e.g. Under Seal Order of June 13, 2018 at 3:25 p.m.*, the exact procedures he undertook to contact approximately 100 drug suppliers cannot be known, nor could Plaintiffs learn the identities of the ten willing and able sellers of small quantities of Pentobarbital. Crucially, the exact amount that the tensuppliers had individually and/or collectively available was not disclosed (and not known by Parker or Inglis). Why contacts with 100 suppliers only generated 30 pages of notes (17 pages of Exhibit 105 were the PowerPoint) was also not explained. However, the remaining records found in Exhibits 105 and 126, reflect minimal contact by text and email, and handwritten notes of other forms of communication (presumably telephonic, but in theory possibly face-to-face). Ex. 105, at Vol. 10, pp. 1486-1494, and at Vol. 11, pp. 1495-1514; Ex. 126, at Vol. 14, p. 1969. Those records reveal that on April 6, 2017, the "Drug Procurer" sent a request for "at least 100 grams" of Pentobarbital (which would be sufficient for no less than ten (10) executions, if each execution required both 5mg doses, and up to twenty (20) if the first dose proved sufficient). Ex. 105, at Vol. 11, p. 1497.⁷³ At 11:00 a.m., that same day, a supplier indicated they had some amount of Pentobarbital for sale, but not "the quantity you need." *Id.* at 1496. No dated records, whether email, texts or handwritten notes, reflect what came of the April 6, 2017 offer to sell some lesser amount of Pentobarbital, nor do they reflect how many executions this lesser quantity would have permitted. *Established by omission from Ex. 105 and the record as a whole.*

Then on an unidentified date (due to redactions) a supplier made a specific offer to the "Drug Procurer;" Pentobarbital would be sold for the price of \$24k for 10 grams, with an additional fee of \$35k⁷⁴ to compound per 10 grams. Ex. 105, at

⁷³ Note, Exhibit 105 is found in two volumes, the end of Vol. 10 and the beginning of Vol. 11.

⁷⁴ Arguably, a decimal point might have been between the 3 and the 5, making this \$3,500 per 10 grams, and not \$35,000 per 10 grams. Alternatively, the supplier may have indicated that they would sell manufactured Pentobarbital for \$24,000 per 10 grams, but if they had to compound it, it would cost \$35,000 total. Absent the "Drug Procurer's" testimony such details are unknown.

Vol.11, p. 1503. A "time till avail" was listed, but the date/time was redacted by the State (as was the majority of this note, like all notes). *Id.* Once the account was approved a "bulk \$" option was indicated. *Id.* Again, Commissioner Parker and Deputy Commissioner Inglis were ignorant of the details of this offer, and did not shed any light on when it was made, and why it was not accepted. *E.g.* XL 1611-12.

To this day, and since 2014, the Tennessee Department of Corrections has had a contract with a drug supplier to provide Pentobarbital; this contract requires Tennessee to pay \$5,000 per year to keep this source of supply open. XL 1612-13. Albeit, according to Deputy Commissioner Inglis, that supplier does not presently have any Pentobarbital. *Id.* at 1614.

The records reflecting attempts to secure Pentobarbital, found in Exhibit 105, that have dates (and/or where the dates were not redacted) reflect the last recorded contact as July 20, 2017. Ex. 105, at Vol. 11, p. 1501. The PowerPoint presentation detailing the roughly 100 suppliers is dated August 31, 2017. Ex. 105, at Vol. 10, p. 1468. Then, the next effort to obtain Pentobarbital (for which any record exists) was an email sent the day before Deputy Commissioner Inglis' deposition, on June 20, 2018. XL 1617; Ex. 126. Thus, it appears that some effort was made in April of 2017,⁷⁵ that was worthy of being recorded. Ex. 105, at Vol. 10, pp. 1486-1494, and Vol. 11, pp. 1495-98. A single email was sent in July of 2017. Ex. 105, at Vol. 11, p.

⁷⁵ Below, appellees' will address the remarkable effort to fail that was made by the "Drug Procurer" prior to engaging in any efforts to succeed.

1499. Then no further actions were worthy of being memorialized by the "Drug Procurer" until the single June 20, 2018 email. Ex. 126.

Had Tennessee purchased the Pentobarbital from the willing sellers it would have lasted for approximately two to three years. XL 1599-1600.

Thus, the proof presented at trial unequivocally established that there had been multiple willing sellers, including at least one who could furnish enough for an execution (10 grams). That supplier was willing to conduct bulk sales, which, clearly indicated the capacity for multiple executions. Had that Pentobarbital been purchased when offered for sale, it would be viable for use, today.

2. Having proven that there were over ten willing and able sellers of Pentobarbital, the State was bound by their own proof.

"It is fundamental that when the State calls a party as a witness it vouches for his or her credibility." *State v. Silva*, 477 S.W.2d 517, 619 (Tenn. 1972). However, under our Rules of Evidence, and case authority, a party may impeach their own witness, or present contrary proof. *State v. Jones*, 15 S.W.3d 880, 891-92 (Tenn. Crim. App. 1999) perm. app. denied February 14, 2000; Tenn. R. Evid. 607.

Rather than impeach or contradict the PowerPoint presentation that they had just introduced through the lead Defendant, Commissioner Tony Parker, counsel for Defendants had the Commissioner ratify it as true and correct:

Q. Commissioner Parker, does this PowerPoint summarize, to the best of your knowledge, does it summarize the Department's efforts to obtain Pentobarbital for lethal injection executions?

A. Yes.

Q. Up through the time it was made?

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A. Yes.

Q. Does it include on Page 10 an entry that says collectively contact was made with close to a hundred potential sources including three major U.S. chemical wholesalers and none of these worked for a number of reasons?⁷⁶

A. That's correct.

XXXVII 1338.

Defense counsel then ratified the accuracy of the PowerPoint a second time, via Defendant Deputy Commissioner Inglis. XL 1670, XLI 1671-72. Ms. Inglis further verified that, while she had no personal knowledge of the contents of the notes and emails found in Exhibit 105, they were produced by the "Drug Procurer." XL 1612.

No witness disputed that the "Drug Procurer" for the State of Tennessee identified ten (10) willing and able suppliers of Pentobarbital. *Established by omission from the record; see also* XL 1612. Similarly, none could discuss, explain, or dispute the notes reflecting a willing seller of at least 10 grams of Pentobarbital.⁷⁷ Pursuant to *Silva* and in the absence of any contrary proof—from a

⁷⁶ Obviously, the definition of "none of these worked" is crucial. As has been shown, previously, none of the suppliers were able to sell enough Pentobarbital for 10 to 20 executions. Thus, under TDOC's requirement that a supplier provide 100 grams they did not "work." However, for purposes of an alternative for Billy Ray Irick (deceased) or future inmates, the issue is not whether the State can get enough Pentobarbital for a dozen executions, but whether they can secure enough for that inmate's execution.

⁷⁷ Perhaps, appellees will claim that this particular note is taken out of context, and if only we could see the redacted portions then we would know it is not what it seems. That is the problem with hiding behind walls of secrecy, and it is a problem entirely of appellees' creation.

person with personal knowledge⁷⁸—the Defendants should be bound by the proof they presented. *Silva*, 477 S.W.2d at 519.

3. This honorable Court should infer that the "Drug Procurer's" testimony would have been adverse to the Defendants and would have established that there were multiple drug suppliers who would have made Pentobarbital feasible and readily available.

Defendants made a choice to belatedly shield the identity of the "Drug Procurer"—despite having originally identified this individual to counsel for the Plaintiffs in pre-litigation responses to TPRA requests. *See Under Seal TR*, I 110-11. Nothing suggested the "Drug Procurer" was intellectually or emotionally unable to withstand the examination and public scrutiny⁷⁹ that was placed on Commissioner Parker, Deputy Commissioner Inglis, and/or Warden Mays. Rather, the Defendants relied on their "legal privilege" to prevent examination of the "Drug Procurer." *Under Seal TR* III 357-365. In a separate section of this brief, appellants have explained why such a "legal privilege" should not have extended to the one witness with first-hand knowledge of the State's efforts (or lack thereof) to

⁷⁸ Obviously, Commissioner Parker and Deputy Commissioner Inglis both testified that the "Drug Procurer" could not procure any Pentobarbital. However, as they had to concede, they do not know what he did, when he did it, or with who. Their testimony regarding unavailability, being devoid of personal knowledge, is of no significance.

⁷⁹ Plaintiffs are not suggesting that Parker, Inglis, or Mays have suffered any ill effects from public scrutiny. Media reports have been evenhanded, and, to the best of counsel's knowledge, none have singled out any of those individuals for scorn, ridicule, or public opprobrium.

secure Pentobarbital. For purposes of this section, appellants will simply observe that the Defendants made a choice to hide the testimony of the one witness who knew what was going on.

Tennessee has long followed the "missing witness rule." *Sweeney v. State*, 768 S.W.2d 253, 259 (Tenn. 1989).

Normally, the failure of a party to produce an available witness who is in a position to know the facts, and who is apparently favorable to him, gives rise to a presumption or inference, permissive and rebuttable in nature, that the testimony of such witness would not sustain the contention of such party.

Raines v. Shelby Williams Indus., Inc., 814 S.W.2d 346, 349 (Tenn. 1991) (quoting Delk v. State, 590 S.W.2d 435, 448 (Tenn. 1979) (dissenting opinion)); see also National Life & Accident Ins. Co. v. Eddings, 221 S.W.2d 695 (Tenn. 1949).

Moreover, Tennessee applies this rule against defendants who fail to offer proof to rebut a *prima facie* case against them. *In re Estate of Nichols*, 856 S.W.2d 397, 402 (Tenn. 1993). In *Runnells v. Rogers*, this Court held that when a *prima facie* case is made, and a defendant fails to offer available witness proof in response, an unfavorable inference should be taken against them. *Runnells v. Rogers*, 596 S.W.2d 87, 90 (Tenn. 1980). *Runnells* quoted from the venerable decision in *Western Union Telegraph* to explain this rule:

[W]here the evidence tends to fix liability on the defendant, and if he has it in his power to offer evidence to rebut the unfavorable inferences which the proof tends to establish, and neglects or refuses to offer such proof, it may be inferred from the facts shown that the fully developed evidence would establish liability upon his part. Runnells, 596 S.W.2d at 90 (quoting Western Union Telegraph Co. v. Lamb, 203 S.W. 752, 753 (Tenn. 1918)).

The PowerPoint presented by Defendants as substantive evidence, as well as the notes regarding the offer to sell 10 grams for \$24,000, created a *prima facie* case that Tennessee could secure Pentobarbital, and that their failure to possess any was due to choice and not unavailability. Thus, under the "missing witness rule" we must presume that if the "Drug Procurer" had been made available to testify, his testimony would have been hurtful to Defendants, and would have contradicted the unsubstantiated claims of Commissioner Parker that the "Drug Procurer" could not find any Pentobarbital. We should presume the *prima facie* case is true and correct, and that the "Drug Procurer" would testify that Pentobarbital was (and is) available from ten or more suppliers.

4. Factually, the record is clear: Pentobarbital was a feasible and readily available alternative, and the State of Tennessee chose not to purchase it; the record is also clear, the "Drug Procurer" and *only* the "Drug Procurer" knows the identity of the roughly 80 willing drug suppliers.

Tennessee could have purchased small quantities of Pentobarbital from ten (10) or more willing suppliers in 2017. At some point a single supplier had at least 10 grams available (enough for a single execution), and was willing to discuss bulk sales (indicating a much larger supply). The only person who knows who these suppliers are, and who has communicated with them, is the "Drug Procurer." For reasons that were not explained, Tennessee chose not to purchase ten small quantities, and/or the 10+ grams that were offered, and instead insisted on only buying 100 grams at a time. To this day, there are close to 80 drug suppliers who would sell to Tennessee should they have Pentobarbital for sale, but only the "Drug Procurer" knows who they are.

Respectfully, this means that Pentobarbital was a feasible and readily available alternative (and, as has been set-forth elsewhere, it would clearly substantially reduce a significant risk of severe pain and mental anguish). The only reason it is not possessed is due to the inscrutable actions of the "Drug Procurer." Moreover, in light of Defendant's choice to introduce substantive proof that there were 10+ willing sellers of Pentobarbital, the missing witness inference, and under the low preponderance of the evidence standard, Plaintiffs easily carried their burden of proof.

> 5. This honorable Court has never defined the temporal dimension of "feasible and readily implemented," however, federal courts of appeal make clear it does not mean that the executioner must presently possess the drugs, only that with reasonable transactional effort they can be obtained.

In *West v. Schofield* this Honorable Court adopted the *Glossip* feasible and readily available alternative requirement, when addressing claims that a form of execution created a risk of severe pain.⁸⁰ *West*, 519 S.W.3d at 564. In *West* the specific parameters of the feasible alternative requirement were not delineated. *Id.*

⁸⁰ As has been argued elsewhere, this Honorable Court did not bind itself to *Glossip* in all cases, and this Honorable Court has never endorsed the proposition that torture would be constitutional, or that an alternative must be proven in cases where the issue is not risk but a certainty of extreme suffering.

The Sixth Circuit makes clear, however, that such a requirement does not mandate that a state "already have the drugs on hand." *In re Ohio Execution Protocol*, 860 F.3d 881, 891 (6th Cir.), cert. denied sub nom. *Otte v. Morgan*, 137 S. Ct. 2238, (2017). Instead, "the State should be able to obtain the drugs with ordinary transactional effort." *Id.*

Had the State of Tennessee used ordinary transactional effort in April and May of 2017, Defendants would possess sufficient Pentobarbital for multiple executions.⁸¹ The failure of Defendants to make such an efforts is not the fault of Plaintiffs.

Recently, the Eighth Circuit in *Johnson v. Precythe* found that the plaintiff had pled nitrogen gas as a feasible and readily available alternative to lethal injection, despite the facts that (a) "further study will be necessary to determine the best delivery system" and (b) Missouri was unwilling to undertake this method of execution. *Johnson v. Precythe*, No. 17-2222, 2018 WL 4055908, at *4 (8th Cir. Aug. 27, 2018). Clearly, it would take some tangible amount of time for Missouri to develop a nitrogen protocol (including deciding on whether delivery should be through mask or gas bag), and secure the appropriate equipment. *Id.* The Eighth Circuit did not find that this would create an "undue delay." *Id.*

6. Other Departments of Correction are able to obtain Pentobarbital.

⁸¹ But for the "Drug Procurer's" cloak of secrecy, and the relevant Defendants' voluntary ignorance, we could better define how many executions. Nonetheless, it seems clear it would be more than one.

The undisputed proof at trial is that Texas and Georgia continue to obtain Pentobarbital for use in carrying out executions. Texas executed Christopher Young using Pentobarbital during the trial. Ex. 140, Ex. Vol. 16-17 2229-2266. "Surely, our TDOC should be as resourceful and able as correction officials in Texas and Georgia in obtaining Pentobarbital." *State v. Irick*, No. M1987-00131-SC-DPE-DD, Sharon G. Lee, J, dissenting from denial of motion to vacate execution, p. 6 (Aug. 6, 2018).

7. The "Drug Procurer" tried to fail; this is constitutionally intolerable.

Glossip requires the State to engage in good faith efforts to obtain lethal injection drugs. *Glossip*, 135 S. Ct. at 2738. That did not happen here.⁸² Of the 47pages of records detailing all of the State of Tennessee's "efforts" to secure Pentobarbital, the most amazing is a text sent by the "Drug Procurer" on April 5, 2017:

I'm running around today so not sure when I'll be open for a call but in the meantime can u send me a list of all companies etc u reached out to about sourcing so I can have it for when we have to show it's unavailable? Thanks

Ex. 105, at Vol. 10, p. 1486.

That is, before sending out any requests for 100 grams of Pentobarbital

(which happened April 6 and 7), or otherwise recording any effort to secure

⁸² The testimony of Inglis and Parker on this point is irrelevant. They have no personal knowledge. Their testimony is complete hearsay and it is not reliable. The Drug Procurer is only unavailable because Defendants refuse to produce the witness. They rely on the Drug Procurer's self-serving hearsay statements that have not been subjected to cross-examination. Far more reliable are the Drug Procurer's written notes – at least those that have not been redacted.

Pentobarbital, the "Drug Procurer" was actively trying to gather proof that his future efforts would fail.

The presumption "that public officials in Tennessee... discharge their duties in good faith and in accordance with the law" has been rebutted. *West v. Schofield*, 460 S.W.3d 113, 131 (Tenn. 2015); *Reeder v. Holt*, 418 S.W.2d 249, 252 (Tenn. 1967). The dignity of this State, this Honorable Court, the Office of the Governor and the Department of Corrections are all sullied by the debased conduct of the "Drug Procurer." It is sad that such an important task was delegated down to the lowest-common denominator, so that we are left with a meager record of minimal efforts that display an active intent to fail.

It would be "absurd...and destructive of the good" should this Court tolerate the arbitrary indolence of the "Drug Procurer." Tenn. Con. Art. I, § 2.⁸³ Due process of law, and the Law of our Land, require better. The "Drug Procurer's" failure to secure Pentobarbital does not establish unavailability, it merely demonstrates bad faith. Thus, the PowerPoint and the relevant notes stand alone as evidence of availability. And, the *Glossip* lack of good-faith requirement has been satisfied. 135 S. Ct. at 2738

⁸³ In an ideal world, there is not case law on this particular point. We presume our government acts competently and conscientiously. There should not be other examples of such low conduct by those vested with the public trust.

As it is, this very important argument (which is not a "throw-away" but is made in sincere good faith) must rely on the bedrock of the Tennessee Constitution for its support; if this Honorable Court has previously chastised members of the government for intentionally failing to fulfill their duties, counsel has failed to find that relevant case law.

e. The Chancery Court committed error by failing to consider Plaintiffs' proposed two-drug alternative, which would have substantially reduced—in fact entirely removed—the risk of severe pain and mental anguish produced by vecuronium bromide, and which would have reduced the inmate's time of suffering by three minutes.

Plaintiffs put on proof from Drs. Stevens, Greenblatt and Lubarsky that a two-drug protocol involving just Midazolam and potassium chloride would substantially reduce (indeed eliminate) the risk of severe pain and mental anguish caused by vecuronium bromide. XXV 162-63, 218; XXVIII 542-43; XLII 1818-21. Defendants did not object to this line of questioning. *Id.* Commissioner Tony Parker agreed that the Department of Corrections could carry out an execution using a twodrug protocol, using just Midazolam and potassium chloride. XXXVII 1315-16. Again, Defendants did not object. *Id.*

Plaintiffs made clear, on the record, at trial, that a two-drug alternative relying on Midazolam and potassium chloride, that removed vecuronium bromide was a feasible and readily available alternative that must be considered under *Glossip* and *West.* XLIII 1933-36, XLV 1966. Plaintiffs submitted that such a protocol "is not only reducing a risk. It's removing a risk. It's removing something that will cause severe pain....It removes that noxious stimuli. It would speed up death by three minutes. Especially in light of pulmonary edema, those are three minutes that are already torturous." XLIII 1936.

However, in denying relief, the Chancery Court only considered a single possible alternative, a single-drug protocol using Pentobarbital. *Order,* XVI 2239-49, 2264. The failure of the Chancery Court to consider the two-drug protocol was

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error, and it was further error to fail to find that such a protocol was feasible and readily available, and that it would substantially reduce (indeed eliminate) the risk of severe pain and mental anguish produced by vecuronium. *Glossip v. Gross*, 135 S. Ct. 2726, 2737 (2015); *West v. Schofield*, 519 S.W.3d 550, 564 (Tenn. 2017). Had the Chancery Court engaged in the proper analysis, and reached the proper factual conclusion, then Tennessee's current three-drug protocol would have been found to violate the Eighth Amendment to the United States Constitution, and Article I, § 16 of Tennessee's Constitution.

1. Plaintiffs, working under incredible time constraints, pled the two-drug protocol as a feasible and readily available alternative that would substantially reduce a significant risk of severe pain and mental anguish.

On January 8, 2018, Defendants approved an earlier version of the threedrug, Midazolam-based protocol that is the subject to this litigation. I 96. The original complaint was filed on February 20, 2018. I 1. Trial commenced on July 9, 2018. XXIV 1. Thus, in four and one-half months, counsel for thirty-three different Plaintiffs⁸⁴ had to complete all discovery⁸⁵, address multiple motions, and file three Complaints. After the Second Amended Complaint was filed on July 3, 2018, and

⁸⁴ At trial, fully ten attorneys directly participated and sat at counsel table. These attorneys came from five different offices: three private each representing a single plaintiff, plus the two Federal Public Defender offices, which represented twenty-six (Middle) and four (East) plaintiffs.

⁸⁵ Depositions were conducted in Boston, MA, Miami, FL, Auburn, AL, Cherokee, NC, Atlanta, GA, and Tulsa, OK, as well as four in Nashville, Tennessee.

concurrent with the filing of Plaintiffs' Trial Brief on July 5, 2018, a mere four days before trial, Defendants published a new protocol, which for the first time removed the option of single-drug Pentobarbital. XII 1589-1690.

Until defendants affirmatively withdrew the one-drug Pentobarbital alternative from the July 5, 2018 protocol, their counsel had been notably unwilling to take a position on the availability of Pentobarbital. At case management conference on April 11, 2018, defense counsel refused to say whether Pentobarbital would be available for the scheduled August 9, 2018 execution, despite vigorous questioning by the Chancellor:

COURT: Are you able to provide the Court information on the State's position concerning paragraphs 431 and 433⁸⁶ and the availability of the drug for Protocol A [single-drug Pentobarbital]?

MR. SUTHERLAND: Well, I think what we have told the Tennessee Supreme Court in the motions to set execution dates that there has been difficulty obtaining the drugs for Protocol A. You know –

COURT: Well, you can understand –

MR. SUTHERLAND: Obviously the Department –

COURT: Excuse me for interrupting. But you can understand how that puts us, then, in an untenable position here in the trial court and all of the litigants, including the State. Under Glossip, that is a fact that we need to

⁸⁶ The first complaint:

 $[\]P$ 431: "The Tennessee Attorney General made no mention of unavailability of drugs in his January 11, 2018 notice to the court."

 $[\]P$ 433: "The current proof in the record is that Defendants have a source for compounded Pentobarbital. To the extent that Defendants dispute this allegation, the proper forum to adjudicate this factual disagreement is through trial and discovery." I, 90.

know. So we've got to have a position on that. Either it's unavailable or it's not.

MR. SUTHERLAND: I think – I guess I would say today, Judge, that I think it would be somewhat premature because unavailability certainly –

COURT: It's not premature because we have an August execution date. We need to know whether it will be available for that execution for the plaintiffs to be able to fulfill the condition of Glossip and for you to be able to argue to me they have not fulfilled their position under Glossip. So we need to know that. That is essential for the case –

COURT: What will be used for the August 9th – will it [Pentobarbital] be available for the August 9th execution? That's the question.

MR. SUTHERLAND: I can't answer that question, Your Honor.

COURT: Well, if you can't answer it then our proceedings here are really meaningless. We've got to have the answer to that because then they can't allege – know what alternative to allege.

COURT: Are you going to have enough [Pentobarbital] for August 9th or not?

MR. SUTHERLAND: Respectfully, Your Honor –

COURT: Yes, sir.

MR. SUTHERLAND: -- The Glossip decision says that they must identify it. They must identify it. They must tell – they must say if B doesn't work, that here's one that is available.

COURT: Yes.

MR. SUTHERLAND: It's not out - it's not our responsibility to tell them what we have. It's their responsibility to identify something that is available.

COURT: I guess we just will have to respectfully disagree...

COURT: ...how can they pled Protocol A as an alternative if we have facts in here that say it's not going to be available for the August 9th execution? And you won't tell us one way or the other whether it's going to be available or not.

That would eliminate – if we knew that, then they could say, okay, we can't use A but we can this and then we can have a trial about that.

Tr. April 11, 2018, XX 11-30 (excerpts, above).

For obvious reasons, the State's single-drug Pentobarbital protocol had been Plaintiffs' preferred alternative under *Glossip* and *West*.⁸⁷ So long as Defendants expressed an intent to employ single-drug Pentobarbital, it had to be Plaintiffs' chosen alternative. However, despite this being the first choice, Plaintiffs had always maintained that other methodologies would reduce pain and suffering.

In the three Complaints that were filed, among other explicit averments, Plaintiffs' repeatedly pled that "vecuronium bromide is not necessary (or is unnecessary) to execute Plaintiffs," and that "[t[he use of vecuronium bromide in Protocol B increases the risk of unnecessary and serious pain and suffering." *January 8, 2018 Complaint,* I 31, ¶¶ 96-97, 37, Heading, 39, ¶ 177; *April 13, 2018*

⁸⁷ (1) One-drug Pentobarbital is painless if done properly, other alternatives reduce suffering but do not eliminate suffering; (2) it had been upheld by the Courts, (3) until July 5, 2018, Defendants maintained that they were continuing to try to secure drugs to perform this protocol, and (4) Defendants had a supplier under contract to provide Pentobarbital. Thus, it was, by far, the "best" alternative. Other alternatives, while meeting *Glossip/West* requirements involve some level of pain and suffering, as, in fact, does the two-drug alternative.

Amended Complaint, III 323, ¶¶ 96-97, 330, Heading, 332, ¶ 177; July 3, 2018

Second Amended Complaint, XI 1446, ¶¶ 96-97, 1454, ¶ 177.88

Plaintiffs in their trial brief filed on July 5, 2018, four days prior to the commencement of trial. stated:

Finally, discovery in this case has revealed at least three other feasible and readily implemented alternatives to Protocol B⁸⁹ as written: (1) Defendants could eliminate the use of vecuronium bromide—according to their own witnesses it is unnecessary to cause death or preventing pain, is a noxious stimuli capable of overcoming any sedative effect of the Midazolam, and prolongs Plaintiffs suffering by at least three minutes, (2) Defendants could reduce the amount of Midazolam to its maximum effective dose thus reducing the pain and suffering caused by injecting a bolus dose of acidic chemical into the veins of Plaintiffs <u>and</u> eliminate the vecuronium bromide; or....

XIII 1747 (emphasis added).

Also in the trial brief, Plaintiffs' argued:

Weeks after Defendant Parker swore under oath that Protocol A is the preferred protocol the state eliminated it in a cynical move presumably designed to eliminate Plaintiffs' argument that a single-drug Pentobarbital lethal injection protocol is a feasible, known, and readily available alternative. Defendants cannot word process away Plaintiffs proof. Moreover, to the extent that this Court finds Defendants last minute maneuver has any impact on this litigation, it should be to estop Defendants from arguing that Plaintiffs have failed to prove an alternative.

⁸⁸ Other statements related to the risks caused by vecuronium bromide and/or its lack of utility are found at ¶¶ 153, 160-176, 230, 231, 302, 303 and 308 in the *Second Amended Complaint*, XI 1416-1563 and in similarly numbered paragraphs in the prior complaints.

⁸⁹ At the time the brief was drafted, Tennessee still had Protocol A using singledrug Pentobarbital, and Protocol B, which was the three-drug method subject to challenge.

XIII, fn. 13.

 Pursuant to Tennessee Rule of Civil Procedure 8.05, Plaintiffs sufficiently pled the two-drug alternative, such that (a)
Defendants had more than adequate notice of this claim, and (b) the Court should have addressed this claim on its merits.

Tennessee "follows a liberal notice pleading standard, which recognizes that the primary purpose of pleadings is to provide notice of the issues presented to the opposing party and court." *Lind v. Beaman Dodge, Inc.*, 356 S.W.3d 889, 894 (Tenn. 2011) (citing *Webb v. Nashville Area Habitat for Humanity, Inc.*, 346 S.W.3d 422, 426 (Tenn. 2011)). It is well-settled Tennessee law that "a complaint 'need not contain in minute detail the facts that give rise to the claim," rather, the complaint "must contain allegations from which an inference may fairly be drawn that evidence on these material points will be introduced at trial." *Riad v. Erie Ins. Exch.*, 436 S.W.3d 256, 270 (Tenn. Ct. App. 2013) (quoting *Trau-Med of America, Inc. v. Allstate Ins. Co.*, 71 S.W.3d 691, 704 (Tenn. 2002) which quoted *Donaldson v. Donaldson*, 557 S.W.2d 60, 61 (Tenn. 1977)). The purpose of pleadings is "to give notice of the issues to be tried so that the opposing party can adequately prepare for trial." *Sanford v. Waugh & Co., Inc.* 328 S.W.3d 836, 848 (Tenn. 2010); *Keisling v. Keisling*, 92 S.W.3d 374, 377 (Tenn. 2002).

The applicable rule of civil procedure, 8.05, states: "Each averment of a pleading shall be simple, concise and direct. No technical forms of pleading or motions are required." Tenn. R. Civ. P. 8.05(1). Whether an issue was sufficiently pled is a matter of law, which is reviewed *de novo* without any presumption of

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correctness. *Mortgage Electronic Registration Systems, Inc. v. Ditto*, 488 S.W.3d 265, 275 (Tenn. 2015); *Lind*, 356 S.W.3d at 895.

This Honorable Court and the Court of Appeals have previously examined trial briefs to determine what claims have been pled. *Napolitano v. Board of Professional Responsibility*, 535 S.W.3d 481, 495 (Tenn. 2017) (pre-trial brief referred to by this Court as source of claim that attorney owed \$40,000 in restitution); *Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 541 (Tenn. 2008) (addressing a post-sale failure to warn claim that was first alleged in plaintiff's trial brief); *Dixon v. Grissom*, No. E201400947COAR9CV, 2015 WL 3643426, at *8 (Tenn. Ct. App. June 12, 2015) (noting that claim was not raised in complaint or in trial brief); *Saweres v. Royal Net Auto Sale, Inc.*, No. M2010-01807-COA-R3CV, 2011 WL 3370350 (Tenn. Ct. App., August 1, 2011) (pre-trial brief quoted from to define plaintiff's complaint; Court of Appeals then found "[t]he matters addressed by the court were clearly put in issue by the pleadings."). Clearly, the trial brief in this case explicitly identified the two-drug protocol as a feasible and readily available alternative. XIII 1747.

At trial, during legal discussion of the two-drug protocol, on both July 17 and 18, counsel for Plaintiffs made clear that it was their position that under Rule 8.05 adequate notice had been provided. XLIII 1940; XLV 1966. Counsel also noted that "this has been a fluid situation. It has been very, very rushed. We did get a new protocol July 5th and we have constantly been almost like hamsters in a wheel trying to keep this whole thing going." *Id.* at 1965-66.

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Thus, in this case, pursuant to *Lind, Riad, Sanford* and Tenn. R. Civ. Pro. 8.05, as well as *Napolitano* and *Flax*, Plaintiffs more than adequately provided notice to the Defendants that a two-drug alternative would be advanced at trial, and to the Chancellor that such should be considered. Under appropriate *de novo* review, without a presumption of correctness, this Court should find that the Chancellor erred, and that the two-drug alternative should have been considered on its merits.

3. Alternatively, Plaintiffs should have been allowed to amend by implied consent, pursuant to Tennessee Rule of Civil Procedure 15.02.

In opening statement, counsel for Plaintiffs noted that they would most likely seek leave to amend the complaint to conform to the proof. XXIV 26. Similarly, Plaintiff's trial brief stated: "plaintiffs may ask leave to amend their complaint to conform to the proof that develops at trial—indeed, in this fluid situation, it is almost certain that the proof will differ from what was anticipated at the time of the complaint's drafting." XIII 1812. Indeed. While the trial brief was being written, Defendants changed their protocol. The trial brief with attachments was 340 pages, and it was filed at 8:02 p.m. XIII 1712 to XIV 2052.⁹⁰ The new protocol had been filed with the Clerk and Master at 1:17 p.m.. XII 1592.

⁹⁰ Plaintiffs will defer to this Honorable Court's collective wisdom as to how timeconsuming such legal writing should be.

Tennessee Rule of Civil Procedure 15.02 permits very liberal amendment of pleadings, including amendments "as may be necessary to cause them to conform to the evidence." The full text of that rule reads:

When issues not raised by the pleadings are tried by express or implied consent of the parties, they shall be treated in all respects as if they had been raised in the pleadings. Such amendment of the pleadings as may be necessary to cause them to conform to the evidence and to raise these issues may be made upon motion of any party at any time, even after judgment; but failure so to amend does not affect the result of the trial of these issues. Provided, however, amendment after verdict so as to increase the amount sued for in the action shall not be permitted. If evidence is objected to at the trial on the ground that it is not within the issues made by the pleadings, the court may allow the pleadings to be amended and shall do so freely when the presentation of the merits of the action will be subserved thereby and the objecting party fails to satisfy the court that the admission of such evidence would prejudice that party in maintaining the action or defense upon the merits. The court may grant a continuance to enable the objecting party to meet such evidence.

Tenn. R. Civ. Pro. 15.02.

It is well-settled that in normal circumstances (not the radically rushed circumstances of this case) that a motion to amend the pleadings to conform to the evidence should be granted if "the new issues were tried by the parties' express or implied consent and whether the defendant 'would be prejudiced by the implied amendment, i.e., whether he had a fair opportunity to defend and whether he could offer any additional evidence if the case were to be retried on a different theory." *Vantage Tech., LLC v. Cross,* 17 S.W.3d 637, 649 (Tenn. Ct. App. 1999) *quoting Zack Cheek Builders, Inc. v. McLeod,* 597 S.W.2d 888, 891 (Tenn.1980).

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"[T]rial by implied consent will be found where [1] the party opposed to the amendment knew or should reasonably have known of the evidence relating to the new issue, [2] did not object to this evidence, and [3] was not prejudiced thereby." *Zack Cheek Builders, Inc. v. McLeod*, 597 S.W.2d 888, 890 (Tenn. 1980); *see also Hyman v. Bd. of Prof1 Responsibility of Supreme Court*, 437 S.W.3d 435, 441 (Tenn. 2014) (as accused lawyer "did not object to the inclusion of [an uncharged allegation of misconduct] this incident was therefore tried by the implied consent of the parties.").

Examining the three parts of the *Zack Cheek* analysis, we see that an amendment to conform to the proof should have been permitted, and that the failure to permit such was an abuse of discretion (as will be further developed below).

A. Zack Cheek analysis Prong One: Defendants knew or reasonably should have known that Plaintiffs were submitting a two-drug alternative.

As has been set-forth in detail above, Plaintiffs' three complaints and the trial brief made very clear that a two-drug alternative would be raised at trial. XI 1446, ¶¶ 96-97, 1454, ¶ 177; XIII 1747. Then in opening statement, Plaintiffs reminded Defendants and the Court, that they would present "other lethal injection options" beyond single-drug Pentobarbital. XXIV 24-25.

Most importantly, after providing warning to Defendants that a two-drug protocol and "other lethal injection options" would be advanced at trial, Plaintiffs then explicitly questioned their expert witnesses and the lead defendant about the two-drug alternative.

The first witness at trial, Dr. Craig Stevens, was unambiguously asked about a two-drug protocol by Plaintiffs' counsel:

Q. From a pharmacological perspective and to a reasonable degree of scientific certainty, would a two-drug protocol involving just Midazolam and potassium chloride, but removing the three-minute interlude with vecuronium, be less painful and cause less suffering than the present three-drug protocol?

A. It would in the sense of death comes sooner.

XXV 162-63. Earlier examination of Dr. Stevens also made clear that (a)

vecuronium would cause "horrific" suffering and (b) it was not needed to cause an

inmate's death (death would be caused by the potassium chloride). XXV 154-56,

159-60.

Plaintiffs' second expert witness, Dr. David Greenblatt, was similarly asked

about the need to employ vecuronium in an execution protocol:

Q. Do you see any effect from vecuronium bromide that would hasten the process of death within this protocol or diminish any pain or suffering that the person being executed experienced?

A. It certainly would not—it would increase rather than diminish pain and suffering. I don't think it would hasten death except that there would be a period of time when they can't breathe. But I—I don't see any benefit to vecuronium.

XXVIII 542-43.

Dr. Lubarsky, the Plaintiffs' final expert, also discussed whether vecuronium bromide served any purpose:

Q. Does the Vecuronium Bromide do anything in the lethal injection protocol to protect the inmates from the sensation of pain?

A. No. As I think we covered, it paralyzes you and prevents anyone from seeing any sign of distress that you might voice or move or try to express.

Q. So instead of providing extra protection against the pain with Potassium Chloride, does it actually act as a stimulus to actually increase the risk of pain?

A. I believe it does, because you're causing air [hunger]⁹¹ and that's known to be a significant added stimulus.

XLII 1818-19.

Subsequently, Dr. Lubarsky explained the medical uses of vecuronium during surgery: (1) to relax the throat muscles and vocal cords, so that a breathing tube can be inserted, (2) to protect against insufficient anesthesia and a patient responding to pain by moving, mid-surgery, and (3) to make it easier to manipulate the patient and their internal organs, by relaxing surrounding muscles. XLII 1823-25. He was asked if these medical reasons were present in Tennessee's protocol, such that vecuronium was needed, and he answered they were not. *Id.* at 1825.

Defendant Commissioner of the Tennessee Department of Corrections Tony Parker was questioned about a two-drug protocol.

Q. Commissioner, is the Department of Correction able to carry out an execution using just Midazolam and Potassium Chloride?

A. I don't understand your question. We have a three-drug protocol. We would have to have all three drugs to carry out an execution.

⁹¹ The transcript reads "air in the lung." However, Plaintiffs aver that the term used by Dr. Lubarsky (and other experts) to describe the sense of suffocation is "air hunger," and that is what was said during this passage.

Q. If the second drug—what role does the second drug play in the execution?

A. The second drug is a paralytic that paralyzes and stops the breathing.

Q. Will the Potassium Chloride alone kill an inmate?

MR. SUTHERLAND: Objection. Foundation.

THE COURT: The Court overrules the objection.

A. I am assuming it could, yes.

Q. If the Midazolam works as you intend it to work and the Potassium Chloride will kill the inmate, then the Vecuronium Bromide really serves no purpose as far as bringing about the death of the inmate, does it?

A. Well, from a layman's term or my opinion, which I'm not a medical professional, if the Potassium Chloride were to stop the heart, obviously, that could kill the inmate. So yes.

XXXVII 1315-16.

Thus, under the Zack Cheek analysis, we see two unambiguous instances where Plaintiffs' counsel raised a two-drug protocol alternative: with the very first witness, Dr. Stevens, and then with the lead defendant, Commissioner Parker. XXV 162-63; XXXVII 1315-16. This was done after multiple warnings had been given that a two-drug protocol would be explored. XIII 1747; XXIV 24-25. Additional questioning with Drs. Stevens, Greenblatt and Lubarsky clearly addressed the two-drug protocol, and further established that such a protocol would substantially reduce a significant risk of pain. XXV 154-56, 159-60; XXVIII 542-43; XLII 1818-19, 1825. Zack Cheek prong one is satisfied, Defendants knew or should have known that a two-drug protocol would be advanced by Plaintiffs as a feasible alternative.
B. Zack Cheek analysis Prong Two: Defendants did not object.

Plaintiffs' counsel will not repeat the quoted testimony from the prior section, but notably Defendants only objected one time, and that one objection was to "foundation." XXXVII 1315-16. At no point did Defendants lodge an objection that a two-drug protocol was irrelevant to the issues in dispute. At no point did Defendants object to an examination that was outside the scope of the Complaint. At no point did Defendants submit an objection under Rule 15.02 and its specific clause: "If evidence is objected to at the trial on the ground that it is not within the issues made by the pleadings..." Tenn. R. Civ. Pro. 15.02.

Instead, learned counsel with decades of experience, having read Plaintiffs' Trial Brief and Complaints and having sat through opening statement, knowingly permitted explicit questioning about the two-drug protocol. *Zack Cheek* prong two is easily satisfied.

C. Zack Cheek analysis Prong Three: Defendants were not prejudiced.

In *Zack Cheek*, this Honorable Court held that consideration of whether the party opposed to the amendment would be prejudiced by the amendment requires consideration of whether the party "had a fair opportunity to defend and whether he could offer any additional evidence if the case were to be tried on a different theory." *Zack Cheek*, 597 S.W.2d at 890-91 (citation omitted).

This Honorable Court recently reasserted that allegations of prejudice must be specific and concrete, and that "vague, speculative, or conclusory allegations are

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insufficient." *Nunley v. State*, No. W201601487SCR11ECN, 2018 WL 3468745, at *23, fn. 26 (Tenn. July 19, 2018). It has long been the law in Tennessee that "conclusory statements made by counsel" are not evidence of prejudice. *State v. Kerley*, 820 S.W.2d 753, 757 (Tenn. Crim. App. 1991).

Defense counsel failed to identify any actual prejudice Defendants had suffered. In addition, any potential prejudice would have been easily cured, as all essential witnesses were available.

In this case, the issue of whether the Chancellor would consider the two-drug protocol as a *Glossipl West* alternative was addressed in open court on July 17, 2018, and then in more detail on the morning of July 18, 2018, prior to the start of Defendants' case. XLIII 1933-34; XLV 1959. Both defense experts, including the Defendants' key witness on medications, Dr. Evans, had yet to take the stand. All of Plaintiffs' experts were physically present and available to be recalled as witnesses by Defendants, if needed. XLVI 2203-04. Defendant Commissioner Parker was also available to be recalled to further address the issue of whether a two-drug protocol was feasible or readily available, or to explain his earlier answer on the subject.

When the two-drug protocol was discussed on July 17, 2018, the Chancellor asked Defendants' counsel if they were prepared to respond, or if they needed more time. Counsel asked for more time, but stated, "Frankly, it sounds like to me that it's possible. We would certainly need to talk to the Department. It sounds like to me it's certainly something we'd do." XLIII 1938.

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On July 18, 2018—again with all six experts available—counsel for Defendants for the first time appeared to claim prejudice: "There's no way to—you know, you can't come in and change the entire complexion of a case, a cause of action at the end of proof when we're getting ready at this moment to defend the claim."⁹² XLV 1985. Specifically, Defendants' counsel submitted that "We didn't question their experts in depositions on this...we'd have to re-do discovery in the case based upon this." *Id.* Finally, Defendants' counsel submitted, "If we had been dealing with this issue in the nature of an alternative—*Glossip* alternative, it would have changed the questioning. It would have changed our approach to that questioning." *Id.* at 1990.

What questions learned counsel for the Defendants would have asked, and why he could not recall the experts who were present in the courtroom to ask these probing questions was not explained. *Id.* at 1990, *established by omission*. Why defense counsel had chosen not to object when the two-drug protocol had been so explicitly raised during Plaintiffs' proof was not addressed. *Id.*

A brief continuance to re-depose the defense experts, or to gather an expert on the "unavailability of removing vecuronium from the protocol" was not requested, though clearly permitted under Rule 15.02. *Id.* Indeed, it was never articulated by defense counsel how it could possibly <u>not</u> be feasible to remove a drug

⁹² Why pleading an alternative that had been fully alleged in the trial brief on July 5, 2018 "changed the entire complexion of the trial"—but publishing an entirely new lethal injection protocol on that same day did not—was not explained by defense counsel.

that their lead Defendant conceded was not needed. XXXVII 1315-16. While it may take some effort to purchase a pharmaceutical, it takes no effort <u>not</u> to purchase a pharmaceutical.

ii. Any claim of prejudice was waived due to failure to lodge a contemporaneous objection.

Defendants' failure to contemporaneously object, as contemplated by Rule 15.02, disadvantaged the Court and Plaintiffs. Under the rule, if evidence is objected to, then

the court may allow the pleadings to be amended and shall do so freely when the presentation of the merits of the action will be subserved thereby and the objecting party fails to satisfy the court that the admission of such evidence would prejudice that party in maintaining the action or defense upon the merits.

Tenn. R. Civ. Pro. 15.02. By failing to make such a contemporaneous objection, Defendants denied the Chancellor the opportunity to hear and weigh their claim of prejudice in a timely manner. *See State v. Baugh*, 152 S.W.3d 453, 465 (Tenn. 2004) (failure to lodge timely objection prevented trial court from having an opportunity to rule).

Under Tennessee law, a failure to object is a waiver of any subsequent claim of prejudice. *Creech v. Addington*, 281 S.W.3d 363, 386 (Tenn. 2009) (failure to lodge timely objection to allegedly misleading jury instructions was waiver); *Baugh*, 152 S.W.3d at 465; *State v. Reid*, 91 S.W.3d 247, 283-84 (Tenn. 2002) (failure to object to prosecutor's allegedly prejudicial closing argument was waiver); *State v. Thompson*, 832 S.W.2d 577, 579 (Tenn. Crim. App. 1991). In this case, having had the two-drug alternative so clearly addressed, so many times both before and during trial, any claim of prejudice was waived by defense counsel's repeated failures to lodge appropriate objections.

iii. The burden of proof was on Defendants to demonstrate prejudice, not on Plaintiffs to show entitlement to amend.

"[T]he court may allow the pleadings to be amended and shall do so freely when the presentation of the merits of the action will be subserved thereby *and the objecting party fails to satisfy the court* that the admission of such evidence would prejudice that party in maintaining the action or defense upon the merits." Tenn. R. Civ. Pro. 15.02 (emphasis added). Rule 15.02 plainly places the burden to establish prejudice on the objecting party. Absent that burden being met, amendment should be "freely" permitted. *Id.* As noted, above, Defendants failed to articulate any form of prejudice.

Thus, no actual concrete prejudice was alleged. All claims of prejudice were mere conjecture. No prejudice was suffered. And any claim of prejudice was waived by defense counsel's failure to object. *Zack Cheek* prong three is easily met as well.

f. Amendments to conform to the proof are regularly permitted by the courts of this state in circumstances that are materially indistinguishable from our own—except that in those cases the parties had significantly more time to prepare for trial than did Plaintiffs.

Courts routinely permit amendments under Rule 15.02, including far more significant amendments than the one at issue here. *See, e.g., Goff v. Elmo Greer & Sons Const. Co., Inc.*, 297 S.W.3d 175, 196-97 (Tenn. 2009) (although plaintiffs' complaint only alleged "intentional and fraudulent misconduct," punitive damages were awarded under amended theory of "reckless" misconduct pursuant to Rule 15.02); *Newcomb v. Kohler Co.*, 222 S.W.3d 368, 382-83 (Tenn. App. 2006) (plaintiffs permitted to amend complaint mid-trial to claim damages of \$57,321 in back pay and \$429,908 in front pay, although no specific damages were enumerated in complaint); *Hobbs v. Hobbs*, 987 S.W.2d 844, 847-48 (Tenn. App. 1998) (although counter-claim in divorce action failed to allege any grounds for divorce, under 15.02, party allowed to amend to conform to evidence of inappropriate martial conduct); *Varley v. Varley*, 934 S.W.2d 659, 665 (Tenn. App. 1996) (although complaint for divorce failed to allege adultery, four witnesses at trial alleged adultery without objection and divorce granted on amended theory of adultery under 15.02).

Meaningfully, the most significant distinction between any of those cases and the present matter is that they were traditional civil cases following traditional, unrushed trial schedules. *Goff*, 297 S.W.3d at 180-81 (suit originally filed in 1997, at least two amended complaints filed, trial began June 2006—8-9 years later); *Newcomb*, 222 S.W.3d at 380-81 (suit filed July 7, 2003, trial commenced April 2005—21 months later); *Hobbs*, 987 S.W.2d at 845 (simple divorce action filed September 23, 1996, trial commenced May 1997—8 months later); *Varley*, 934 S.W.2d at 660 (another divorce, filed May of 1994, final hearing April 1995—11 months later). In this case, four-and-a-half months passed from the filing of the initial complaint to the inception of a trial that would last over two-weeks.

> 4. The Chancellor summarily denied Plaintiffs leave to plead a two-drug alternative; her ruling did not involve any legal analysis under either Rule 8.05 or Rule 15.02; the Chancellor

abused her discretion by applying an incorrect legal standard and by reaching an illogical decision.

After significant discussion of the two-drug protocol, and of Plaintiffs' intent

to argue that it was a feasible and readily available alternative that substantially

reduced a risk of severe pain and mental anguish, XLIII 1929-1941; XLV 1958-1990,

the Chancellor issued an oral ruling, which did not address Rule 8.05 at all:

Rule 15.02 of the Tennessee Rules of Civil Procedure provides that when an issue is not raised by the pleadings or tried by expressed or implied consent of the parties, they shall be treated in all respects as if they had been raised in the pleadings.

The Court denies the Rule 15.02 motion to amend. The Court finds that the issue of removal of Vecuronium Bromide as an alternative protocol under Glossip was not tried by expressed or implied consent of the parties. The motion is denied.

XLV 1990-91.

Subsequently, the court issued a written order, which, in relevant part

provided as follows:

The Court denied Plaintiffs amending the pleadings to assert removal of vecuronium bromide from the Tennessee three-drug July 5, 2018 lethal injection protocol as a known, feasible and available alternative, *see Glossip...*This potential cause of action was known or could have been known by the Plaintiffs upon the filing of the lawsuit, and this cause of action has not been tried by express or implied consent....

XV 2138.

A. The abuse of discretion standard, while deferential, is not supine.

"A trial court abuses its discretion when it applies an incorrect legal standard or reaches a decision that is against logic or reasoning that causes an injustice to the party complaining." *State v. Russell*, 382 S.W.3d 312, 317 (Tenn. 2012); *State v. Gomez*, 367 S.W.3d 237, 243 (Tenn. 2012). This Honorable Court has defined the standard as "[a]n abuse of discretion occurs when the trial court (1) applies an incorrect legal standard, (2) reaches an illogical or unreasonable decision, or (3) bases its decision on a clearly erroneous assessment of the evidence. *State v. McCoy*, 459 S.W.3d 1, 8 (Tenn. 2014); *State v. Mangrum*, 403 S.W.3d 152, 166 (Tenn. 2013); *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 524 (Tenn. 2010). This court has also made clear that "a silent record" is not entitled to a presumption of legal regularity. *State v. Pollard*, 432 S.W.3d 851, 862 (Tenn. 2013).

B. The Chancellor employed an incorrect legal standard that is contrary to the logic of *Zack Cheek* and is not based on any known authority.

The standard employed by the Chancellor in denying Rule 15.02 amendment was "whether this cause of action was known or could have been known upon the filing of suit." XV 2138. This standard is not found in *Zack Cheek* or any other precedent of this Court or of the Court of Appeals.⁹³ Indeed, this standard is directly contrary to the logic of all other 15.02 cases; clearly in *Goff* the plaintiffs could have known to plead "recklessness" in their original complaint; in *Newcomb*, plaintiffs knew they had missed back pay and front pay; and in *Varley*, the wife was

 $^{^{93}}$ Westlaw search: adv: 15.02 /p known /p "cause #of action" has no case results in the Tennessee database as of 8/31/2018 at 9:59 a.m.

aware that she was leaving her husband because of his adultery. *Goff*, 297 S.W.3d at 196-97; *Newcomb*, 222 S.W.3d at 382-83; *Varley*, 934 S.W.2d at 665. Indeed, if such a standard had been applied in *Zack Cheek*, the amendment, requested more than 30-days *after* judgment had been entered, would never have been permitted. *Zack Cheek*, 597 S.W.2d at 889-90. Finally, in *Hyman*, this Honorable Court found it acceptable to amend a complaint to add an additional and entirely independent act of misconduct that the State presented at trial—clearly, the State had to have known about this misconduct before trial (otherwise they would not have subpoenaed witnesses to prove it). *Hyman*, 437 S.W.3d at 441, fn. 4.

Moreover, despite being directed to *Zack Cheek* and *Vantage Tech*⁹⁴ and the three-part analysis contained in those cases, the Chancellor did not attempt to apply the controlling standard. *See* XLIII 1939-41

Thus, the Chancellor's ruling was an abuse of discretion as she applied an incorrect legal standard, while completely ignoring proper analysis. *McCoy*, 459 S.W.3d at 8; *Mangrum*, 403 S.W.3d at 166; *Lee Med., Inc.*, 312 S.W.3d at 524.

C. Under Rule 15.02 there was implied consent, and the Chancellor's failure to find such was illogical and unreasonable.

Plaintiffs set-forth above why, under *Zack Cheek*'s three-part analysis, a Rule 15.02 amendment was proper. It is sufficient to simply note that the Chancellor's failure to engage in this analysis and to reach the obviously correct conclusion was

⁹⁴ The Chancellor acknowledged her knowledge of this case, noting it was "our noncompete case." XLIII 1939.

illogical and unreasonable, and thus, was an abuse of discretion. *McCoy*, 459 S.W.3d at 8; *Mangrum*, 403 S.W.3d at 166; *Lee Med., Inc.*, 312 S.W.3d at 524.

D. It was an abuse of discretion to ignore Rule 8.05.

Plaintiffs submitted that there was no need to amend the complaint, as the two-drug alternative had been adequately pled. XLIII 1940, XLV 1966-67. Specifically, Plaintiffs' counsel argued:

I haven't necessarily perceived it as an amendment of the pleadings to conform to the proof. I do think under 8.05 we did provide adequate notice. We did in the original complaint, the amended complaint, say Vecuronium is unnecessary, that that's said in multiple paragraphs.

XLV 1966.

This contention was left entirely unaddressed by the Chancellor. *Established by omission from the record*. The Chancellor failed to engage in the proper legal analysis, as discussed above. Thus, the Chancellor employed an incorrect legal standard (no standard at all), and reached an illogical and unreasonable result. This is an abuse of discretion. *McCoy*, 459 S.W.3d at 8; *Mangrum*, 403 S.W.3d at 166; *Lee Med., Inc.*, 312 S.W.3d at 524.⁹⁵

E. The Chancellor's errors caused an injustice to Plaintiffs.

It is an abuse of discretion when a court "applies an incorrect legal standard or reaches a decision that is against logic or reasoning that causes an injustice to

⁹⁵ This Honorable Court's standard of review of the ultimate issue under 8.05 is *de novo. Mortgage Elec. Registration Sys.*, 488 S.W.3d at 275.

the party complaining." *Russell*, 382 S.W.3d at 317. In this case, for the reasons that will be addressed in the immediately following section, analysis of a two-drug protocol would have resulted in a finding that Tennessee's three-drug protocol is unconstitutional. Thus, now-deceased Plaintiff Billy Ray Irick would not have been executed with the torturous three-drug protocol, but with a two-drug protocol⁹⁶ that would have substantially reduced (eliminated) a significant risk of severe pain and mental anguish. The remaining Plaintiffs will suffer a similar injustice, due to the Chancellor's failure to follow controlling legal precedent, and due to the Chancellor's illogical and unreasonable conclusions.

F. The United States Supreme Court makes clear that a constitutional claim will not be limited by specific arguments.

The United States Supreme Court permits litigants to advance new arguments in support of their broader constitutional claims. *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 331 (2010); *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995). In *Citizens United*, the plaintiffs dismissed their facial challenge to the relevant campaign finance statute and only advanced an as-applied challenge. *Citizens United*, 558 U.S. at 329-30. Nonetheless, the Court addressed the facial constitutionality of the campaign finance statute (and, of course, found it

⁹⁶ Or, if the Defendants are not really so confident in the efficacy of Midazolam, and if they do not believe their pharmacy expert that Midazolam would have rendered Mr. Irick immobile and insensate to pain, then they would not have executed him as scheduled, as to do so would have let the public see his full reaction when the potassium chloride began coursing through his veins.

unconstitutional): "Citizen United's argument that *Austin* should be overruled is 'not a new claim.' Rather, it is—at most—"a new argument to support what has been a consistent claim: that [the FEC] did not accord [Citizens United] the rights it was obliged to provide by the First Amendment." *Id.* at 331 (quoting *Lebron*, 513 U.S. at 379).

The Court in Citizen United also provided a warning against overly

restrictive interpretations of facial and as-applied challenges:

[T]he distinction between facial and as-applied challenges is not so well defined that it has some automatic effect or that it must always control the pleadings and disposition in every case involving a constitutional challenge. The distinction is both instructive and necessary, for it goes to the breadth of the remedy employed by the Court, not what must be pleaded in a complaint. The parties cannot enter into a stipulation that prevents the Court from considering certain remedies if those remedies are necessary to resolve a claim that has been preserved. Citizens United has preserved its First Amendment challenge to § 441b as applied to the facts of its case; and given all the circumstances, we cannot easily address that issue without assuming a premise—the permissibility of restricting corporate political speech—that is itself in doubt.

Citizens United, 558 U.S. at 331 (citing United States v. Treasury Emp., 513 U.S.

454, 477–478 (1995)).

The logic of *Citizens United* is compelling on our facts. Under that precedent, it was not necessary for Plaintiffs to plead the 2-drug alternative in the complaint (although, appellants submit such was done under our liberal notice pleadings and Rule 8.05), rather, once the claim was made that the 3-drug protocol was "cruel and unusual," then the trial court was free to consider the 2-drug alternative. In *Lebron*, the plaintiff argued, for the first time to the U.S. Supreme Court, that Amtrak was part of the federal government. *Lebron*, 513 U.S. at 378-39. In permitting this rather dramatic change of course, the Court held: "Lebron's contention that Amtrak is part of the Government is in our view not a new claim...but a new argument to support what has been his consistent claim: that Amtrak did not accord him the rights it was obliged to provide by the First Amendment." *Lebron*, 513 U.S. at 379.

The arguments that were newly invoked in *Citizens United* and *Lebron* were of significantly greater significance than an alternative method of execution. Obviously, *Citizens United* is the most important campaign finance decision of the last decade, and it was based on an argument for the invalidation of a statute that had not been raised until the case reached the Supreme Court. Similarly, in *Lebron*, the plaintiff's contention about the very legal nature of the defendant changed on appeal. Conversely, nothing has changed in this case, it has always been consistent: Tennessee's three-drug protocol is cruel and unusual.

Thus, at worst, the 2-drug protocol alternative is a new argument in support of a constitutional claim, that should have been considered by the Chancery Court, and which should be considered by this Honorable Court. Under Rules 8.05 and 15.02 and under United States Supreme Court precedent, it was error for the Chancellor to fail to address the constitutional issue on its merits, and based on the proof presented at trial.

5. A two-drug protocol of Midazolam and potassium chloride would substantially reduce (entirely eliminate) the significant risk of

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severe pain and mental anguish that will be produced by vecuronium bromide, and it will substantially reduce the duration of severe pain and mental anguish produced by the Midazolam.

The proof from Plaintiffs' experts was overwhelming and unassailed: (1) vecuronium will cause suffocation that is horrific and akin to being buried alive; (2) Midazolam will not render an inmate insensate to this suffering; (3) Midazolam will cause pulmonary edema, that will cause blood and fluids to fill the inmate's lungs until his heart is stopped; (4) the inmate's heart will be stopped and death will be caused by the subsequent injection of potassium chloride; (5) potassium chloride will kill before suffocation from vecuronium would become fatal; thus, (6) vecuronium is unnecessary; (7) vecruonium only prolongs the duration of an execution and the suffering of pulmonary edema; (8) vecuronium causes severe pain and mental anguish in its own right, and (9) an execution would involve significantly less pain, and death would result more quickly, if vecuronium was removed from the lethal injection protocol. XXV 161-63, 219-220; XXVIII 542-43; XLII 1818-21.

Neither of Defendants' experts, Dr. Evans or Dr. Li, disputed Plaintiffs' experts' conclusions regarding the horrific pain a sensate inmate would suffer from vecuronium. *Established by omission.* As has been noted before, the Chancellor accepted the findings of Plaintiffs' experts and acknowledged their expertise. XVI 2251,

Finally, Defendant Commissioner Parker admitted that a two-drug protocol was feasible and readily implemented. XXXVII 1315-16. Indeed, it is impossible after an exercise of logic and reason to reach any conclusion other than that a twodrug protocol must be feasible and readily available: if the State of Tennessee can get three drugs, they can easily choose not to get, or not to use, one of those three.

The necessary standard under *Glossip* and *West* is clear, and it was met in this case with the two-drug protocol. First, under the current three-drug protocol there is a substantial risk of harm, that the three-drug protocol is sure or very likely to cause severe pain or needless suffering. *Glossip*, 135 S. Ct. at 2737; *West*, 519 S.W.3d at 563-64. Second, Plaintiffs have identified an alternative method that is feasible, readily implemented, and which will significantly reduce the substantial risk of pain of the vercuronium bromide—indeed it will eliminate the risk presented by the paralytic entirely. *Glossip*, 135 S. Ct. at 2737; *West*, 519 S.W.3d at 564.

Additionally, counsel would highlight the term "needless suffering" from both *Glossip* and *West*. Although execution with Midazolam and potassium chloride will be awful—the inmates will begin to drown in their own fluids, and they will then burn alive with chemical fire—the vecuronium needlessly extends this entire process by three minutes, while adding yet another form of completely needless pain and mental suffering. Plaintiffs have proposed an alternative that will remove both forms of needless suffering.

Had the Chancellor correctly addressed the two-drug protocol on its merits, she would have found that the *Glossip* and *West* standards had been met, and that the three-drug protocol violated the 8th Amendment, and Article I, § 16. This Honorable Court should now make such a finding.

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- f. Tennessee's three-drug, Midazolam-based protocol will cause severe physical pain and extreme mental anguish for up to 18 excruciating minutes; it thus amounts to constitutionally forbidden torture.
 - 1. Appellants pled that the Tennessee three-drug lethal injection protocol inflicts torture upon the condemned, and they submitted that there was no need to identify an alternative to torture.

In the Amended Complaint, filed July 3, 2018, the inmates submitted that a

three-drug protocol that relied on Midazolam to render inmates insensate and

unresponsive to pain was unconstitutional, as it would result in the torture of the

condemned. *E.g.* TR XI, 1423, ¶ 3; 1509, ¶¶ 561-62; 1540, ¶ 662; 1541, ¶ 665.

Factually, among many pertinent allegations, Plaintiffs submitted:

301. The first drug utilized in Protocol B, Midazolam, has no painkilling properties.

302. The second drug utilized in Protocol B, vecuronium bromide, causes paralysis and severe mental anguish and terror.

303. The second drug utilized in Protocol B, vecuronium bromide, causes suffocation and severe mental anguish, terror, and pain.

304. The third drug utilized in Protocol B, potassium chloride, causes severe pain upon intravenous injection.

305. The third drug utilized in Protocol B, potassium chloride, causes severe pain from cardiac arrest.

306. Suffocation from the administration of vecuronium bromide and pain from the injection of potassium chloride is constitutionally unacceptable.

TR XI, 1467-68.

338. [M]idazolam is inappropriate for use as the first drug in a three-drug protocol because its pharmacokinetic properties do not and cannot prevent

constitutionally intolerable pain and suffering nor render Plaintiffs unaware of constitutionally intolerable pain, suffering and terror.

•••

340. Midazolam does not and cannot prevent or relieve pain.

341. Midazolam does not and cannot prevent a human being's awareness to the serious and severe pain, suffering, and terror caused by the second and third drugs used in Protocol B.

•••

344. Administration of vecuronium bromide creates a feeling of suffocation and terror in persons who are aware and sensate.

345. Vecuronium bromide serves no purpose in the protocol other than to act as a chemical veil that prevents witnesses from observing signed that an inmate is aware and able to feel the searing pain caused by the administration of potassium chloride.

•••

347. The administration of potassium chloride is sure or very likely to result in the searing pain similar to being burned alive from the inside in persons who are aware and sensate.

Id. at 1473-74.

Legally, Plaintiffs submitted:

3. The Eighth Amendment prohibits cruel and unusual punishment, including executions which "involve the unnecessary and wanton infliction of pain," *Gregg v. Georgia*, 428 U.S. 153, 173 (1976), or which "involve torture or a lingering death." *In re Kemmler*, 136 U.S. 436, 447 (1890) (citing *Wilkerson v. Utah*, 99 U.S. 130, 135

322. There is a substantial, objectively constitutionally intolerable risk that Plaintiffs will unnecessarily suffer serious pain and suffering under new Protocol B.

Id. at 1470.

324. New Protocl B violates the Eighth and Fourteenth Amendments to the United States Constitution and Tennessee Constitution Article I, § 16.

Id. at 1471.

351. The administration of Protocol B therefore violates evolving standards of decency...where the Protocol as written is sure and likely to result in terror, pain, and agony in violation of Plaintiff's right to human dignity.

Id. at 1474.

662. Punishments which involve torture or a lingering death are clearly contrary to the Eighth Amendment. *Wilkerson*, 99 U.S. at 136.

Id. at 1540.

The inmates have explained why, when a method of execution rises to the

level of torture, there is no requirement to prove an alternative. XIII, 1759-62.

Plaintiffs unambiguously asserted that the protocol met the torture standard. Id. at

1761. "The use of Midazolam amounts to torture, which violates the Eighth

Amendment and Article I, § 16, and must be prohibited, whether or not Plaintiffs

can identify an alternative method." Id. at 1761-62.

2. For 140 the United States Supreme Court has maintained that the 8th Amendment prohibits torture, barbarism and unnecessary cruelty.

The Supreme Court first defined the outer limits of the 8th Amendment in

1878:

Difficulty would attend the effort to define with exactness the extent of the constitutional provision which provides that cruel and unusual punishments shall not be inflicted; but it is safe to affirm that punishments of torture, such as those mentioned by the commentator referred to, and all others in the same line of unnecessary cruelty, are forbidden by that emendment [*sic*] to the Constitution.

Wilkerson v. State of Utah, 99 U.S. 130, 135–36 (1878).

The Court specifically identified such punishments that qualified as torture as: "Cases...where the prisoner was drawn or dragged to the place of execution, in treason; or where he was embowelled alive, beheaded, and quartered, in high treason. Mention is also made of public dissection in murder, and burning alive in treason committed by a female." *Wilkerson*, 99 U.S. at 135.

The Court reiterated its holding in *Wilkerson* in 1890 in *In re Kemmler*, in which the Court held that "burning at the stake, crucifixion, breaking on the wheel, or the like" are "manifestly cruel and unusual." *In re Kemmler*, 136 U.S. 436, 446 (1890). The Court further explained that "[p]unishments are cruel when they involve torture or a lingering death." *Id.* at 447.

Justice Kennedy, writing for the majority in 2010, reiterated the vitality of these opinions: "The Cruel and Unusual Punishments Clause prohibits the imposition of inherently barbaric punishments under all circumstances...' [P]unishments of torture,' for example, 'are forbidden."' *Graham v. Florida*, 560 U.S. 48, 59 (2010), *as modified* (July 6, 2010) (quoting *Wilkerson v. Utah*, 99 U.S. 130, 136 (1879)).

> 3. No less than five current members of the United States Supreme Court agree that the Eighth Amendment categorically prohibits torture or forms of execution that are akin to torture regardless of alternatives. Every current Justice agrees to the principles set-forth in *Wilkerson* and *In re Kemmler*.

The majority opinion in *Graham* cited above, appears explicit: "barbaric punishments" are prohibited "under all circumstances." *Graham*, 560 U.S. at 59. However, out of an abundance of caution, counsel for appellants can point to five current Justices of the United States Supreme Court who have affirmatively rejected the alternative requirement, and who believe that if a punishment is inherently barbaric, then it categorically violates the 8th Amendment. Moreover, every current Justice has written and/or joined opinions upholding the vitality of *Wilkerson* and *In re Kemmler*.

A. The *Baze* standard of Roberts and Alito: inhuman and barbarous punishments are prohibited; the alternative requirement applies when considering a risk, not a certainty.

Baze v. Rees, the plurality opinion written by Chief Justice Roberts, and joined in by Justice Alito,⁹⁷ reiterated the precedent of *In re Kemmler*: "Punishments are cruel when they involve torture or lingering death; but the punishment of death is not cruel, within the meaning of that word as used in the Constitution. It implies there something inhuman and barbarous, something more than the mere extinguishment of life." *Baze v. Rees*, 553 U.S. 35, 49 (2008) (quoting *In re Kemmler*, 136 U.S. 436, 447 (1890). Immediately after reaffirming this basic

⁹⁷ Counsel submit that five current justices have unequivocally agreed that the 8th Amendment categorically prohibits torture, regardless of the existence of an alternative. In reaching the count of five, neither the Chief Justice, nor Justice Alito are included. This is not to say that Roberts, C.J. and Alito, J. disagree that torture is prohibited, rather, unlike the five who are counted, their opinions contain a small measure of ambiguity.

principle, the plurality explained: "Petitioners do not claim that lethal injection or the proper administration of the particular protocol adopted by Kentucky by themselves constitute the cruel or wanton infliction of pain...Instead, petitioners claim that there is a significant risk that the procedures will *not* be properly followed." *Baze*, 553 U.S. at 49. It was in this context of risk or possibility, that the Supreme Court articulated the alternative requirement.

B. Justice Thomas rejects *Baze* and *Glossip* alternatives; he believes the 8th Amendment categorically prohibits torture; either a punishment is cruel and unusual or it isn't.

Justice Thomas,⁹⁸ joined by Justice Scalia, concurred in the result in *Baze*, but he refused to "subscribe to the plurality opinion's formulation of the governing standard." *Baze*, 553 U.S. at 94, (Thomas, concurring in result). Justice Thomas believes that the "Framers intended to prohibit torturous modes of punishment akin to those that formed the historical backdrop of the Eighth Amendment." *Id.* at 99. In rejecting the need for an alternative, he wrote: "It strains credulity to suggest that the defining characteristic of burning at the stake, disemboweling, drawing and quartering, beheading, and the like was that they involved risks of pain that could be eliminated by using alternative methods of execution." *Id.* at 101-02.

Since *Baze*, Justice Thomas has remained adamant that the 8th Amendment is a categorical guarantee. In *Miller v. Alabama*, Justice Thomas (again joined by

⁹⁸ Justice Thomas is the first Justice that Plaintiffs' counsel counts as part of the five current justices who explicitly would hold that the 8th Amendment prohibits torture, regardless of the existence of alternatives.

Justice Scalia) reiterated: "the Cruel and Unusual Punishments Clause, as originally understood, prohibits "torturous *methods* of punishment." *Miller v. Alabama*, 567 U.S. 460, 506 (2012) (Thomas, J. dissenting) (*emphasis* in original). In his concurrence in *Glossip*, Justice Thomas maintained that "the broader interpretation of the Eighth Amendment advanced in the plurality opinion in *Baze* is erroneous." *Glossip v. Gross*, 135 S. Ct. 2726, 2750 (2015) (Thomas, J., concurring).

C. No less than four additional justices join with Justice Thomas and agree that the 8 Amendment categorically prohibits torture.

Justice Thomas is joined by four current Justices of the U.S. Supreme Court in explicitly calling for a categorical approach to 8th Amendment violations. Justice Sotomayor, joined by Justices Breyer, Ginsburg and Kagan, wrote in dissent in *Glossip*: "This Court has long recognized that certain methods of execution are categorically off-limits." *Glossip*, 135 S. Ct. at 2793 (Sotomayor, J., dissenting).

Those four justices submitted that the 8th Amendment prohibits "inherently barbaric punishments *under all circumstances.*" *Id.* (quoting *Graham v. Florida*, 560 U.S. 48, 59, 130 S. Ct. 2011 (2010)). "Irrespective of the existence of alternatives, there are some risks 'so grave that it violates contemporary standards of decency to expose *anyone* unwillingly to." *Id.* at 2794 (quoting *Helling v. McKinney*, 509 U.S. 25, 36 (1993).

> D. Ultimately, the majority, and possibly a unanimity, of the United States Supreme Court hold that there is no need to plead an alternative to torture.

Thus, the four dissenters in *Glossip*, plus Justice Thomas, are firmly on the record as categorically objecting to torture—regardless of alternatives. Moreover, the Chief Justice (joined by Justice Alito) clearly acknowledged the controlling standard of *In re Kemmler*, when composing the plurality opinion in *Baze*. Justice Gorsuch has not yet had opportunity to weigh in as a Supreme Court Justice. However, he joined in a majority opinion, while on the 10th Circuit Court of Appeals, that reiterated the bedrock standards set-forth in *Kemmler* and *Wilkerson*: "the Eighth Amendment [disallows] punishments of torture ... and all others in the same line of unnecessary cruelty" and "punishments are cruel when they involve torture or a lingering death." *The Estate of Lockett by & through Lockett v. Fallin*, 137 S. Ct. 2298 (2017) (citing *Baze*, 553 U.S. at 48; *In re Kemmler*; 136 U.S. at 447; and *Wilkerson*, 99 U.S. at 136).

Thus, every Justice of the United States Supreme Court has either explicitly (five justices), or implicitly (three justices), agreed that there is a categorical line of cruelty, beyond which an execution cannot pass.

> 4. The United States Supreme Court's definition of a punishment that is so inhuman and barbarous that the 8th Amendment prohibits it: for four justices our protocol has already been found to be barbarous; for the Chief Justice and Justice Alito it would be an execution of a conscious inmate with a paralytic and potassium chloride.

The Chief Justice, joined by Justice Alito, wrote in *Baze* that:

It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride.

Baze, 553 U.S. at 53.

As discussed herein, Tennessee's three-drug protocol cannot render an inmate insensate to pain, and will, in fact, cause additional suffering beyond that envisioned in *Baze* due to the injection of a small bottle of acid into the inmate's veins producing pulmonary edema, and causing the inmate to drown in his own blood and bodily fluids. As Midazolam, unlike sodium thiopental, cannot render an inmate insensate to the misery of drowning, the suffering of suffocation or the horror of being chemically burned by potassium chloride, per the Chief Justice's formulation, our protocol is "constitutionally unacceptable." *Baze*, 553 U.S. at 53.

Four more justices have come out even more explicitly against our protocol, on a much more meager record. Justice Sotomayor's dissent in *Glossip*, joined by Justices Breyer, Ginsburg and Kagan, found that those petitioners were "at the very least likely to prove that, due to Midazolam's inherent deficiencies, there is a constitutionally intolerable risk that they will be awake, yet unable to move, while chemicals known to cause 'excruciating pain' course through their veins." *Glossip*, 135 S. Ct. at 2793 (Sotomayor, J., dissenting). Sotomayor then reiterated that the 8th Amendment prohibits "inherently barbaric punishments *under all circumstances.*" *Id.* at 2793 (quoting *Penry v. Lynaugh*, 492 U.S. 302, 330 (1989) (emphasis in original). Although the four justices did not further define what would

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qualify as "inherently barbaric," they implicitly made clear that injecting a sensate inmate with a paralytic and potassium chloride met this standard.

Thus, there are six justices who have concluded that using a paralytic and potassium chloride on a sensate inmate would be unconstitutional. That is sufficient to establish that Tennessee's protocol categorically violates the 8th Amendment.

5. The forms of execution that have been found to be cruel and unusual: the gas chamber and electrocution inflict pain and suffering similar to that inflicted in Tennessee's protocol.

Although a majority of the United States Supreme Court has not yet found any method of execution to be unconstitutional, at least two methods of execution have been found "cruel and unusual" by other courts: the gas chamber and electrocution. In *Fierro v. Gomez*, the district court found that California's use of the gas chamber violated the 8th Amendment based on the following factual findings:

[B]ased on the evidence presented at trial, the testimony of the experts and the scientific literature introduced as exhibits, the court finds that inmates who are put to death in the gas chamber at San Quentin do not become immediately unconscious upon the first breath of lethal gas. The court further finds that an inmate probably remains conscious anywhere from 15 seconds to one minute, and that there is a substantial likelihood that consciousness, or a waxing and waning of consciousness, persists for several additional minutes. During this time, the court finds that inmates suffer intense, visceral pain, primarily as a result of lack of oxygen to the cells. The experience of "air hunger" is akin to the experience of a major heart attack, or to being held under water. Other possible effects of the cyanide gas include tetany, an exquisitely painful contraction of the muscles, and painful build-up of lactic acid and adrenaline. Cyanide-induced cellular suffocation causes anxiety, panic, terror, and pain.

Fierro v. Gomez, 865 F. Supp. 1387, 1404 (N.D. Cal. 1994), *aff'd*, 77 F.3d 301 (9th Cir. 1996), *cert. granted, judgment vacated*, 519 U.S. 918 (1996), and *vacated sub nom. Fierro v. Terhune*, 147 F.3d 1158 (9th Cir. 1998).

The Ninth Circuit upheld the District Court's factual finding, and concluded that:

The district court's findings of extreme pain, the length of time this extreme pain lasts, and the substantial risk that inmates will suffer this extreme pain for several minutes require the conclusion that execution by lethal gas is cruel and unusual. Accordingly, we conclude that execution by lethal gas under the California protocol is unconstitutionally cruel and unusual and violates the Eighth and Fourteenth Amendments.

Fierro, 77 F.3d at 308-09.

The *Fierro* court followed *In re Kemmler* and its prohibition on executions involving torture or a lingering death. *Id.* at 306. The court also unfavorably compared the gas chamber to hanging (which it had upheld just two years earlier in *Campbell v. Wood*). *Id.* at 306-07. Further, the *Fierro* court distinguished its holding from that of the Fourth and Fifth Circuits that had both upheld poison gas. *Id.* at 308-09 (referencing *Gray v. Lucas,* 710 F.2d 1048 (5th Cir.1983) and *Hunt v. Nuth,* 57 F.3d 1327 (4th Cir.1995). In regards to the Fifth Circuit's decision, the Ninth observed:

Unlike the instant case, however, neither the district nor appellate court had the benefit of extensive expert witness testimony that had been subjected to searching cross-examination. Nor, apparently, did either court have the benefit of extensive prison medical records documenting inmates' deaths by lethal gas and the lengths of time that these inmates likely remained conscious after exposure to the gas.

Id. at 309.

The Ninth Circuit similarly discounted the Fourth Circuit's conclusion as also being based on a record that lacked both expert witnesses and "official records that set forth in detail what occurred in the gas chamber during an execution." *Id.* As the only appellate court that had the benefit of an "eight day trial," the Ninth Circuit was able to conclude that "execution by lethal gas is cruel and unusual." *Id.*

The primary source of unconstitutional suffering was "air hunger," *Fierro*, 865 F. Supp. at 1404, which is but one of the painful and terrifying components of Tennessee's protocol. The secondary painful stimuli from gas was identified as muscle contractions and the build-up of lactic-acid, *Id.* Here, inmates are drowning in bodily fluids, buried alive unable to cry out, suffocating, and then being injected with the excruciatingly painful "chemical fire" of potassium chloride. And this process lasts from 10-18 minutes. This pain and suffering is significantly more torturous than the "15 seconds to one minute" of suffering that could be followed by "several additional minutes" of "waxing and waning consciousness" that was struck down in *Fierro.* 875 F. Supp. at 1404.

Ultimately, with California's statutory adoption of lethal injection, plaintiffs were found to lack standing to challenge the gas chamber—thus, the judgment was vacated. *Fierro v. Gomez*, 519 U.S. 918 (1996), and *vacated sub nom. Fierro v. Terhune*, 147 F.3d 1158 (9th Cir. 1998). However, the Ninth Circuit reiterated its holding in *LaGrand v. Stewart*, in which it enjoined Arizona from executing anyone by means of lethal gas. 173 F.3d 1144 (9th Cir. 1999). The *LaGrand* court accepted Arizona's admission that the proof at trial would be no different than that presented in *Fierro*, and thus "[t]here appears to be no reason to put the parties to the ritual of creating a new record in this case to parallel *Fierro*. We already know what conclusion is compelled by that record." *Id.* Respectfully, the record in our case compels a similar conclusion.

Electrocution has also been found to be unconstitutionally cruel and unusual. In *Dawson v. Georgia* the Georgia Supreme Court held that "[t]he traditional humanity of modern Anglo-American law forbids the infliction of unnecessary pain in the execution of the death sentence." 554 S.E.2d 137, 142 (Ga. 2001) (quoting *Louisiana ex rel. Francis v. Resweber*, 329 U.S. 459, 463 (1947) (plurality opinion)). In rejecting electrocution, the Georgia Supreme Court was not worried about risks, rather, "we hold that death by electrocution, with its specter of excruciating pain and its **certainty of cooked brains and blistered bodies**, violates the [Georgia] prohibition against cruel and unusual punishments." *Id.* at 144 (emphasis added).

The Nebraska Supreme Court rejected electrocution with similar force, under that State's constitutional prohibition against cruel and unusual punishments^{99:}

Besides presenting a substantial risk of unnecessary pain, we conclude that electrocution is unnecessarily cruel in its purposeless infliction of physical violence and mutilation of the prisoner's body. Electrocution's

⁹⁹ Identical to the 8th Amendment to the United States Constitution: "Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." Neb. Con. Art. I, § 9.

proven history of burning and charring bodies is inconsistent with both the concepts of evolving standards of decency and the dignity of man. Other states have recognized that early assumptions about an instantaneous and painless death were simply incorrect and that there are more humane methods of carrying out the death penalty. Examined under modern scientific knowledge, "[electrocution] has proven itself to be a dinosaur more befitting the laboratory of Baron Frankenstein than the death chamber" of state prisons. We conclude that death by electrocution as provided in § 29–2532 violates the prohibition against cruel and unusual punishment in Neb. Const. art. I, § 9.

State v. Mata, 745 N.W.2d 229, 278 (Neb. 2008).

The Nebraska Supreme Court reached its ultimate conclusion after a lengthy and detailed factual analysis. *Id.* at 268-278. In this, the Court summarized the

underlying findings of the trial court:

First, high voltage causes intolerable pain sensations by direct excitation of peripheral sensory nerves. Second, electricity causes widespread excitation of brain neurons. Third, applying external electricity to the brain can damage brain neurons by interrupting their natural polarity and lead to the loss of neuron function. The court concluded, however, that the loss of function was most critical in the brain stem because those neurons are the most indispensable to respiration and life. Fourth, high voltage causes intense muscle contractions throughout the body, called muscle tetany. The muscles remain locked in full contraction as long as the current is applied. Fifth, high voltage will not cause fibrillation of the heart. Fibrillation is an arrhythmia in which the heart quivers in a chaotic pattern instead of intermittently contracting. Sixth, current flowing through the body will cause thermal heating, known as joule heating. But it is impossible to predict heating in any particular part of the body because of wide variations in the current flow.

Id. at 271.

The Court also concluded that "[b]urning of the prisoner's body is an inherent part of an electrocution." *Id.* at 269. The Nebraska Supreme Court adopted the trial court's finding that "some prisoner's would remain conscious for 15 to 30 seconds or during the entire application of the current...[and] some prisoners could revive and have revived and regained consciousness." *Id.* at 272.

The Court observed that pain was inherent in electrocution:

Obviously, a conscious prisoner would suffer excruciating pain from the electrical burning that is occurring in the body. But...there are other ways a high voltage current causes pain...[T]he electric current that did enter the brain would excite multiple areas in the brain known to cause pain when electrically stimulated. Also, alternating current, which alternates in polarity 60 times per second and is used in electrocutions, is known to repetitively excite nerve tissue...a prisoner would experience extreme air hunger because the prisoner cannot breathe while his or her diaphragm is rigidly contracted.

[A] prisoner experiences extreme pain and suffering from electrical stimulation of sensory nerves in the skin and muscles. [T]he skin is rich in nerve fibers with skin receptors that send messages to the brain when stimulated. Muscles also have pain receptors, so the violent contractions of muscles throughout the body would be painful. In addition, the heart's contraction is like the pain of a heart attack.

Mata, 745 N.W.2d at 277.

Finally, and most pertinent to our cause (and most relevant to the learned

Chancellor's finding that 10-18 minutes of pain is not unconstitutional), the

Nebraska Supreme Court concluded:

We reject the State's argument that electrocution would not be cruel and unusual punishment if a prisoner remained conscious for 15 to 30 seconds. Fifteen to thirty seconds is not a blink in time when a human being is electrically on fire. We reject the State's argument that this is a permissible length of time to inflict gruesome pain. It is akin to arguing that burning a prisoner at the stake would be acceptable if we could be assured that smoke inhalation would render him unconscious within 15 to 30 seconds.

Id. at 278.

Respectfully, the Supreme Court of Nebraska's analysis and logic is compelling, and their conclusion is directly on-point. Tennessee's protocol will result in many minutes of pain, suffering and anguish, not just 15 to 30 seconds. Those minutes are "not a blink of time when a human being is [chemically] on fire." Our protocol is, in the words of their learned Justices, something better fit for the laboratory of the Baron Frankenstein.

Ultimately, the facts of Tennessee' 10-18 minutes of suffering are much worse than the shorter periods of pain and suffering found unconstitutional by the Ninth Circuit and the Supreme Courts of Nebraska and Georgia.

g. This Honorable Court long-ago made clear that Article One, § 16 of the Tennessee Constitution prohibits punishments that involve "torture, lingering death, wanton infliction of pain, or like methods." This prohibition does not contain any comparative analysis; an inmate is not required to prove a readily feasible alternative to burning at the stake, or that reasonable transactional efforts would provide a substitute to drawing and quartering.

Without equivocation, this Honorable Court held in 2005 that "punishments may not include torture, lingering death, wanton infliction of pain, or like methods." *Abdur'Rahman v. Bredesen*, 181 S.W.3d 292, 306 (Tenn. 2005). In *Abdur'Rahman* this Court examined whether a lethal injection protocol that relied on the barbiturate, sodium Pentothal, as the first drug "offends either society or the inmate by the infliction of unnecessary physical pain and suffering." *Id.* at 307. Based on the evidence in that record, this Court concluded that inmates executed using a sodium Pentothal protocol, would not experience "any pain or discomfort;" thus it was constitutional. *Id.* at 308.

Abdur'Rahman expressly interpreted both the state and federal constitutional prohibitions against "cruel and unusual punishments." *Abdur-Rahman*, 181 S.W.3d at 305-06. This Court recognized that under either constitutional provision, torture was prohibited. *Id.* at 306.

Later in *West v. Schofield*, this Court explicitly addressed three claims: "(1) the [single drug Pentobarbital] protocol is unconstitutional because it creates a substantial <u>risk</u> of serious harm; (2) the protocol is unconstitutional because it creates a substantial <u>risk</u> of a lingering death; and (3) the trial court erred by dismissing their claim that the protocol is unconstitutional because it requires the State to violate federal drug laws." *West v. Schofield*, 519 S.W.3d 550, 552 (Tenn. 2017), *cert. denied sub nom. West v. Parker*, 138 S. Ct. 476 (2017), and *cert. denied sub nom. Abdur'Rahman v. Parker*, 138 S. Ct. 647 (2018), *reh'g denied*, 138 S. Ct. 1183 (2018) (emphasis added). The Plaintiffs' substantive claims in that facial challenge were limited to matters of <u>risk</u>, or "possibilities." *Id.* at 565. The *West* Court was not confronted with a claim that the protocol was torture, *per se*. Such a claim is presented here.

In in the 2017 *West* opinion, while examining the first claim, the risk of serious harm, this Court employed *Glossip's* analytical framework for resolving

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claims of "unacceptable risk of severe pain." *Id.* at 563. In denying relief, this Court determined that the *West* plaintiffs had failed to establish a "substantial risk of serious harm;" instead the dangers were "mere possibilities." *Id.* at 565.

This Court's resolution of the second claim, "Risk of Lingering Death," is of greater importance. This Court recognized that "punishments are cruel when they involve torture or a lingering death...." Id. at 566 (citing Estelle v. Gamble, 429 U.S. 97, 103 (1976) and In re Kemmler, 136 U.S. 436, 447 (1890)). In disposing of this claim, this Court did not require Plaintiffs to prove that they could provide a faster or less torturous method of death; rather this claim was dealt with on its substantive merits (which this Court found to be lacking): "[W]e decline to hold that a lethal injection protocol that causes unconsciousness within seconds violates the Eighth Amendment because it may take an hour or more for the inmate's heart to cease all electrical activity or because there may be some possibility that the inmate could be resuscitated after being declared dead...." Id. at 567. This Court declined to determine what would qualify as a lingering death, but noted that other precedents "imply strongly" that it takes longer than an hour, and would be a death during which "the inmate is consciously suffering." *Id.* The *West* plaintiffs did not claim "Torture," and thus this Court did not further address or define the issue.

1. Tennessee' definition of torture: the infliction of severe physical or mental pain upon [a human] while he or she remains alive and conscious.

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To the best of counsel's review, this Honorable Court has never defined "torture" in the Eighth Amendment and Article I, § 16 contexts (nor, for that matter, has this Court defined "lingering death" outside of the *dicta* in *West*).

Obviously, the proof in this case—unlike the proof in any other known lethal injection case heard by this Court or any court—was explicitly presented to establish that the condemned will suffer both severe physical and mental pain, while sensate and aware, and thus the condemned will be tortured. *Davidson*, 509 S.W.3d at 219; *Willis*, 496 S.W.3d at 730-31. The proof is unequivocal (and the Chancellor's findings are not to the contrary) the condemned's physical pain will be great, and he will suffer mental anguish. *Van Tran*, 864 S.W.2d at 486; *Irick*, 762 S.W.2d at 132. Pursuant to *Abdur'Rahman*, this torture violates the Tennessee constitution, Article I, § 16. 181 S.W.3d at 306.

2. Alternatives apply to risk, not certainty; we never can tolerate the needless infliction of suffering.

This violation of our protection against cruel and unusual punishments does not hinge on the existence of alternatives. Rather, this Court examined alternatives in the *West* context, where the issue was the risk or possibility of undesired events occurring during execution. In that context, this Court required that petitioners prove the existence of an alternative that entailed "a lesser risk of pain." *West*, 519 S.W.3d at 565. In the torture context, the issue is not risk—rather it is the unconstitutional inevitability that an inmate will suffer severe pain and mental anguish, while conscious. In *Glossip*, the Court held that the death penalty has been held to be constitutional, so it therefore follows that there must be a means to carry it out. But that simple proposition can be subject to abuse. It bears remembering that when the Supreme Court found the death penalty constitutional, and reversed *Furman*, it did so with caution:

As we have seen, however, the Eighth Amendment demands more than that a challenged punishment be acceptable to contemporary society. The Court also must ask whether it comports with the basic concept of human dignity at the core of the Amendment...Although we cannot "invalidate a category of penalties because we deem less severe penalties adequate to serve the ends of penology," the sanction imposed cannot be so totally without penological justification that it results in the gratuitous infliction of suffering.

Gregg v. Georgia, 428 U.S. 153, 182–83 (1976) (internal citations deleted).

Thus, under the Tennessee Constitution, as well as that of the United States, Tennessee's three-drug protocol must be struck down, regardless of alternatives,

because it involves torture, in that it inflicts severe pain, mental anguish and

needless suffering for the last lengthy minutes of the condemned's life.

h. We must reject the unconstitutional attack on freedom of conscience that is embodied in the State of Tennessee's claim that death row inmates deserve a torturous death as punishment for the actions of pharmaceutical companies who have declined to sell their healing products for use in the termination of life.

In closing argument, the State of Tennessee submitted that "[t]he reason [lethal injection drugs are] not available...is the death penalty opponents have applied pressure on drug manufacturers not to provide drugs for...lethal injection executions." Tr. July 23, 2018, L 67. No proof was presented at trial in support of this claim. *Established by omission from the trial record.* Nonetheless, the Chancellor appeared to agree with this contention, and invoked a much-abused passage from *Glossip*: "anti-death-penalty advocates pressured pharmaceutical companies to refuse to supply the drugs used to carry out death sentences." *Glossip*, 135 S. Ct. at 2733; XVI 2233.

Appellants object to the State's argument and the Chancellor's acceptance of it for multiple reasons. First, the Chancellor and State seem to confuse the limited persuasive powers of the men on death row and their court appointed counsel, with the incredible persuasive power of religious leaders and moral authorities around the world. *See* http://www.umc.org/what-we-believe/political-community#deathpenalty (last visited September 3, 2018 at 2:08 p.m.) (United Methodist Church position against the death penalty, which "denies the power of Christ to redeem, restore and transform all human beings"); Jane Onyanga-Omara, *Pope Francis changes Catholic Church teaching on death penalty, declares it 'inadmissible'*, USA TODAY (August 2, 2018, 11:22 a.m.),

https://www.usatoday.com/story/news/world/2018/08/02/pope-francis-changeschurch-teaching-death-penalty/887495002/; David Paulsen, *Atlanta Bishop rallies opposition to death penalty with book of articles by faith, legal leaders,* Episcopal News Service, February 12, 2018.¹⁰⁰

¹⁰⁰ Obviously, thousands of churches and church leaders, political figures, business executives, retired judges and former commissioners of departments of correction could be referenced in a string-cite that would cover thousands of pages. Appellants simply wish to make the point that many influential individuals, around the world, who are NOT members of any hypothetical "Death Penalty Abolitionist Organization," have spoken out against capital punishment.
Secondly, this claim does violence to modern Supreme Court precedents upholding religious liberty and the freedom of conscience.

Thirdly, this claim ignores the clearly established First Amendment Rights of corporations to participate in the political sphere.

Fourth, the implicit suggestion that some QAnon aligned secret cabal of death penalty abolitionists are responsible for Tennessee's "Drug Procurer's" ineptitude, indolence and perverse choice to fail (which the record clearly reflects is why Tennessee failed to purchase Pentobarbital post-*West* when there were no less than ten willing and able sellers) is completely unsupported by anything in the factual record. Ex. 105, *TDOC Documents re: Securing LICs*, at Vol. 10, pp. 1477, 1486-94, at Vol 11. pp. 1495-1512.

Fifth and finally, it is illogical and perverse to suggest that more painful forms of punishment are appropriate, because business leaders refuse to provide the tools for less painful executions.

The constitutional underpinnings of the second and third concerns will be developed further, below.

1. The First Amendment's free-exercise clause protects the religious liberty rights of individual citizens and corporations, so that they can choose, based on their own personal religious beliefs, not to participate in terminating human life.

The State's position, and the Chancellor's Order, unconstitutionally attack the religious liberties of citizens, including corporate leaders, who sincerely believe that they must follow the Commandment from God unto Moses on Sinai: "Thou shalt not kill."¹⁰¹

In *Burwell v. Hobby Lobby Stores, Inc.*, the Court upheld the religious liberty rights of three corporations to not purchase health insurance that provided certain forms of contraception. – U.S. –, 134 S. Ct. 2751 (2014). It was the sincerely held belief of the corporations that the contraceptives led to termination of a living fetus, which would be a "sin against God to which they are held accountable." *Id.* at 2764-66. *Hobby Lobby* explained that the free-exercise clause protects "not only belief and profession but the performance of (or absention from) physical acts...Business practices that are compelled or limited by the tenets of a religious doctrine fall comfortably within that definition." *Id.* at 2769-70 (internal citations deleted).

In *Masterpiece Cakeshop, Ltd. v. Colorado Civil Rights Com'n*, the Court upheld the religious liberty rights of a baker not to sell cakes that would be used to celebrate same sex weddings – U.S. –, 138 S.Ct. 1719 (2018). *Masterpiece Cakeshop* is explicit that under the free exercise clause of the First Amendment, the government "cannot act in a manner that passes judgment upon or presupposes the illegitimacy of religious beliefs and practices." *Id.* at 1731.

Both of these cases reject the position of death penalty advocates that it is somehow immoral for major drug corporations to decline to sell drugs that will be used in executions. These companies have a constitutionally protected religious

¹⁰¹ This would be the Sixth Commandment of the Jewish faith, and the majority of Protestant faiths, while it is viewed as the Fifth Commandment by the Catholic Church.

liberty to abstain from terminating life. *Hobby Lobby*, 134 S. Ct. 2769-70. They should be free from the moral judgment of the Attorney General that suggests that their belief in "Thou Shalt Not Kill" is illegitimate. *Masterpiece Cakeshop*, 138 S. Ct. at 1731.

2. Corporations have protected First Amendment Rights pursuant to *Citizens United*.

Implicit in the argument of the State and in the Chancellor's Order, is the conclusion that corporations must be unthinking and apolitical capitalist entities that are not entitled to moral judgment, and must, instead, sell their product to the highest bidder. If *Hobby Lobby* and *Masterpience Cakeshop* have not sufficiently put such a notion to rest, then *Citizens United* should.

Clearly, in modern America, corporations have the same First Amendment rights as individuals. *Citizens United*, 558 U.S. at 342 (enumerating all of the cases that recognize that "First Amendment protection extends to corporations"). "Political speech does not lose First Amendment protection 'simply because its source is a corporation." *Id.* (quoting *First Nat'l Bank of Boston v. Belloti*, 435 U.S. 765, 784 (1978)). Thus, just as an individual baker can choose not to sell his cakes for a purpose to which he objects, an individual corporation can choose not to sell drugs for use in ending human life.

3. The Tennessee Constitution, Article I, § 3 protects the rights of conscience to a greater extent than the First Amendment, and the Tennessee Preservation of Religious Freedom Act provides statutory relief for unconstitutional government burdens on religious liberty.

Article I, § 3, on its face, provides more comprehensive protections of religious liberty and "the rights of conscience" than does the First Amendment:

That all men have a natural and indefeasible right to worship Almighty God according to the dictates of their own conscience; that no man can of right be compelled to attend, erect, or support any place of worship, or to maintain any minister against his consent; that no human authority can, in any case whatever, control or interfere with the rights of conscience; and that no preference shall ever be given, by law, to any religious establishment or mode of worship.

Tenn.Con. Art. I, § 3.

The courts of Tennessee have long recognized that Article I, § 3 provides "substantially stronger" protections of religious liberty than the First Amendment. *State ex rel. Swann v. Pack*, 527 S.W.2d 99, 111 (Tenn. 1975);*Carden v. Bland*, 288 S.W.2d 718, 721 (Tenn. 1956) ("[O]ur own organic law is broader and more comprehensive in its guarantee of freedom of worship and freedom of conscience."); *Martin v. Beer Bd. for City of Dickson*, 908 S.W.2d 941, 946 (Tenn. Ct. App. 1995) (detailed historical analysis of Article I, § 3; notes "substantially stronger guaranty of religious freedom than its federal counterpart").

In 2009, with the enactment of the Tennessee Preservation of Religious Freedom Act (TPRFA), Tenn. Code. Ann. § 4-1-407, our legislature made a clear decision to favor religious liberty and freedom of conscience over governmental authority. In most relevant part, this act prevents the government from substantially burdening a person's free exercise of religion unless such a burden is "essential to further a compelling governmental interest, and the least restrictive means of furthering that compelling interest." T.C.A. § 4-1-407(c). The "Exercise of

Religion" protected by the TPRFA is defined by Article I, § 3 of the Tennessee Constitution and the First Amendment to the U.S. Constitution. T.C.A. § 4-1-407(a)(1). Thus, the definitions of free exercise found in *Cakeshop* and *Hobby Lobby* are applicable under the TPRFA. Plainly, the use of a pharmaceutical company's medications, outside of proper distribution controls, and in violation of contract, would run afoul of the TPRFA.

Just as a baker cannot be compelled by the government to decorate cakes in a manner that offends his religious values, under Tennessee law, drug manufacturers cannot be compelled to allow their intellectual property to be used for the termination of human life.

4. The constitutional rights of both citizens and corporations not to participate in executions must be respected; Plaintiffs ought not to be punished for those citizens exercising their constitutional rights.

When this Honorable Court reaches its conclusion on the merits of Plaintiffs' substantive claims, Plaintiffs hope that the illogical, unconstitutional and religiously intolerant position of the State will be rejected, and that the right of pharmaceutical companies not to participate in executions will be recognized. Moreover, the evidence-free claim that Billy Ray Irick, Ed Zagorski and their lawyers belong[ed] to a secret conspiracy to overbear the corporate will of multibillion dollar drug companies, must be finally put to rest.

It would be unfair to Plaintiffs if constitutional protections against torture were abandoned or reduced, based on a false-belief that the Plaintiffs are somehow responsible for the State's inability to kill them in a "more humane" manner. Indeed, it would be a perverse warping of democratic principles if the exercise of constitutional rights by corporations, religious leaders and a groundswell of citizens was used to justify Tennessee's wanton infliction of barbaric deaths on the condemned. Indeed, it would seem more rational to reconsider the very constitutionality of the death penalty, when essential members of the public are no longer willing to participate.

II. Defendants' promulgation of the Protocol violates Plaintiffs' substantive due process rights (Count VIII).

Plaintiffs are entitled to judgment in their favor on their claims that the Defendants' promulgation of the Protocol shocks the conscience and, thus, violates their substantive due process rights under the Fourteenth Amendment and Article 1, § 8 of the Tennessee Constitution. First, the evidence at trial proves that Defendants' actions in formulating the Midazolam based three-drug protocol meets the substantive due process standard applicable in this context—deliberate indifference—in that their actions were arbitrary, irrational, and so egregious that it shocks the conscience. Second, Defendants' argument that Plaintiffs' substantive due process claim is precluded by their Eighth Amendment claim has no merit.

> a. Defendants violated Plaintiffs' substantive due process rights. Their conduct in promulgating Protocol B was deliberately indifferent to Plaintiffs' rights and was arbitrary, irrational, and so egregious that it shocks the conscience.

"Substantive due process . . . is implicated where an executive agency of government acts in a manner that is (1) arbitrary, irrational or improperly motivated or (2) so egregious that it shocks the conscience." *Abdur'Rahman v. Bredesen*, 181 S.W.3d 292, 309 (Tenn. 2005) (citing *County of Sacramento*, 523 U.S. at 840; *Parks Properties v. Maury County*, 70 S.W.3d 735, 744 (Tenn. Ct. App. 2001)).

Analysis of a substantive due process claim "demands an exact analysis of circumstances," as "[d]eliberate indifference that shocks in one environment may not be so patently egregious in another." County of Sacramento, 523 U.S. at 850. Thus, the standard of liability varies in a substantive due process claim depending on the amount of time prison officials had to make decisions concerning inmate welfare. For example, "a much higher standard of fault than deliberate indifference has to be shown for officer liability in a prison riot," Id. at 852-53 (citing Whitley v. Albers, 475 U.S. 312, 320-21 (1986)), or where a motorist is killed during a highspeed chase by police officers, id. at 855, because officers in those situations must act "in haste, under pressure, and frequently without the luxury of a second chance." Id. (quoting Whitley, 475 U.S. at 320). Further, prison officials and police in these circumstances "calling for fast action have obligations that tend to tug against each other. Their duty is to restore and maintain lawful order, while not exacerbating disorder more than necessary to do their jobs." Id. at 854. Here, where prison officials had ample time to make a decision about the drugs to be used in an execution, deliberate indifference is the correct standard for a substantive due process claim.

The crux of Plaintiffs' substantive due process claim is that Defendants selected a method of execution without investigating the effects of using Midazolam as the first drug in the three-drug protocol despite an explicit warning from their

supplier about the ineffectiveness of Midazolam for use in an execution by lethal injection. This conduct is especially egregious given the history of litigation surrounding three-drug protocols. In September 2017, before Defendants adopted a Midazolam-based option, Defendants' Drug Supplier explicitly warned them by email that their "subjects may be able to feel pain from the administration of the second and third drugs" because Midazolam "does not elicit strong analgesic effects." The supplier suggested that the State "[c]onsider the use of an alternative."

From:	an a		
Sent: Thursday,	September 07,	2017 12:58 P	M
To: Subject: RE: Up	dtao		
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*** This is an EXTERNAL email. Please exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email - STS-Security. ***

Hello

That stuff is readily available along with potassium chloride. I reviewed several protocols from states that currently use that method. Most have a 3 drug protocol including a paralytic and potassium chloride. Here is my concern with Midazolam. Being a benzodlazepine, it does not elicit strong analgesic effects. The subjects may be able to feel pain from the administration of the second and third drugs. Potassium chloride especially. It may not be a huge concern but can open the door to some scrutiny on your end. Consider the use of an alternative like Ketamine or use in conjunction with an opioid. Availability of the paralytic agent is spotty. Pancuronium, Rocuronium, and Vecuronium are currently unavailable. Succinylcholine is available in limited quantity. I'm currently checking other sources. I'll let you know shortly.

Regards,

Ex. 114, *Sept. 7, 2017 Email from Drug Supplier to Drug Procurer*, at Vol. 12, p. 1628. Trial testimony establishes that, although the email put Defendants on notice that using Midazolam would lead to Plaintiffs' suffering, they failed to heed the supplier's warning by inquiring with the supplier or other qualified experts about the problems with using Midazolam as the first drug in a lethal injection protocol.

Courts impose liability for mere deliberate indifference where prison officials

do not encounter "unforeseen circumstances demand[ing] an officer's instant judgment." *Id.* at 853. "[L]iability for deliberate indifference to inmate welfare rests upon the luxury enjoyed by prison officials of having time to make unhurried judgments, upon the chance for repeated reflection, largely uncomplicated by the pulls of competing obligations. When such extended opportunities to do better are teamed with protracted failure even to care, indifference is truly shocking." *Id.*

Defendants in this case had the luxury to make unhurried judgments to select drugs for the State's lethal injection procedure that would not cause Plaintiffs needless suffering, and they were deliberately indifferent for failing to do so. Commissioner Parker testified that he was the primary individual responsible for making the decision to use Midazolam. Yet, he did not even take the time to contact the Drug Supplier to ask about the supplier's email warning that Midazolam would not keep Plaintiffs from experiencing pain and that the State should consider alternative drugs. Nor did he delegate that call to a subordinate. Instead, Commissioner Parker chose to rely on people he personally knew—likely leaders of other departments of corrections who are also political appointees—rather than experts that could have informed him about the severe risk inherent to Midazolam. This choice to ignore an explicit warning from the State's own supplier and failure to investigate the destructive effects of the use of a bolus dose of Midazolam as part of an execution protocol was arbitrary and irrational to the point of shocking the conscience. When Defendants chose Midazolam as the first drug in their three-drug protocol they were aware that its use is controversial and is associated with

numerous problematic executions. Defendants had "extended opportunities to do better," in choosing a humane lethal injection protocol.¹⁰² Their failure to do so, "teamed with protracted failure even to care," "is truly shocking." *Id.*

Defendants conduct is more egregious when viewed in light of the Department's knowledge of the agony, suffering, and torture that Plaintiffs will experience from the second and third drugs if Midazolam does not render them insensate. Also troubling is the Departments history of intransigence and failure to correct known deficiencies – even in the face of proof from their own experts.

Tennessee's first two executions (Coe and Alley) used a three-drug cocktail that used the barbiturate sodium thiopental as the first drug. This protocol was "copy-catted" from other states. Ex. 106, *Abdur'Rahman v. Sundquist*, Ex. Vol. 106. On February 1, 2007, Governor Bredesen revoked the protocol which he referred to as a "cut and paste job." Ex. 107, *Executive Order*, at Vol. 16. At the request of Governor Bredesen a committee was formed to study the state's lethal injection protocol. Debbie Inglis was on the committee. The committee recommended a one drug protocol which is what their expert recommended. The Commissioner rejected the committee's recommendation, and readopted the controversial three-drug protocol on April 30, 2007. On May 9, 2007, Philip Workman was executed.

On September 19, 2007, after hearing testimony from gubernatorial and TDOC officials, the lethal injection protocol which had been used to execute Coe, Alley, and Workman was declared unconstitutional by the United States District

¹⁰² Nothing prevented Defendants from stockpiling API for pentobarbital.

Court for the Middle District of Tennessee. Ex. 108, *Harbison v. Little*, 511 F. Supp. 872 (M.D. Tenn. 2007), Ex. Vol. XI 1534. Significantly, the Court held that: 1) there was a substantial risk that the inmates would remain conscious; 2) there was no consciousness check: 3) executioners were not adequately trained; 4) administration of the drugs was not adequately monitored; 5) the State knowingly disregarded an excessive risk by failing to follow the committee's recommendation to use a one-drug protocol, adequately train the executioners, and implement appropriate safeguards. Though this order was later vacated by the Sixth Circuit, the district court fact findings were not overturned. Many of these same risks continue today. On February 4, 2009, Steve Henley was executed. On December 2, 2009, Cecil Johnson was executed.

On November 22, 2010, Chancellor Bonnyman struck down the lethal injection protocol that was used to execute Coe, Alley, Workman, Henley and Johnson. Ex. 109, *West v. Ray*, No. 10-1675-I. Chancellor Bonnyman's ruling echoed the federal district court's ruling in *Harbison*.¹⁰³ Two days after the Chancellor's order, the TDOC relented and adopted a consciousness check. In 2011, the State of Tennessee illegally obtained sodium thiopental which was seized by the DEA. No Tennessee inmate has been executed under the three-drug protocol struck down by Chancellor Bonnyman.

On September 27, 2013, the State adopted a single drug protocol. From that date until June 20, 2018 (the date of Parker's deposition), the State maintained that

¹⁰³ Harbison was granted executive clemency.

they could obtain pentobarbital for executions. The State did not eliminate pentobarbital as an option in the protocol until July 5, 2018. The trial proof established that between September 27, 2013 and October 19, 2017, eleven midazolam-based executions took place where the inmate demonstrated physical signs that he was sensate and in pain during the execution: Dennis McQuire, Paul Howell, Clayton Lockett, Joseph Wood, Christopher Brooks, Ronald Smith, Ricky Gray, Kenneth Williams, Ronald Phillips, Garry Otte, and Torrey McNabb. *See* Attachment A, Timeline of Indifference.

In spite of all of this, TDOC adopted a midazolam-based three drug protocol. And, instead of adopting safeguards to protect the inmates, defendants took affirmative action to conceal signs of consciousness increasing the risks to the inmate because these measure interfere with the Warden and Executioner's ability to recognize evidence that the inmate is experiencing pain. These measures include the strap configuration on the gurney and the act of taping the inmates' hands to the gurney. Both of these measures prevent movement in a sensate and aware inmate. Nevertheless Billy Irick did move and strain against the straps after the consciousness check.¹⁰⁴

The use of vecuronium bromide in the protocol is intended to conceal the pain and suffering of the condemned. So too is the modification to the execution gurney

¹⁰⁴ Recently obtained records show that TDOC did not have the required back-up dose of Midazolam prepared. In fact, the Midazolam that was used was prepared two hours after the other drugs and within a minute of injection. The records are troubling and still being reviewed.

which now straps down the shoulders and chest of the inmate which will further prohibit him from alerting officials to the fact that he is aware and sensate. The modification was intentional. The only purpose for these measures is to conceal the ineffectiveness of the Midazolam from the public. The failure of the State to purchase and use an EKG, EEG or BIS monitor, when such monitors were important to the Court in *Glossip* is similar evidence of the Department's indifference. The failure to do so is intentional. When one considers that the EKG strip shows that Joseph Wood's heart was still beating when he was declared dead, one can imagine why TDOC refuses to employ these safeguards.

The Plaintiffs have shown a violation of their substantive due process rights. Accordingly, they respectfully request that the Court declare that the July 5, 2018 protocol violates the Eighth and Fourteenth Amendments and Article 1, § 8 of the Tennessee Constitution as it violates substantive due process and shocks the conscience.

b. Plaintiffs' substantive due process claim is not barred by their method-of-execution claim.

The Chancery Court erroneously held that Plaintiffs' substantive due process claim was subsumed by Plaintiff's method of execution claim. XVI 2264. This misconstrues Plaintiffs' substantive due process claim, which does not challenge the *use* of Midazolam—*that* is their method-of-execution challenge (Count I)—but instead alleges that the *process* by which Defendants decided to use Midazolam in its protocol shocks the conscience. The Chancery Court also misconstrues the law in this area.

This Court decided on the merits a substantive due process claim brought by inmates challenging an execution protocol, even though the inmates also had a method-of-execution claim under the Eighth Amendment and Tennessee constitutions. Abdur Rahman, 181 S.W.3d at 309.105 There, the Court rejected the inmates' substantive due process claim, concluding that there was "nothing arbitrary, irrational, improper or egregious in the Department of Correction following the legislative mandate to implement lethal injection as a method of punishment" or "in the manner in which the Department implemented a lethal injection protocol, i.e., by studying the lethal injection protocols of other states and the federal government and by using those protocols as models for the creation of Tennessee's protocol." Id. at 310. The Court also based its decision on its conclusion that the inmates had not prevailed in their "cruel and unusual punishment issue" as there was no evidence that the State's lethal injection protocol in place at the time created "an unreasonable risk of unnecessary pain and suffering." Id. The facts underlying Plaintiffs' substantive due process claim in this case are different than those raised in the 2005 Abdur'rahman case, and do, in fact, constitute a substantive due process violation.

¹⁰⁵ In another context, the Tennessee Court of Appeals stated: "We know of no State court authority stating that a substantive due process claim cannot be brought when another provision of the State constitution could also apply to the conduct or injury alleged." *Consolidated Waste Systems, LLC v. Metropolitan Government of Nashville & Davidson County*, No. M2002-02582-COA-R3CV, 2005 WL 1541860 at *25 (Tenn. Ct. App. June 30, 2005) (upholding a finding that a zoning ordinance violated a would-be developer's equal protection rights and also his substantive due process rights based on its arbitrariness).

It is also clear under United States Supreme Court jurisprudence that Plaintiffs can pursue both an Eighth Amendment claim and a substantive due process claim because the challenged government behavior is sufficiently distinct. In *City of Sacramento*, the Supreme Court considered a claim brought under 42 U.S.C. § 1983 alleging that police officers violated the Fourth Amendment rights of a motorcyclist who died while they pursued him at high speeds. Id. at 836-37. The Court rejected the officers' argument that the plaintiffs' substantive due process claim was improper because it was "necessarily governed by a more definite provision of the Constitution"—the Fourth Amendment. Id. at 841-42. The Court held that "s]ubstantive due process analysis is i inappropriate in this case only if respondents' claim is 'covered by' the Fourth Amendment. It is not." Id. at 843. As the Supreme Court held, "[w]here a particular Amendment provides an explicit textual source of constitutional protection against a particular sort of government behavior, that Amendment, not the more generalized notion of substantive due process, must be the guide for analyzing these claims." *City of Sacramento*, 523 U.S. at 842 (quoting Albright v. Oliver, 510 U.S. 266, 273 (1994) (plurality opinion of REHNQUIST, C.J.) (quoting Graham, 490 U.S. at 395 (emphasis added). However, as the Court noted several times. Graham

does not hold that all constitutional claims relating to physically abusive government conduct must arise under either the Fourth or Eighth Amendments; rather, *Graham* simply requires that if a constitutional claim is covered by a specific constitutional provision, such as the Fourth or Eighth Amendment, the claim must be analyzed under the standard appropriate to that specific provision, not under the rubric of substantive due process. *Id.* at 843 (quoting *Lanier*, 520 U.S. at 272, n. 7). As a result, courts allow substantive due process claims to proceed alongside Fourth or Eighth Amendment claims where each claim challenges distinct government conduct.¹⁰⁶

Here, the "particular sort of government behavior" challenged by Plaintiffs' method-of-execution claim is different than that challenged in their substantive due process claim. *Id.* at 842. Plaintiffs' substantive due process claim relates to Defendants' adoption of an execution protocol that they were explicitly warned would cause Plaintiffs' to experience constitutionally intolerable pain. It is about the Defendants' decision-making process. That claim is not—and *cannot*—be "covered by" their method-of-execution claim. *City of Sacramento*, 523 U.S. at 843.

III. The protocol violates plaintiffs' right to counsel and access to courts. (Count V).

The Protocol violates Plaintiffs' right to counsel and access to the courts under the First, Eighth, and Fourteenth Amendments to the United States Constitution and Article 1, §§ 8, 16, and 17 of the Tennessee Constitution in the following ways: (1) from the observation room, attorneys cannot observe the

¹⁰⁶ For example, a district court in Wisconsin allowed a substantive due process claim as well as a Fourth Amendment claim against a police officer who allegedly sexually assaulted a woman while responding to a call she made for police assistance. *Lemons v. City of Milwaukee*, No. 13-C-0331, 2016 WL 3746571, at *16 (E.D. Wis. July 8, 2016). The *Lemons* court also noted that the Seventh Circuit has recognized and permitted substantive due process in the context of claims by victims of sexual assault by law enforcement. *See Alexander v. DeAngelo*, 329 F.3d 912, 916 (7th Cir. 2003); *Wudtke v. Davel*, 128 F.3d 1057, 1063 (7th Cir. 1997).

syringes, and therefore cannot ascertain the sequence and timing of the injections from the different syringes;¹⁰⁷ (2) the vecuronium bromide is a paralytic, which will prevent the attorney from recognizing any signs of the inevitable suffering when the Midazolam fails to prevent serious pain and suffering;¹⁰⁸ (3) the official witness room does not provide a telephone for Plaintiffs' attorney to contact co-counsel or the court in the foreseeable event that the execution process results in unnecessary and constitutionally intolerable pain;¹⁰⁹ and (4) does not permit an additional defense counsel witness to be present forcing the only defense counsel witness to leave the official witness room in search of a phone should it be necessary to contact the court, leaving the condemned inmate with no counsel in the official witness room.¹¹⁰

Plaintiffs' proof at trial established the real barriers to observation that defendants place between counsel and her client. Federal Public Defender Ben Leonard took detailed measurements of the execution chamber and official witness room. XXXIII 891.He provided those measurements to the Court. *Id.* 897; Ex. 83, *Ben Leonard's Diagram of the Execution Chamber*, at Vol. 8, p. 1185. He prepared a schematic of the gurney. XXXIII 897. He identified photos of the chamber and the gurney during his testimony. XXXIII 905-15; *see also*, Exhibits 85-93, *Photographs*

¹⁰⁷ The proof established that other states now permits defense counsel to view the pushing of the syringes.

¹⁰⁸ The proof established that Arizona has agreed to never again use a paralytic. ¹⁰⁹ Defendant Parker was agreeable to providing telephone access during his deposition then reversed his position afterward.

¹¹⁰ Defendant Parker was agreeable to allowing a second attorney to be present during executions then reversed his position afterward.

of the Execution Chamber, at Vol. 8, p. 1187-95. Mr. Leonard described the strap configuration of the gurney and how the straps were bolted to the gurney. *See also* Ex. 84, Ben *Leonard's Diagram of the Execution Gurney*, at Vol. 8, p. 1186. He also described the number of video cameras and telephones with landlines present in the execution chamber and official witness room. *Id.* 916.

Witnesses Julie Hall, Dale Baich, and Robin Konrad provided graphic testimony regarding the harm that befell their client, Joseph Wood, when they were prohibited access to a telephone in the execution chamber. XXV 222-290; XXV-XXVI 291-311; XXVII 325-468. Carol Wright described similar problems. XXX 698-99. Six of the other seven jurisdictions that have used Midazolam do not limit the attorney witnesses to just one witness. *See generally*, XXVII 325-468 (multiple attorney witnesses in Arizona); XXI 766-793 (Alabama, same); XXXI 794-816 (Florida, same); XXXI 816-30 (Arkansas, same); XXXI 830-48); XXXI 850-70 (Oklahoma, same). The remaining jurisdiction, Ohio, has a telephone placed in a position where the attorney can continue to view the execution chamber while on the phone with the Court. XXX 670.

"It is clear that prisoners have a constitutional right to have meaningful access to the courts" *Lewis v. Casey*, 518 U.S. 343, 347 (1996). The "right to file for legal redress" is more valuable to a prisoner than to any other citizen: "Inasmuch as one convicted of a serious crime and imprisoned usually is divested of the franchise, the right to file a court action stands . . . as his most 'fundamental political right, because [it is] preservative of all rights."" *Thaddeus–X v. Blatter*, 175

F.3d 378, 391 (6th Cir. 1999) (quoting *Hudson v. McMillian*, 503 U.S. 1, 15 (1992)) (Blackmun, J., concurring in the judgment). Thus, "inmate access [must be] adequate, effective and meaningful." *Bounds v. Smith*, 430 U.S. 817, 822 (1977). In evaluating a claim of denial of meaningful access to the courts, courts must "weigh[] the interests of the prison as an institution (in such matters as security and effective operation) with the constitutional rights retained by the inmates." *Thaddeus–X*, 175 F.3d at 390; *see also Turner v. Safley*, 482 U.S. 78, 89–91 (1987). In order to raise a claim, a prisoner must demonstrate that he "ha[s] suffered, or will imminently suffer, actual harm." *See Lewis*, 518 U.S. at 349; *accord Hadix v. Johnson*, 182 F.3d 400, 404–06 (6th Cir.1999).

The United States District Court for the Middle District of Tennessee held that an inmate

has the right under the First, Eighth and Fourteenth Amendments to have some access to his counsel during the last hour before the execution and to have his counsel witness the execution, from either the witness room or a room with closed circuit live television transmission. His counsel must have access to a telephone with an unimpeded outside line *at the time* that he or she witnesses the execution.

Coe v. Bell, 89 F. Supp. 2d 962, 967 (M.D. Tenn.), *vacated as moot*, 230 F.3d 1357 (6th Cir. 2000) (emphasis added). The district court held "given society's (and the state's) interest in assuring that capital punishment is carried out in a humane manner and the minimal inconvenience to the state, this court finds the plaintiff's position well taken." Thus, the court held that inmate Coe was "entitled to an injunction prohibiting Defendant from preventing his counsel from witnessing Plaintiff's execution in order to safeguard Plaintiff's constitutional right of access to

the courts to address violations of his Eighth Amendment right against cruel and unusual punishment." *Id.* Although the Sixth Circuit vacated the district court's injunction on appeal, that was only because the case was moot and did not fit the capable-of-repetition-yet-evading review exception to the mootness doctrine, partly because an inmate in Coe's position would have time to litigate the issue again and partly because Tennessee had subsequently enacted a statute providing an inmate the right to have counsel present for his execution. *Id.; see* Tenn. Code Ann. § 40-23-116(8).

The district court's reasoning in *Coe* is sound and should be followed here. Pursuant to the statute passed after the holding in *Coe*, Defendants now permit one counsel to be physically present for Plaintiffs' executions. However, given the nature of the new three-drug protocol—exacerbated by Defendants' new plan to use compounded drugs—counsel's mere presence is not sufficient to ensure Plaintiffs' right to counsel and the courts. Plaintiffs have an actual injury, in that their executions are sure or very likely to be unnecessarily painful, yet their counsel will be unable to observe the painfulness of the execution or reach the courts to seek redress. Plaintiffs' demonstrated that Midazolam is incapable of rendering inmates insensate to pain, which makes it particularly dangerous for Defendants to couple with a paralytic that makes it impossible for Plaintiffs to show—and their counsel to observe—that they are suffering. Given the known ineffectiveness of Midazolam and the lack of any instruction in the Protocol for the timing of the syringe pushes, counsel must be able to see the sequence and timing of the injections from the different syringes, see the inmate well enough to observe indications that he has awareness and is experiencing pain, and have access to an outside telephone line to contact the court to alert it to any Eighth Amendment violation during an execution.

As Plaintiffs have shown that they will "imminently suffer [] actual harm," *Lewis*, 518 U.S. at 349, by lack of access to counsel and the courts, their constitutional rights must be weighed against the prison's interests in such matters as security and effective operation. *Thaddeus–X*, 175 F.3d at 390. Defendants have given no persuasive justification for not allowing counsel the access they request.

The only concerns Defendants have offered for allowing counsel a better view of the syringes and the inmate is that counsel not be able to see the executioner's face. But Defendants could set up a video monitor to allow counsel a closer observation of the injection site, the syringe pushes, and the inmate's face without allowing counsel to see the executioner's face. V 647-50 (Sealed deposition).

As to the use of the paralytic, Defendants have offered no justification, Commissioner Parker agreed that an execution could be carried out without the paralytic. XXXVII 1316.

As to the use of a phone line, Ms. Inglis' testimony is illuminating. She was clear that the reason the department deprives counsel of a phone is because she does not want them to call the Court and possibly have the Court interrupt an execution:

Q: Do you see any problems with having a phone in there for the defense attorney?

A: I do see some issues.

Q: What issues?

A: Yes. I mean, there's not to be any photographing or recording. That's one. The other would be interruption of an execution without knowing sort of - the Court not having enough information to make a decision about what would happen if an execution was staying in the middle of it.

Q: But would you agree that if a lawyer is not permitted to hae a phone to call the Court if a problem comes up, that the execution may go forward in a manner that would be unconstitutional?

A Well, no. I'm not going to agree with that, but the attorney can leave and call the Court.

XL 1648-49. Inglis admits that it is Defendant's intent to deprive the inmate access to the Courts.

Commissioner Parker testified in deposition that he saw no problem with allowing counsel to have an outside phone line. (Parker Dep. at 274:19-22 ("I would certainly not be opposed in any way to providing the attorneys access to communications that they would need to do their job."); *see also* 273:23- 274:1.) However, counsel for Defendants immediately retracted that offer by email communication, without explanation. This Court should allow Plaintiffs access to a phone line, just as the district court enjoined the Riverbend Warden to provide to Coe's counsel. Plaintiffs' constitutional rights clearly outweigh Defendants' concerns, all of which can be accommodated in a manner that protects Plaintiffs' rights.

In a recent dissent from the Supreme Court's denial of an application for stay

of execution and denial of certiorari, Justice Sotomayor articulated perfectly

inmates' right to counsel and to access to the courts:

I continue to doubt whether Midazolam is capable of rendering prisoners insensate to the excruciating pain of lethal injection and thus whether Midazolam may be constitutionally used in lethal injection protocols. . . . When prison officials seek to limit that right, the restriction is permitted only if "it is reasonably related to legitimate penological interests." Turner v. Safley, 482 U.S. 78, 89 (1987). Here, the State has no legitimate reason-penological or otherwise-to prohibit Arthur's counsel from possessing a phone during the execution, particularly in light of the demonstrated risk that Midazolam will fail. See Arthur, 580 U. S., at ——, 137 S. Ct., at 733 (detailing "mounting firsthand evidence that Midazolam is simply unable to render prisoners insensate to the pain of execution"). To permit access to a telephone would impose no cost or burden on the State; Arthur's attorneys have offered to pay for the phone and provide it for the State's inspection. The State's refusal serves only to frustrate any effort by Arthur's attorneys to petition the courts in the event of yet another botched execution. Its action means that when Thomas Arthur enters the execution chamber tonight, he will leave his constitutional rights at the door.

Arthur v. Dunn, 137 S. Ct. 1521, 1522 (Sotomayor, J., dissenting) (some citations omitted). Although the Supreme Court did not decide to grant cert in the *Arthur* case, that cannot be interpreted as a repudiation of Justice Sotomayor's concerns given the small percentage of cases in which the Court grants certiorari and the myriad reasons it my deny certiorari in any particular case. Justice Sotomayor's opinion is persuasive authority on the merit of Plaintiffs' claims that Defendants have "no legitimate reason—penological or otherwise—to prohibit their counsel from having phone access to the court during an execution." *Arthur*, 137 S. Ct. at 1522.

The Chancery Court erroneously held that Plaintiffs' claim is based on

speculation that something may go wrong. Plaintiffs have reliable scientific evidence that Midazolam is scientifically incapable of rendering an inmate insensate to pain, thus assuring the need for counsel to observe the execution better than they currently are able given the configuration of the execution chamber and the need for counsel to be able to reach the court to seek relief. Where *Glossip* emphasized the importance of safeguards, the safeguards addressed in Count V (removal of the paralytic, access to a phone, additional counsel in the chamber, and the ability to view the syringes) are all important safeguards.

These safeguards were lacking in Mr. Irick's execution. As a result, the Department did not follow their protocol because no back-up syringes of Midazolam were prepared. *See* Attachment A to Motion to Expand the Record, TDOC Public Records. Mr. Irick showed signs of awareness and sensation, and yet the Warden proceeded with the execution. *See* Attachment B to Motion to Expand the Record, September 2, 2018 *Declaration of Dr. David Lubarsky*.

The Court's reliance on *Whitaker v. Collier*, 862 F.3d 490 (5th Cir. 2017), which is misplaced. XVI 2274. Unlike *Whitaker*, plaintiffs do not allege a Sixth Amendment right-to-counsel claim. Second, the plaintiffs in *Whitaker* had only speculative evidence about potential mishaps and did not plead that the protocol violated the Eighth Amendment on its face. Here, Plaintiffs do not claim that they will suffer because of a mishap. They have pled that they will suffer when the protocol is carried out as intended. *Arthur v. Comm'r*, 680 F. App'x 894, 901-10 (11th Cir. 2017), is also unavailing because, unlike Arthur, Plaintiffs here proved an

Eighth Amendment violation.

To the extent that T.C.A. § 40-23-116 is interpreted as preventing more than one defense counsel witness to be present during an execution, then it is unconstitutional because there is no compelling reason to exclude an additional attorney and the inmates right to counsel at execution is fundamental. *See Planned Parenthood of Middle Tenn. v. Sundquist*, 38 S.W. 1 (2000).

For these reasons, Plaintiffs respectfully request that this Court reverse the judgment of the Chancery Court and hold that the July 5, 2018 Protocol violates the First, Eighth, and Fourteenth Amendments to the United States Constitution and Article 1, §§ 8, 16, and 17 of the Tennessee Constitution, as the protocol (1) fails to provide Plaintiffs' counsel adequate visual access to the execution to allow proper monitoring of the proceedings; and (2) fails to provide telephone access between Plaintiffs' counsel, and the courts, which violates Plaintiffs right to access the courts.

IV. The trial court's denial of Plaintiff Edmund Zagorski's motion to amend the complaint to raise an as-applied challenge to the unqualified Drug Supplier/Compounder was an abuse of discretion.

Plaintiffs first learned of the Department's intent to compound Midazolam on June 21, 2018. Less than an hour before the deposition of Debbie Inglis, counsel for Defendants called Plaintiffs' counsel to inform them that he had just learned of the intent to compound Midazolam. During Inglis' deposition, Plaintiffs learned that Defendants intended to have their secret supplier compound the Midazolam. Prior to the deposition, Plaintiffs did not know, and could not know, that the Defendants intended to use this drug supplier to compound the drugs for then-protocol B.

The January 8, 2018 protocol did not explicitly indicate, or even suggest, that compounded drugs might be used for the three-drug Midazolam protocol, then called "Protocol B." In fact, it was the opposite: the Protocol indicated that the 3drug protocol would use commercially manufactured chemicals. The "Procurement" instructions for the 3-drug (Midazolam) protocol require the RMSI procurement officer to contact "the Procurement Officer at DeBerry Special Needs Facility (DSNF) to order the needed chemicals." Ex. 1, 1/8/2018 Lethal Injection Manual, at Vol. 1, p. 37. DeBerry Special Needs facility has a pharmacy license and therefore can order commercially manufactured chemicals. TE Vol. XL, p. 1615 (testimony of TDOC Deputy Commissioner and general counsel Debbie Inglis). This is inn contrast to the "Procurement" instructions for then-Protocol A (pentobarbital), which required the warden to obtain a physician's order and submit that to a pharmacy. Moreover, Plaintiffs' counsel were aware that the West v. Schofield decision had upheld the use of compounded pentobarbital. On its terms, the January 2018 lethal injection manual made a plain distinction in the source and nature of the chemicals to be used for the two protocols. Moreover, at the time of Ms. Inglis's deposition, Plaintiffs had received discovery productions and Tennessee Public Records Act productions from TDOC that contained email communications, invoices, and photographs that all indicated TDOC had acquired manufactured

chemicals for the 3-drug Protocol B.

If, as the Chancery Court concluded, the January 2018 protocol manual gave notice that TDOC may use compounded chemicals for the 3-drug Protocol B, then there was no reason for Defendants' counsel to call Plaintiffs' counsel to give notice of the compounding plan, nor was there need for TDOC to revise the Protocol manual to explicate the use of compounded Midazolam.¹¹¹

At the time that Plaintiffs learned this information from Defendants' counsel, they knew the identity of the State's secret supplier for manufactured Midazolam, from information in documents that were produced by the State in response to a Public Records Act request. Plaintiffs knew that the supplier was not licensed in its home state for high-risk sterile compounding, as required to compound Midazolam.¹¹² Other 5, Ex. 1 (sealed). Plaintiffs also knew that the compounder was not licensed in Tennessee – at all. They further knew that the owner had been subject to discipline by the owner's state Board of Pharmacy for failing to reveal a conviction of a misdemeanor crime on the individual's Application for Pharmacy License and that the chief pharmacist had been disciplined by the state Board of Pharmacy for failing to Pharmacy for failing to properly supervise a pharmacy employee. Other 5, Ex. 2 (sealed). They

¹¹¹ From the recently produced TDOC materials, it appears that the protocol continues to evolve. Apparently, the drugs for Mr. Irick's execution were mixed at the prison at the last minute. They were also frozen, rather than refrigerated, although the protocol calls for the drugs to be maintained at room temperature in a heavy gauge steel container. There is no evidence that RMSI has a freezer for the storage of lethal injection drugs.

¹¹² The secret source's website specifically stated that it was updating its clean room and only engaged in non-sterile compounding, meaning it did not have the necessary license to compound Midazolam.

knew. Other 5, Ex. 3 (sealed). This knowledge was reason for Plaintiffs <u>not</u> to believe or suspect that Defendants would acquire compounded lethal injection chemical from that source. Therefore Plaintiffs could not have known any earlier than June 21, 2018, when they received explicit notice that the Defendants would actually use a non-licensed pharmacist with a history of disciplinary problems with its state Board of Pharmacy to compounded Midazolam.

Upon learning of Defendants' intention to compound Midazolam for the upcoming scheduled executions, Plaintiffs acted with haste to amend their complaint to add claims related to this development. On June 25, 2018, four days after Ms. Inglis' deposition, Plaintiffs filed a motion alerting the court to these problems with the State's drug supplier and requesting, among other things, leave to amend their complaint to add factual allegations and new legal claims regarding the unwritten protocol involving the use of compounded Midazolam and to add as-applied claims on behalf of Plaintiffs Irick, Zagorski, and Miller, the plaintiffs with execution dates already set. IX 1150-1227 (Pls.' 6/25/15 mot. and exhibits regarding compounded Midazolam) at 1151-52, 1160, 1163. On June 26, 2018, the court ordered Defendants to respond to Plaintiffs' allegations about their drug supplier. IX 1233-39. On June 27, 2018, the court ruled that it would hold Plaintiffs' motion to amend in abeyance pending Plaintiffs' forthcoming formal motion to amend the complaint. X 1259-65. That same day, Defendants responded to Plaintiffs' allegations. IX 1240-58. In particular, Defendants acknowledged that the "pharmacist/person/entity who is compounding the Midazolam" has been subject to disciplinary orders from their

state Board of Pharmacy, but asserted that this fact was inconsequential. IX 1253. On June 28, 2018, a week after Ms. Inglis' deposition, Plaintiffs moved to file a Second Amended Complaint to add as-applied claims related to the State's drug supplier's lack of proper credentials and clear pattern of misconduct. X 1275-1349 (Pls.' 6/28/18 mot. and exhibits). Specifically, Plaintiffs moved to amend the complaint to allege that the secret source: (1) was not properly licensed in the State of Tennessee; (2) did not have adequate facilities to compound high-risk sterile injectables; and (3) has a disciplinary history that calls into question their competence to provide sterile, stable, potent chemicals for lethal injections in the State of Tennessee. The Chancery Court denied the request, citing undue delay. The following day, the trial court denied Plaintiffs' motion to add as-applied challenges. X 1353-63 (6/29/18 order). The court's primary reason for denying the motion to amend was that Plaintiffs had unduly delayed bringing the claims related to compounding. X at 1357-62. As set forth above, Plaintiffs had no indication that Defendants would use compounded chemicals for the 3-drug (Midazolam) Protocol B, and in fact had clear indications from Defendants to the contrary, including the "procurement" procedures of the lethal injection manual. The court did not squarely address Plaintiffs' claims about the as-applied challenges related to the State's drug supplier.

Plaintiffs' promptly filed a motion to reconsider. X 1399-1407 (Pls.' 7/2/18 motion to reconsider); VII 967 (under seal, Pls.' 7/2/18 notice of filing exhibit to motion to reconsider under seal); Other 5 (under seal, exhibits 1-3 to Pls.' 7/2/18 motion to

reconsider); XII 1564-72 (Defs.' 7/3/18 response); XII 1577-81 (Pls.' 7/3/18 reply). In their motion to reconsider, Plaintiffs attached the exhibits—redacted and under seal—documenting the licensing status and disciplinary history of the secret source listed above.¹¹³

The court denied Plaintiffs' motion to reconsider as well, based on its reasoning in its initial order on the motion to amend. XII 1585-88. As to Plaintiffs' allegations about the particular lack of licensing and disciplinary issues regarding the State's drug supplier, the court ruled that it would allow Plaintiffs to make an offer of proof at trial, XII 1586-87. As recounted in the procedural history, at trial, the court so circumscribed the offer of proof (providing a list of questions Plaintiffs could ask Debbie Inglis with no follow-up questions allowed), that the Plaintiffs declined to ask Ms. Inglis the questions and instead made a proffer on the record of what they anticipated the evidence would show if they had been permitted to make the offer of proof necessary for the record. XLII 1682-89.

This court reviews rulings on motions to amend pleadings for abuse of discretion.

Pratcher v. Methodist Healthcare Memphis Hosps., 407 S.W.3d 727, 741 (Tenn.

¹¹³ Plaintiffs took care to redact even that which is under seal in order to protect the identity of the secret source from accidental disclosure. Plaintiffs are not responsible for any disclosures made by TDOC staff regarding the identity of the secret source to any person or entity. Plaintiffs do not agree with Defendants' interpretation of the law in this area, but have no need or desire to publicly name the source. The only statute that addresses this matter is a subsection of the Tennessee Public Records Act, Tenn. Code Ann. § 10-7-504(h)(1), which exempts the identity of the source from disclosure under the public records act. There is no law that protects their identity if discovered through investigation. However, it is deeply troubling that the Department would take advantage TPRA to use a secret unqualified source to compound drugs for executions.

2013). Respectfully, the trial court's June 29th and July 3rd orders denying Plaintiffs' motion to amend were an abuse of discretion.

Tenn. R. Civ. P. Rule 15.01 provides that leave to amend "shall be freely given when justice so requires." This Court wrote in *Gardiner v. Word*, 731 S.W.2d 889 (Tenn. 1989):

Rule 15 ... "needs no construction, it means precisely what it says, that 'leave shall be freely given.' " 527 S.W.2d at 92. Cases since *Branch v. Warren* have emphasized the liberality with which trial courts should approach the question of whether a pretrial motion to amend should be granted. See, e.g., *Craven v. Lawson*, 534 S.W.2d 653, 655 (Tenn. 1976); *Walden v. Wylie*, 645 S.W.2d 247, 250 (Tenn. App. 1982); *Douglass v. Rowland*, 540 S.W.2d 252, 256 (Tenn. App. 1976); see also *Merriman v. Smith*, 599 S.W.2d 548, 559 (Tenn. App. 1979); cf. *Liberty Mutual Insurance Co. v. Taylor*, 590 S.W.2d 920, 921 (Tenn. 1979).

Id. at 891. "In considering whether to grant a motion to amend, a trial court should consider several factors such as undue delay in filing the amendment, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and the futility of the amendment." *Id.* at 891–92. None of these factors weigh against Plaintiffs.

Plaintiffs drafted and filed their initial complaint less than two months after learning of the State's new protocol promulgated on January 8, 2018. In so doing,

they relied on the language of the Protocol that made a distinction between procedures for procuring pentobarbital and Midazolam and TDOC's TPRA productions which revealed that they had obtained manufactured Midazolam. Based on TDOC's representations, Plaintiffs diligently and expeditiously pursued their right to relief. It was Defendants' conduct that prevented Plaintiffs from learning of this frightening turn of events.

In *Gardiner*, this Court found that the trial court erred in finding undue delay. In so doing the Court looked to the conduct of the defendants. Here, Defendants promulgated an entirely new protocol on the eve of trial, which for the first time provided for compounding Midazolam. If Plaintiffs' conduct is not diligent, then diligence does not exist.

V. The trial court erred in dismissing Counts 2 and 3

a. Count II is legally sufficient.

Count II asserts that Tennessee's three-drug midazolam protocol violates evolving standards of decency which define the parameters of the Eighth and Fourteenth Amendments and Article 1 §16 of the Tennessee Constitution and the government's obligation to respect the dignity of all persons. *Hall v. Florida*, 572 U.S. __, 134 S. Ct. 1986 (2014); *Trop v. Dulles*, 356 U.S. 86, 101 (1958) (assessing a state's punishment against the evolving standards of decency that mark the progress of a maturing society). Defendants' argued in their motion to dismiss that there is no basis for relief on this claim, even if a method of execution violates evolving standards of decency. II 219. This is incorrect. In considering a method-of-execution challenge, a court must consider four criteria, including the requirement that the method of execution not violate evolving standards of decency. As the Tennessee Supreme Court held in the 2005 *Abdur Rahman* case:

The analysis is quite simila

The analysis is quite similar in cases where the challenge is not simply to the type of punishment but also to the method for carrying out the punishment. *See* [*State v. Webb*, 750 A.2d 448, 454 (Conn. 2000)] (analyzing whether methods of execution are cruel and unusual). The United States Supreme Court has considered, for instance: (1) whether a method of execution comports with the contemporary norms and standards of society; (2) whether a method of execution offends the dignity of the prisoner and society; (3) whether a method of execution inflicts unnecessary physical pain; and (4) whether a method of execution inflicts unnecessary psychological suffering. *Weems*, 217 U.S. at 373. These factors dictate that punishments may not include torture, lingering death, wanton infliction of pain, or like methods. *Estelle*, 429 U.S. at 102; *In re Kemmler*, 136 U.S. 436, 447 (1890).

Abdur'Rahman v. Bredesen, 181 S.W.3d 292, 306 (Tenn. 2005).¹¹⁴ Torture is but one way that a method of execution may violate the Eighth Amendment. *In re Kemmler*, 136 U.S. at 447 (holding that a method of execution violates the Eighth Amendment not just when it inflicts unnecessary pain, but also when it creates a lingering death). "The Eighth Amendment also demands that a penalty accord with 'the dignity of man." *Hope v. Pelzer*, 536 U.S. 730, 738 (2002).

In *Wilkerson v. State of Utah*, 99 U.S. 130 (1878), the United States Supreme Court observed that the terms "cruel and unusual" were difficult to "define with

¹¹⁴ The Tennessee Supreme Court in *Abdur'Rahman* and Plaintiffs' complaint both look to the practice of the states to determine the current status of this evolution. *Id.* at 306-307.

exactness" and declined to provide a comprehensive definition. *Id.* at 136. The terms "cruel" and "unusual" are by their very nature mutable. What may well have been accepted, or even deemed essential, in an earlier time (e.g., burning at the stake) now unquestionably would be both cruel and unusual. Under the facts presented in that case, the Court held only that "it is safe to affirm" that "punishments of torture ... and all others in the same line of unnecessary cruelty, are forbidden." *Id.* It did not hold that only methods of execution which inflict torture violate the Eighth Amendment.

An execution method can be unconstitutional if the method represents "devolution to a more primitive" method. *Glossip*, 135 S. Ct. at 2796- 97 (Sotomayor, J., dissenting). In order to determine which punishments are so disproportionate as to be cruel and unusual, the Supreme Court has "established the propriety and affirmed the necessity of referring to 'the evolving standards of decency that mark the progress of a maturing society." *Roper v. Simmons*, 543 U.S. 551, 560–61 (2005) (quoting *Trop*, 356 U.S. at 100-01). "This is because '[t]he standard of extreme cruelty is not merely descriptive, but necessarily embodies a moral judgment. The standard itself remains the same, but its applicability must change as the basic mores of society change." *Kennedy v. Louisiana*, 554 U.S. 407, 419 (2008) (quoting *Furman v. Georgia*, 408 U.S. 238, 382 (1972) (Burger, C.J., dissenting)).

A national consensus can exist against a punishment even though it is legally permitted by a majority of states. The mere infrequency of a particular punishment suffices to establish a national consensus against the practice. *Graham v. Florida*,

62-67 (2010). When deciding whether a punishment practice is "unusual" in the constitutional sense, the Supreme Court has looked to the number of states engaging in that practice. See, e.g., Atkins v. Virginia, 536 U.S. 304, 313-16 (2002); Roper, 543 U.S. at 564-66; Glossip, 135 S. Ct. at 2777 (Breyer, J., dissenting). The meaning of "cruel" and "unusual" as used by the Framers in drafting the Eighth Amendment should be determined by looking to the evolving practices of the "advanced" societies that share the country's Anglo-Saxon heritage. See Roper, 543 U.S. 561; Atkins, 536 U.S. at 321; Thompson v. Oklahoma, 487 U.S. 815, 826-30 (1988). The "consistency of direction of change" away from a particular punishment is also a relevant factor in evaluating whether our society, as a whole, still tolerates the punishment. See Roper, 543 U.S. at 566.

In 2013, Defendants intentionally and deliberately abandoned the three-drug method (including the excruciatingly painful second and third drugs), in favor of moving to what they believed to be a more humane execution method using a single drug. Defendants knew that removing the paralytic drug and potassium chloride from a lethal injection protocol removed two sources of needless, unnecessary physical pain and torturous mental suffering and anguish from their execution protocol. Besides Tennessee, only one other state has renounced a three-drug method of execution, moved forward with a one-drug method, but then later reintroduced the three-drug method. Defendants' revival of a three-drug protocol using a paralytic drug and potassium chloride violates standards of decency and is therefore "cruel" and "unusual." By intentionally reintroducing the second and third

drugs back into Defendants' execution protocol—and by utilizing midazolam as the first drug even though it is widely known to be unable to render an inmate insensate to the excruciatingly painful second and third drugs—Defendants have intentionally, knowingly, or recklessly moved backward to an execution method that increases the substantial risk of harm and needless pain and suffering, thereby contravening the evolving standards of decency in violation of Plaintiffs' Eighth Amendment rights.¹¹⁵ III 349-52 (Amd. Compl., ¶¶ 332-38, 348-51) (alleging that the trend of the practices among the sister states is to abandon the use of midazolam).

Although all states that permit capital punishment provide for lethal injection as a manner of execution, only a small fraction of those states actually carry out their executions using a three-drug midazolam protocol. Midazolam was once used for lethal injection in seven states. Of the 31 states that still retain the death penalty as a valid sentencing option, only five states currently allow midazolam to be used as the first drug in a three-drug method of execution. Thus, only 16% of death penalty states—which account for less than 10% of all state and

¹¹⁵ Thirty-one states retain the death penalty as a sentencing option but, in practice, the majority of these states have abandoned carrying out those executions. As a result, only a minority of states actively execute death row prisoners. Of those thirty-one states that still formally retain the death penalty, twelve states have not executed an inmate in almost ten years or longer. None of these twelve states permit execution by a three-drug midazolam method. Thus, while nineteen states have formally abolished the death penalty, at least another twelve have done so in practice. As a result, similar to the calculations by the Court in *Atkins* and *Roper*, thirty-one states have rejected the punishment challenged in the complaint.
federal jurisdictions—sanction the use of the midazolam three-drug method in executions. As of July 2017, the total population of those five states is estimated to be 34,723,639 whereas the United States' population is estimated to be 325,719,178. Accordingly, almost 90% of the U.S. population lives in a state that does not condone using a midazolam three-drug method to execute inmates. The consistency of direction of change away from the three-drug midazolam method of execution demonstrates it is disfavored under current standards of decency.

Plaintiffs sufficiently set forth a cause of action based on evolving standards of decency. Defendants offered no authority limiting or overruling controlling Eighth Amendment jurisprudence and the trial court erred in dismissing Count II.

b. Count III is legally sufficient.

Count III asserts that the three-drug midazolam option utilizing drugs not sanctioned for animal euthanasia—violates the government's obligation under the Eighth and Fourteenth Amendments and Article 1 §16 of the Tennessee Constitution to respect the dignity of all persons. *Estelle v. Gamble*, 429 U.S. 97, 102 (1976) (holding that the Eighth Amendment embodies "broad and idealistic concepts of dignity, civilized standards, humanity, and decency"); *Trop*, 356 U.S. at 101 (holding that a state's punishment is assessed under the Eighth Amendment against the evolving standards of decency that mark the progress of a maturing society); *see also McCleskey v. Kemp*, 481 U.S. 279, 300 (1987) (capital punishment must accord with the dignity of man).

Defendants argued in their motion to dismiss that there is no basis for relief on this claim, even if Defendants inflict a punishment on Plaintiffs that denies their humanity. II 220 ("[T]he concept of 'dignity of man' provides no separate basis for relief."). Defendants misunderstand the nature of this count. They argue that any cause of action arising under the Non-Livestock Animal Human Death Act is foreclosed by this Court's 2015 *Abdur'Rahman* decision. But Plaintiffs' invocation of that Act is not as a cause of action but as an illustration of how Defendants' execution protocol deprives them of human dignity. *See Hancock v. Avery*, 301 F. Supp. 786 (M.D. Tenn. 1969) (holding punishment was unnecessarily cruel where a prisoner was forced to live and eat under animal-like conditions); *Bonds v. Tenn. Dep't of Corr.*, No. 1:16–cv–00085, No. 1:16–cv–00089, 2016 WL 7131507, *4 (M.D. Tenn. Dec. 6, 2016) (denying motion to dismiss § 1983 claim based on inhumane conditions of confinement).

For many of the same reasons as set forth above (and incorporated herein), the trial court erred in dismissing Count III of Plaintiffs' complaint. Plaintiffs allege that Defendants' lethal execution protocol treats them in a manner considered intolerable for even family pets. III 352-53 (Amd. Compl. ¶¶ 356-358). Defendants offered no argument that being treated worse than a pet is in any way consistent with any concept of human dignity. Rather, Defendants argued that—even if basic human dignity is violated by their decision to administer vecuronium bromide and potassium chloride to the Plaintiffs in the course of inflicting punishment—they may do so without violating the Eighth Amendment and Article 1, §16 of the

Tennessee Constitution so long as they do not also torture Plaintiffs in the process. II 219-21. *But see Hope*, 536 U.S. at 745 (finding that handcuffing prisoners to a hitching post amounts to "obvious cruelty" and treats prisoners "in a way antithetical to human dignity"). But Defendants cite no authority to support that proposition and *Abdur'Rahman*, 181 S.W.3d at 292, *Wilkerson*, 99 U.S. at 130, and Eighth Amendment jurisprudence provide otherwise.¹¹⁶ Accordingly, Plaintiffs sufficiently pled a cause of action, and the trial court erred in dismissing Count III of Plaintiffs' complaint.

VI. The trial court abused its discretion by imposing extreme restrictions on Plaintiff's ability to conduct discovery essential to its claims.

The applicable standard of review for pretrial discovery decisions is abuse of discretion. *West v. Schofield*, 460 S.W.3d 113, 120 (Tenn. 2015) (citing *Benton v. Snyder*, 825 S.W.2d 409, 416 (Tenn. 1992)). "The abuse of discretion standard of review does not [] immunize a lower court's decision from any meaningful appellate scrutiny." *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 524 (Tenn. 2010) (citation omitted). "An abuse of discretion occurs when the trial court applies incorrect legal

¹¹⁶ Defendants cited in support of their motion to dismiss this Court's 2015 *Abdur'Rahman* decision—the very case in which the Court recognized that a method of execution may not violate the dignity of man. *Abdur'Rahman* held only that the Non-Livestock Animal Humane Death Act did not create a cause of action for the plaintiff. *Id.* at 313. It in no way posited an opinion on whether treating a human being in a manner not allowed for even a pet was contrary to the principles of human dignity. Notwithstanding their convictions, Plaintiffs are entitled to the same dignity afforded all humans, and that dignity remains protected by the Eighth Amendment and Article 1, §16 of the Tennessee Constitution. *Roper*, 543 U.S. at 560 ("By protecting even those convicted of heinous crimes, the Eighth Amendment reaffirms the duty of the government to respect the dignity of all persons.").

standards, reaches an illogical conclusion, bases its decision on a clearly erroneous assessment of the evidence, or employs reasoning that causes an injustice to the complaining party." *West*, 460 S.W.3d at 120 (citing *State v. Banks*, 271 S.W.3d 90, 116 (Tenn. 2008)).

As this court held in its 2015 *West* decision, analysis of a litigant's right to discovery begins "with the text of Tennessee Rule of Civil Procedure 26.02(1):

Parties may obtain discovery regarding any matter, *not privileged*, *which is relevant to the subject matter involved in the pending action*, whether it relates to the claim or defense of the party seeking discovery or to the claim or defense of any other party, including ... the identity and location of persons having knowledge of any discoverable matter. It is not ground for objection that the information sought will be inadmissible at the trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence.

West, 460 S.W.3d at 120 (quoting Tenn. R. Civ. P. 26.02(1) (emphasis in original).

"Thus, before a trial court may order matters divulged under this Rule, it must make a threshold determination that the matters sought are (1) not privileged and (2) relevant to the subject matter of the lawsuit." *Id.* at 121. As explained in *West*, relevancy means that the information has some probative value with respect to the subject matter involved in the pending litigation. *Id.* at 125-26.

Here, the trial court repeatedly imposed restrictions on Plaintiffs' ability to conduct discovery on issues relevant—indeed central—to their claims, each time based on an erroneous interpretation of this Court's 2015 *West* decision's holding that the identities of individuals involved in the execution process are not relevant to a method-of-execution challenge. However, Plaintiffs here were not seeking the identities of those involved in the execution process for the sake of knowing their identities, but instead for the sake of gaining access to the information those individuals possessed. The court could have easily crafted (or invited the parties to craft) measures to maintain the confidentiality of individuals involved in the execution process without depriving Plaintiffs of access to individuals who possess information relevant to Plaintiffs' claims. The four orders at issue are as follows:

a. May 7, 2018 order denying Plaintiffs' first motion to compel discovery

On May 7, 2018, the trial court abused its discretion by issuing an order sharply restricting Plaintiffs' ability to conduct discovery needed to present evidence of an alternative method of execution as required by *Glossip* and *West*. V 617-32 (5/7/18 Order).¹¹⁷ The court ruled that, on the basis of the "survey of other jurisdictions and approval of those as consistent with the public policy of Tennessee" contained in *West*, 460 S.W.3d at 122-25, the following identities must be kept confidential:

- the identities of supplies [sic] of the substances necessary to carry out lethal injection executions,
- the State employees who procured those substances,
- persons directly involved in the execution, such as the execution team, and
- the manufacturer, supplier, compounder, prescriber of the drugs, medical supplier or medical equipment for the execution.

V 624.

The court disallowed or limited Plaintiffs' discovery in the following ways:

• disallowed discovery based on the September 7, 2017 email from Defendants' supplier of lethal injection chemicals (Direct Source) about the inefficacy of

¹¹⁷ II 244-84 (Pls.' 4/9/18 mot.); III 390-405 (Defs.' 4/20/18 resp.); IV 455-84 (Pls.' 4/27/18 reply); IV 541-64 (Pls.' supplemental facts in support); XXI 1-140 (5/2/18 oral argument transcript).

midazolam for relieving the pain of the second two drugs because information that Defendants might have about the efficacy of Protocol B (midazolam) is "cumulative to their own expert and witnesses' testimony, *id.* at 627;

- disallowed discovery on availability of pentobarbital from anyone other than the "named, nonconfidential Defendants," on the basis that "Plaintiffs' challenge is a facial constitutional challenge," *id.*;
- allowed Plaintiffs to obtain certain documents from Commissioner Parker and Warden Mays about their knowledge of the availability of pentobarbital for the upcoming executions but not to know the "source and basis of [their] knowledge," *id.* at 678;
- denied Plaintiffs' motion to compel answers to Interrogatory 1 (which requests the contact information for "all persons having knowledge of" the September 7, 2017 email from the Direct Source) "except for the named Defendants," because this Court's 2015 *West* decision prohibits discovery of persons inquired about, *id.* at 629; *see also id.* at 618 (quoting Interrogatory 1).
- denied Plaintiffs' motion to compel answers to Interrogatory 2 regarding the persons who drafted, revised, prepared and/or promulgated the January 8, 2018 Protocol as "not relevant because the Plaintiffs' challenge in this case is to the constitutionality of the Protocol as written," *id.*;
- categorically "denied as not calculated to lead to the discovery of admissible evidence on a facial constitutional challenge," the request for production of documents as to a wide array of issues relevant to Plaintiffs' claims listed in the court's order, including, inter alia, "the persons who gathered and considered information regarding a change to the execution protocol"; "the methods of execution that were considered when changing the protocol"; "the intended purpose for the drugs chosen for new Protocol B and the information considered regarding such purposes"; "the information gathered and considered regarding alternative methods"; Defendants' knowledge about the unnecessary and severe pain and suffering caused by the second two drugs in Protocol B; "Defendants' knowledge of available safeguards to ensure Plaintiffs are unable to experience the unnecessary and severe pain and suffering from the vecuronium bromide and potassium chloride used during their executions and why such safeguards are not included in Protocol B"; "whether Defendants know that midazolam has a ceiling effect" or "know that that paradoxical effect is a known and recurring problem with the administration of midazolam," id. at 630-31.
- b. May 24, 2018 order denying Commissioner Parker and Warden Mays' motion for a protective order seeking to quash their depositions but imposing extreme limitations on the scope of their depositions

On May 24, 2018, the trial court abused its discretion by imposing extreme and unwarranted limitations on the time and scope of Commissioner Parker and Warden Mays' depositions.¹¹⁸ Other 2 (sealed, unredacted 5/24/18 order); X 1364-89 (redacted 5/24/18 order); X 1350-1352 (6/28/18 order to redact 5/24/18 order pursuant to 6/13/18 order (VI 738-45) and place on public docket). Plaintiffs sought to depose these individuals to discover what they knew about Defendants' efforts to obtain pentobarbital—Plaintiffs' identified alternative method of execution. The court was correct in ruling that Parker and Mays' request to quash the depositions was "a superficial application and over-simplification of *Glossip v. Gross* and a misapplication of *West v. Schofield*." Other 2, pp.1-2.

As the trial court properly held, Defendants' position that a facial challenge only requires looking to the text of the protocol because the "Protocol speaks for itself" is simply wrong. Other 2, pp. 4-5, 7. The court was correct in holding that Plaintiff have the right to conduct discovery as to the second *Glossip* prong of availability, although it was mistaken in concluding (in this order and the others discussed here) that they do not have the right to conduct discovery on every element of their claims. As the court noted, this Court's 2017 *West* decision held that *Glossip* places the burden on a claimant to plead and prove both prongs of the test. *Id.*, p. 7 (quoting *West 2017* and *Glossip*). But, of course, Plaintiffs have the burden of proving all of their claims.

¹¹⁸ V 661-671 (Parker and Mays' 5/21/18 motion for protective order); V 672-674 (court's 5/21/18 order staying deposition); XXII 1-63 (5/21/18 hearing on protective order motion, particularly pp. 7-13, 42-45).

Despite allowing Plaintiffs to depose Commissioner Parker and Warden

Mays, based on its misunderstanding of *West 2015*, it placed the following

limitations on his deposition:

- limited both depositions to six hours, *id.*, p.18;
- imposed limitations on the scope of the depositions by "incorporat[ing] its reasoning and authorities from the May 7, 2018" order, *id.*;
- disallowed questions relevant to *Glossip* prong one, *id.*;
- restricted questions relevant to *Glossip* prong two to "information solely within their possession that is calculated to lead to the discovery of admissible evidence on this essential element . . . [which] is permissible even under a facial challenge," *id.*;
- restricted questions as to their other claims to the "limited" issues related to their "knowledge of the logistics of administering and implementing Protocol B as written, *id.*, p.19;
- enumerated an exclusive list of permissible topics, *id.*, pp.19-20;
- enumerated a long list of impermissible topics, including (1) any other available alternative drug for use in Tennessee's lethal injection protocol; (2) identities and identifying information about the chemicals necessary to carry out lethal injection executions; (3) identities and identifying information of the State employees who procured those substances; (4) identities and information of the persons directly involved in the execution; (5) identities and identifying information of the manufacturer, supplier, compounder, prescriber of the drugs, medical supplier, or medical equipment for the execution; (6) identities and identifying information regarding a change to the execution protocol; (7) all of the long list of topics listed as prohibited in its May 7, 2018 order, *id.*, pp. 21-22.

c. June 12, 2018 order denying the question Plaintiffs certified during Commissioner Parker's deposition

The trial court erred in its June 12, 2018 order denying Plaintiffs' certified question from Commissioner Parker's deposition. Other 1, pp.1, 5-6 (under seal); X 1390-98 (redacted); X 1350-1352 (6/28/18 order to redact 6/12/18 order pursuant to 6/13/18 order (VI 738-45) and place on public record). The court denied Plaintiffs'

request to have Commissioner Parker respond to the question they certified during his deposition: "Which Departments of Correction [has Commissioner Parker] consulted with"? Other 1 (6/12/18 order at pp. 5-6, sealed). The court found that the question was not permitted under the court's May 24 2018 order limiting the scope of depositions. Other 1, pp.5-6.

The context of the question was Plaintiffs' attempt to identify which departments of correction Commissioner Parker had consulted with to locate pentobarbital, as the discussion at the deposition made clear. III 443-45 (sealed, Parker Dep.). Plaintiffs' counsel conducting the deposition explained: "[W]e believe that we are entitled to inquire as to States that you have had general discussions with about the ability to obtain pentaobarbital [sic] and other execution drugs for execution and that we would want to ask you for the specific names of places that you have consulted." III 444 (sealed). Counsel followed this explanation with an immediate request that the court reporter certify the question. III 444-45 (sealed).

Plaintiffs sought the information about which departments of corrections Commissioner Parker had talked with in his search for pentobarbital because it would have provided information about a source for pentobarbital. *See State v. Irick*, No. M1987-00131-SC-DPE-DD (Tenn. Aug. 6, 2018) (Lee, J., dissenting) ("Surely, our TDOC should be as resourceful and able as correction officials in Texas and Georgia in obtaining pentobarbital"). The trial court abused its discretion in not allowing this question.

d. June 13, 2018 order denying Plaintiffs' motion to compel the deposition of a TDOC staff member and an associate Riverbend warden and

imposing extreme limitations on the scope of TDOC General Counsel/Assistant Commissioner Debbie Inglis' deposition testimony

In its June 13, 2018 order on Plaintiffs' second motion to compel, the court abused its discretion by (1) denying the motion to compel the deposition of a TDOC staff attorney and an associate warden at Riverbend; and (2) granting the motion to compel the deposition of Debbie Inglis, the TDOC Deputy Commissioner, but imposing extreme limitations on the scope of the deposition that are not supported by law. VI 738-45.¹¹⁹ The trial court again incorporated by reference the draconian discovery limitations contained in its May 7, 2018 order. V 617-32. As Plaintiffs stated in their motion to compel and reply thereto, they believe on the basis of knowledge, experience, and public records that Ms. Inglis, a TDOC staff member (whom Plaintiffs have referred to throughout this litigation as the "Drug Procurer"), and an assistant warden at Riverbend possess non-privileged information that is relevant to the Plaintiffs' remaining claims. XVII 2430 (Pls.' motion).¹²⁰

The record is replete with evidence that the TDOC Drug Procurer was the individual responsible for procuring lethal injection chemicals for the State, including the following:

• As detailed in Plaintiffs' motion to compel, the Drug Procurer's name appears in an email obtained by Plaintiffs' counsel through a public

¹¹⁹ I 107-III 355 (Pls.' 6/1/18 motion and mem. under seal); XVII 2429-XIX 2678 (Pls.' 6/1/18 redacted motion and exhibits); III 356-66 (Defs.' 6/8/18 resp., under seal); VII 901-66 (Pls.' 6/11/18 reply, under seal); XVII 2363-2428 (Pls.' 6/11/18 redacted reply and exhibits).

¹²⁰ Plaintiffs referred to the latter two individuals by name in its original filing, but later redacted the names in response to the court's order. Here, Plaintiffs refer to these individuals by their job descriptions and, therefore, cite to the redacted version of the pleadings.

records request to TDOC that suggests that the individual has relevant information regarding the availability of drugs necessary to carry out a lethal injection in Tennessee. XVII 2432. The email sender (presumably the pharmacy that provides the State with lethal injection chemicals— "Direct Source") addresses the Drug Procurer by name and states that the Direct Source is receiving another shipment the next day of midazolam and vecuronium bromide and will give the Drug Procurer the details when it arrives. XVII 2432 (Pls.' motion). Plaintiffs' motion details other email exchanges that also clearly indicate that the Drug Procurer was the one communicating with Direct Source. *Id.*, 2432-33.

- Plaintiffs' motion to compel also explained that Inglis, the Drug Procurer's supervisor, testified in the 2015 trial before Chancellor Bonnyman that "one of [her] attorneys" was responsible for making calls to locate a pharmacist willing to compound the lethal injection chemicals." *Id.*, 2433 (citing transcript).
- Ms. Inglis' trial testimony indicated that the Drug Procurer was the only person tasked with locating lethal injection chemicals. XL at 1609 (Drug Procurer was only TDOC person working on locating drugs); at 1611 (all of the information about availability of pentobarbital presented in the PowerPoint to top decision makers came from the Drug Procurer); at 1619 (Drug Procurer did the search with Source B for the chemicals to be used for Protocol B); at 1627, 1631 (Inglis was "caught in the middle" between the Procurer and the Commissioner); 1643 (Inglis does not know when the Commissioner learned that manufactured midazolam was not available).
- Commissioner Parker's trial testimony indicates that the Drug Procurer was tasked with locating lethal injection chemicals. XXXV 1152 (Inglis and "her staff" "play a big part" in the lethal injection "process" and he relies on what they tell him other people have told him).

Indeed, the chancery court made a finding of fact that Commissioner Parker

and Assistant Commissioner Debbie Inglis "delegate[d] the task of investigating

supplies of pentobarbital to a member of their staff." XVI 2242 (7/26/18 final order).

The court also referenced the "staffer delegated to research sources" in discussing

the meaning of a text message by the "staffer" to an unidentified person,

presumably the Direct Source of the State's lethal injection chemicals. The author of

the text message—the Drug Procurer—texted the Direct Source to ask for "a list of all companies etc u reached out to about sourcing so I can have it for when we have to show it's unavailable." XVI 2246. The court makes a finding of fact as to this message that "the staffer delegated to research sources was putting together a PowerPoint presentation for the boss/superior" *Id.*

The Drug Procurer appears to be the only person in Tennessee State government who has first-hand knowledge about the availability of pentobarbital. He also likely has relevant information as to Defendants' knowledge of the September 7, 2017 email from the Direct Source warning about midazolam's ineffectiveness and what actions were taken in response to the email, which is relevant to Plaintiffs' substantive due process/shocks the conscience claim. As discussed in the section of this brief addressing the Plaintiffs' showing of an alternative execution method as required by *Glossip*, Plaintiffs were extremely prejudiced by the inability to depose the Drug Procurer and obtain information about documents and information in his control.

As to the Riverbend assistant warden, as Plaintiffs' motion to compel states, the protocol explicitly provides that if the warden cannot perform his duties during an execution, the assistant warden is required to carry out the execution. XVII 2435. Thus, the assistant warden is familiar with the protocol and has knowledge of the execution procedures that have not been reduced to writing but are part of the protocol, such as the timing of the syringe pushes. The assistant warden is also responsible for security at the prison and so has unique information about what, if

any, security challenges might be presented by allowing Plaintiffs' counsel telephone access during executions or adequate visual access to the execution to allow counsel to properly monitor the proceedings, which are relevant to Count V, Plaintiffs' access to counsel and to the courts claim. XVII 2435-36.

As to the strict restrictions on Plaintiffs' questioning of Ms. Inglis, Plaintiffs' motion to compel sets forth numerous bases for their belief that she has information relevant to their claims. XVII 2433-35. The damage to Plaintiffs ability to conduct discovery caused by the trial court's refusal to allow Plaintiffs to depose the Drug Procurer was exacerbated by the court's restrictions on the scope of questions Plaintiffs could ask during Ms. Inglis' deposition.

e. These orders were an abuse of discretion.

The trial court abused its discretion in repeatedly restricting Plaintiffs' discovery in all the ways articulated in *West 2015*. That is, the court applied incorrect legal standards, reached an illogical conclusion, based its decision on a clearly erroneous assessment of the evidence, and employed reasoning that caused an injustice to the complaining party. 460 S.W.3d at 120.

First, the court applied incorrect legal standards. As to Plaintiffs' burden to prove *Glossip* prong 1, the court incorrectly concluded that Plaintiffs had no right to conduct discovery as to that prong because their method-of-execution claim is a facial challenge. There is simply no support in law or logic for this holding. As discussed elsewhere in this brief, there is nothing about a facial constitutional challenge that deprives a plaintiff from conducting discovery on matters on which they have the burden of proof.

As to Plaintiffs' burden to prove a "feasible and readily implemented" alternative to under *Glossip* prong 2 and their other causes of action, the court applied the wrong legal standard in that it interpreted this Court's 2015 decision in *West*, 460 S.W.3d at 125-31, as precluding Plaintiffs from obtaining discovery from individuals protected by the execution-secrecy provisions in Tennessee Public Records Act ("TPRA), Tennessee Code Annotated § 10-7-504(h).¹²¹

The trial court extended the 2015 *West* decision well beyond its facts and holding. That decision only held that the *identity* of those involved in the lethal injection process was not relevant to a method-of-execution claim. Plaintiffs here do not seek the *identity* of those involved in the lethal injection process. Instead, they seek to obtain *information* from individuals who have information and documents relevant to Plaintiffs' claims. Again, the trial court could craft measures to protect those individuals' identities. To prevail on a method-of-execution claim under *Glossip* and 2017 *West*, Plaintiffs must be able to conduct discovery to obtain evidence to meet their burden of proof on both prongs of *Glossip*. Neither the execution secrecy

¹²¹ Tenn. Code Ann. § 10-7-504(h)(1) provides confidentiality from disclosure under the Public Records Act "those parts of the record identifying an individual or entity as a person or entity *who or that has been or may in the future be directly involved* in the process of executing a sentence of death" This includes "a person or *entity involved in the procurement or provision of chemicals*, equipment, supplies and other items for use in carrying out a sentence of death." *Id.* (emphasis added). By its terms this statute does not apply to court proceedings and discovery. No court has ever held that it does. In *dicta*, the Tennessee Supreme Court pondered the possibility of creating a common law privilege – but it declined to do so. No privilege exists under case law or statute.

provision of the TPRA nor the 2015 *West* decision hold otherwise. ¹²² If they did, Tennessee would effectively be insulated from a challenge that it violates the state and federal constitutional prohibitions against cruel and unusual punishments. As this is contrary to the law and an illogical conclusion, the court's orders constitute an abuse of discretion.

The court also abused its discretion by basing its decisions on a clearly erroneous assessment of the evidence with respect to its conclusions that General Counsel/Assistant Commissioner Debbie Ingis, Commissioner Parker, and Warden Mays could provide the information needed by Plaintiffs to prove their claims. As Plaintiffs' motions to compel made clear, these individuals were unable to answer most questions about the State's search for pentobarbital, because they simply were not the individuals charged with conducting that search and so had no personal knowledge to respond to many important questions Plaintiffs posed during their depositions.¹²³

¹²² It is important to note that at the time of the 2015 *West* decision, inmates were not required to prove an alternative method of execution to prevail in a method-of-execution challenge. Further, the Defendants did not abdicate the responsibility to obtain execution drugs to a third party until 2017.

¹²³ Plaintiffs are unable to cite to Ms. Inglis' deposition transcript because it is not in the record, but the deposition transcripts in the record for Commissioner Parker and Warden Mays show many examples of their limited knowledge on a number of issues relevant to Plaintiffs claims. *See, e.g.*, IV 495-96 (Parker does not know whether a prescription for compounded pentobarbital was filled at RMSI) (under seal); *id.* at 500 (Parker does not know if TDOC ever possessed pentobarbital) (under seal); *id.* at 516-17 (Parker does not know what "that stuff" is in reference to an email apparently sent from the State's drug supplier to its Drug Procurer that says "[t]hat stuff is readily available, along with potassium chloride.") (under seal);

Last, the trial court's orders severely restricting the scope of Plaintiffs discovery constitute an abuse of discretion because they caused a grave injustice to Plaintiffs. The discovery orders effectively deprived Plaintiffs of the ability to obtain evidence to bolster their claims. These restrictions impacted their ability to obtain proof for all of their claims, including their substantive due process and access to counsel and courts claim. But the restrictions had the most detrimental impact on their method-of-execution claim. Simply put, Defendants had information about the availability of pentobarbital, and the court's orders denied Plaintiffs the ability to obtain that information. Refusing to allow them to depose the Drug Procurer—the

id. at 543-45 (Parker does not know about a packet of emails entitled "Update" obtained by Plaintiffs through a TPRA request in which the author—presumably the Drug Procurer—says "[s]o the word from the powers that be is that they first want to try to find Midazolam if there (sic) none out there to get.") (under seal); *id.* at 552-53 (Parker does not know about a September 1, 2014 contract between a pharmacist and TDOC in which TDOC requests that the pharmacist provide drugs necessary to carry out an execution by lethal injection.) (under seal); *id.* at 554 (Parker does not know whether TDOC has terminated this contract with the pharmacist) (under seal); *id.* at 589 (Parker does not know why TDOC would only accept a minimum of ten executions worth of pentobarbital.) (under seal); V 601-04 (Parker has no personal knowledge of and cannot authenticate any documents that TDOC produced in this litigation) (under seal); *id.* at 605 (Parker is unaware of any other information about TDOC's attempts to obtain pentobarbital other than what was discussed during his deposition.) (under seal).

VI 766 (Mays does not know whether anyone at Riverbend is attempting to obtain pentobarbital for the upcoming executions.) (under seal); *id*. (Mays does not know whether there will be any pentobarbital for the upcoming executions.); *id*. at 803 (Mays states that the only knowledge he has of how a lethal injection execution should be carried out is from the manual and trainings); *id*. at 854 (Mays does not know of anyone outside of TDOC attempting to obtain pentobarbital on behalf of TDOC) (under seal).

one person responsible for locating pentobarbital for the State—hampered their ability to prove that pentobarbital is a "feasible and readily implemented" alternative to the midazolam protocol. This is the clearest example of the court's abuse of discretion, but the summary of the orders above shows that the trial court crafted a complicated maze of questions Plaintiffs could not ask and information they could not obtain.

The court's discovery orders identified here were an abuse of discretion and cannot stand, or else this State's law will effectively insulate Tennessee's execution methods from state or federal constitutional review.

VII. The Chancery Court erred in allowing the testimony of Dr. Feng Li, where Defendants knowingly hired him despite his unavailability, failed to exercise due diligence, and acted in bad faith.

The Chancellor erred in accommodating the Defendants' request to have defense expert Dr. Feng Li testify after the conclusion of the trial—at a time when Plaintiff's experts were unavailable to provide rebuttal evidence. Defendants had at least seven months to obtain an expert—or several experts—in addition to Dr. Lee Evans for the July hearing. Defendants knew when they adopted Protocol B (the midazolam option) in January 2018 that it would be challenged by Plaintiffs. They also knew when Dr. Li would be out of the country. Defendants were on notice that the Court intended to set this case for trial when they appeared in Court on April 16, 2018. Plaintiffs suggested a trial date for which Dr. Li was available. Defendants then countered with a proposed trial date when Dr. Li was not available and sat silent about his unavailability. The Chancellor accepted defendant's proposed date—thereby making Dr. Li unavailable. In light of these uncontested facts, the Chancellor's acquiescence to the post-trial presentation of Dr. Li's testimony was an abuse of discretion.

a. Relevant timeline.

In 2017, Dr. Feng Li planned a trip to Africa from July 7-21, 2018.
 Affidavit of Dr. Feng Li, ¶ 4, VI 710. Dr. Feng Li is a forensic pathologist (one of seven employed by Forensic Medical Management of Nashville). Curriculum vitae of Dr. Feng Li, VI 712; <u>http://forensicmed.com/pathologists/</u>, last visited June 2, 2018).

2. In September of 2017, Defendants began examining a revision to their Lethal Injection Protocol, so that it would incorporate Midazolam as the first drug of an alternative three-drug method of execution. XXXVI, 1237. The Defendants began consulting with other trusted individuals (whose names and identities have not been provided by Defendants) regarding the use of Midazolam in this potential new protocol. XXXVI 1230. Defendant Parker testified that or more of these trusted individuals was a medical professional. XXXVI 1232. Plaintiffs were precluded from knowing the identity of the medical personnel (learning only that that person consulted was not an anesthesiologist, XXXVI 1233) leaving the possibility that Dr. Li was the "medical personnel" consulted by the department.

3. On January 8, 2018, the Lethal Injection Protocol that is the subject of this lawsuit was formally approved by Defendant Tony Parker. XXXVI 1209.

4. On January 18, 2018, Plaintiffs Abdur'Rahman, Hall, Irick, Johnson, Miller, Sutton, West, Wright, and Zagorski filed a Response to the Motion to Set Execution Dates in the Tennessee Supreme Court asserting that a challenge would be filed to the new lethal injection protocol and requesting that the Supreme Court establish an expedited litigation schedule. M1988-00026-SC-DPE-PD (Abdur'Rahman); E1997-00344-SC-DDT-DD (Hall); M1987-00131-SC-DPE-DD (Irick); M1987-00072-SC-DPE-DD (Johnson); E1982-00075-SC-DDT-DD (Miller); E2000-00712-SC-DDT-DD (Sutton); M1987-00130-SC-DPE-DD (West); M1985-0008-SC-DDT-DD (Wright); M1996-00110-SC-DPE-DD (Zagorski). This notice was served on Deputy Tennessee Attorney General Jennifer L. Smith. *Id.* Thus, as of January 18, 2018, Defendants were on notice that litigation regarding the newly adopted lethal injection protocol was imminent.

5. On February 15, 2018, counsel for Plaintiffs Abdur'Rahman, Hall, Irick, Johnson, Miller, Sutton, West, Wright and Zagorski filed with this Court a Notice of Intent to Respond to Motion to Set Execution Dates, and asked to be given fourteen (14) days to do so. M1988-00026-SC-DPE-PD (Abdur'Rahman); E1997-00344-SC-DDT-DD (Hall); M1987-00131-SC-DPE-DD (Irick); M1987-00072-SC-DPE-DD (Johnson); E1982-00075-SC-DDT-DD (Miller); E2000-00712-SC-DDT-DD (Sutton); M1987-00130-SC-DPE-DD (West); M1985-0008-SC-DDT-DD (Wright); M1996-00110-SC-DPE-DD (Zagorski). In this Notice, Plaintiffs for the second time alerted the State of their intent to challenge the constitutionality of the new lethal injection protocol. *Id*.

6. On February 20, 2018, Plaintiffs filed their original complaint in this cause. I 1.

7. On April 6, 2018, Defendants responded to a request for interrogatories and identified a single expert witness, Dr. Roswell Lee Evans.

8. On April 9, 2018 as requested by the Court, Plaintiffs filed a proposed scheduling order which suggested that trial would be held from June 18 to June 27, 2018.

9. On April 10, 2018, Defendants filed their own proposed scheduling order, suggesting that a 3-4 day trial be held starting July 16, 2018.

10. The Chancellor convened a scheduling conference on April 11, 2018. XX 1-75. All parties were on notice that the purpose of the conference was to set an expeditious trial date in light of Mr. Irick's August 9, 2018 execution date. At the conference, this Court heard the positions of both sides, and then determined that trial would be set from July 9 to July 18, 2018. II, 285; XX 42.

11. After setting the trial date and verifying availability of counsel, this Chancellor asked Plaintiffs if they had experts ready for trial. Plaintiffs responded:

We tentatively have experts lined up. We're just going to have to now run the dates past them to be sure that they'll be able to be here or we'll have to get substitute experts.

XX 46.

12. At this scheduling conference Defendants verified that they had provided notice of a single expert witness, Dr. Evans (*see also*, II 272; *see also* XX

49); the court gave the defense until May 11, 2018 to provide notice of any additional experts. II, 285.

13. On May 3, 2018, Defendants contacted Dr. Li about participating in the case. XLVIII 118.

14. On the May 11th deadline, Defendants provided notice of two
expert witnesses: Dr. Evans (who had previously been disclosed) and Dr. Feng Li.
IX¹²⁴ 1085. This notice did not make any mention of Dr. Li's "unavailability" as a
witness. *Id.*

15. On May 21, 2018—almost three weeks after Defendants belatedly contacted him, the Defendants revealed that Dr. Li was not available for trial, as he would be in Tanzania. XXII 39; *see also* VI 705, Defendants' Motion to Permit Medical Expert, Dr. Feng Li to Testify by Evidentiary Deposition In Lieu of Appearance at Trial with Attachment, filed June 1, 2018. Defendants indicated that they wanted to offer an evidentiary deposition instead of his live testimony. *Id.*

16. At the May 21, 2018 conference, Plaintiffs stated that they would object to Dr. Li testifying by way of evidentiary deposition. XXII 39. Plaintiffs proposed that the State ask to vacate the upcoming execution dates, so that there would be adequate time to conduct a trial and to permit Dr. Li's testimony:

This is not a normal civil case. In a normal civil case, a case of this magnitude, we're not going to trial for a year. We offered the State that if they would simply go to the Tennessee Supreme Court and announce

¹²⁴ Confusingly designated in the record as VIIII.

to vacate Mr. Ira's¹²⁵ [sic] date. We have dates intact. Dr. Li can testify. We can have some more time.

We are not in control of this schedule. The State is entirely in control of the schedule. They knew this was going to come. They should have been talking to Dr. Li back in January. And when they found out he was scheduled to be in Tanzania, they should have found another expert. That's really not plaintiff's fault and we shouldn't have to accommodate that.

XXII 47.

17. The Chancellor denied the defendants' motion for Dr. Li to testify by evidentiary deposition based upon the court's "determination that Defendants' presenting the expert testimony by deposition and not in person was unfairly prejudicial to Plaintiffs." XIX 1228.

18. On June 19, 2018 the defendants filed a Renewed Motion to Permit Dr. Feng Li to Testify by Evidentiary Deposition; Or, to Testify Out-of-Order; Or, to Continue This Trial. XVIII 1070. Plaintiffs filed a response in opposition on June 22, 2018.

19. On June 23, 2018, the court held another status conference to discuss the state's proposal of holding the proof open until June 23 for the presentation of Dr. Li's testimony. XXIII 1-14. At the time of that hearing, Defendants had still not provided Dr. Li's report to Plaintiffs. *Id.* Following that conference, Dr. Li's report was provided and the court ruled that Dr. Li's testimony would be taken on June 23. IX 1228. The court changed its ruling for two reasons: "First, Counsel

¹²⁵ A mis-transcription of "Irick," referring to Billy Ray Irick.

for the Defendants has affirmatively stated as officers of the Court that they 'have triad and have been unable to secure an expert witness to replace Dr. Feng Li, M.D.... Second, at the time the Court denied Dr. Li's testimony at trial by evidentiary deposition, the Defendants did not provide the Court with any alternative solutions for Dr. Li's testimony. The Defendants' first Motion made no reference or suggestions that Dr. Li could be available to testify live in court on Monday, July 23, 2018." *Id.* The Chancellor stated that "because of the nature of this litigation" she had previously determined that an evidentiary deposition in lieu of appearance was unfairly prejudicial. *Id.*

b. Legal Argument.

The Defendants claimed that the court's accommodation was necessary because: (a) Dr. Li was scheduled to be on vacation more than 100 miles away from Nashville at the time of trial and, therefore, qualified as an "unavailable witness" under Rule 804; (b) that the out-of-time testimony would not cause Plaintiffs prejudice; and (c) that they were entitled to this accommodation because they were unable to find another witness willing to testify in Dr. Li's stead. The Chancellor abused her authority in allowing defendants to proceed with Dr. Li's testimony after the close of the proof—when Plaintiffs' experts were unavailable to return.

1. A party who knowingly hires an unavailable expert has procured that expert's absence from trial; they have not have not exercised due diligence and they have not acted in good faith; thus, they cannot avail themselves of Tennessee Rule of Evidence 804.

The Defendants claimed that Dr. Li was unavailable as defined by

Tennessee Rule of Evidence 804(a)(6), because he was to be over 100-miles from trial, due to his long-planned vacation to Africa. However, a witness is not deemed unavailable if his "absence is due to the procurement or wrongdoing of the proponent of a statement for the purpose of preventing the witness from attending or testifying." *Tenn.R.Evid. 804.*

As the factual recitation, above, makes clear, Dr. Li's inability to appear in court in July was not a surprise to defendants. Clearly, Dr. Li was not contacted, or retained, until after the April 11, 2018, conference; he testified at trial that the first contact he had with the Defendants about this case was on May 3, 2018. XLVIII 118. Thus, Defendants affirmatively chose to engage an expert knowing he would be in Africa at the time of trial.

Defendants had been working on the protocol since some time in 2017; they have never denied that they were aware that a change to the protocol would necessitate litigation. Defendants had since 2017 to secure an expert who would commit to attending the trial; that they failed to did so does not justify designation of their expert as "unavailable."

While, (not surprisingly) there is not a large body of case law regarding litigants knowingly hiring experts who cannot be present in court, such conduct is not permitted. The Second Circuit Court of Appeals first explained the rationale for preventing such:

[U]nlike the typical witness whose involvement with the case may depend on the fortuity of his observing a particular event and whose presence at trial is often involuntary, a party ordinarily has the opportunity to choose the expert witness whose testimony he desires and invariably arranges for his presence privately, by mutual agreement, and for a fee. Although a requirement of an attempt to secure the voluntary attendance of a witness who lives beyond the subpoena power of the court is not ordinarily imposed before prior testimony can be used in civil litigation, we think that such a requirement is particularly appropriate when dealing with the testimony of expert witnesses whose earlier attendance is almost invariably secured by such voluntary arrangements.

Carter-Wallace, Inc. v. Otte, 474 F.2d 529, 536 (2d Cir. 1972), cert. denied, 412 U.S.

929 (1973) (internal citations deleted).

The rule of *Carter-Wallace* has been followed around the country. In New

Jersey it has been expressed as follows:

[I]t is the responsibility of trial counsel to discuss . . . [the expert's] voluntary attendance at trial. If the expert is beyond the jurisdiction of the court to compel attendance at trial, it is the responsibility of the party offering the expert to ascertain the willingness and availability of the expert to appear at trial. The proponent of the expert must attempt to arrange a trial date at which the expert can appear. Since the expert is under the control of the offering litigant, due diligence must be used to secure the attendance of the witness at trial.

Thompson by Thompson v. Merrell Dow Pharm., Inc., 551 A.2d 177, 189 (N.J.

Super. App. Div. 1988) (12 expert witnesses' prior testimony found

inadmissible).

In Puerto Rico, Carter-Wallace was followed leading to the rejection of

two expert witnesses:

Rio Mar Defendants are responsible for selecting their own expert witnesses and presumably have control over them. Rio Mar Defendants designated Dr. George Richard Braen and Dr. Enrique Carrazana as their experts on July 8, 2008. Rio Mar Defendants have offered no explanation for the purported unavailability of either George Richard Braen or Enrique Carrazana after having been designated approximately 10 months ago. Rio Mar Defendants have not shown that they have requested these chosen experts to appear at trial nor that they have offered to pay for the expert's fee and expenses. Thus, Rio Mar Defendants appeared to have "procured" the absence of these experts to take advantage of the expert's deposition testimony and save on paying their professional fees in violation of Fed.R.Civ.P. 26(a)(2). Hence, Dr. Braen and Dr. Carrazana are not unavailable for purposes of Fed.Evid.R. 804.

Fiorentino v. Rio Mar Assocs., LP, SE, No. CV 01-2653(PG), 2009 WL 10680817, at *2 (D.P.R. Apr. 21, 2009).

Courts in both Massachusetts and Delaware have reached the same conclusion as the District Court for Puerto Rico, and held that litigants "procured" an expert's unavailability when they hired an expert who would be out of the jurisdiction at the time of trial. "By selecting an expert from Arizona, the plaintiff's counsel 'procured' the absence of his expert from the Commonwealth in the sense that he voluntarily created a situation in which his expert would be out of the Commonwealth unless he should make arrangements for the expert's appearance at trial." Caron v. Gen. Motors Corp., 643 N.E.2d 471, 474 (Mass. App. 1994). An identical result, using near identical language (replacing Arizona with Texas) was reached in Aubrey Rogers Agency, Inc. v. AIG Life Ins. Co., No. CIV.A.97-529 MMS, 2000 WL 135129, at *2 (D. Del. Jan. 13, 2000). That court explained that: "Parties are expected to use other reasonable means to procure the attendance of their experts because the parties select their experts and arrange for their appearance at trial." Id. See also, Hanson v. Parkside Surgery Center, 872 F.2d 745, 750 (6th Cir. 1989) ("plaintiff's inability to procure the witness'

attendance at trial was at least in part due to plaintiff's own lack of diligence."); Myers v. Estate of Alessi, 560 A.2d 59, 66 (Md. App. 1989) ("appellants alone were responsible for selecting an expert who resided in Washington. They were responsible for the decision not to pay him to attend trial."); Holmes v. Merck & Co., Inc., No. 2:04CV00608-BES(GWF), 2006 WL 1744300, at *2 (D. Nev. June 22, 2006) (finding that depositions are admissible when "for legitimate and unanticipated reasons, the expert was not available to testify at trial;" but not when "the proponent failed to make adequate efforts to secure the attendance of the expert witness at trial.").²

Plaintiffs have not found a case in Tennessee where a litigant intentionally hired an expert who could not be present at trial. However, the Court of Criminal Appeals has repeatedly held that a criminal defendant who wishes to use Tennessee Rule of Evidence 804 to introduce hearsay from an unavailable witness must first make a "good-faith effort" to obtain and/or locate the witness prior to trial. *State v. Cureton,* 38 S.W.3d 64, 79 (Tenn.Crim.App.2000) (good faith effort to secure witness's attendance required); *State v. Finchum*, No. E2001-01072-CCA-R3CD, 2002 WL 31190924, at *6 (Tenn. Crim. App. Oct. 2, 2002) (defendant failed to make good faith effort to locate and secure witness); *State v. Amos*, No. 01C01-9601-CC- 00011, 1997 WL 602949, at *5 (Tenn. Crim. App. Sept. 30, 1997) (to introduce former testimony under TRE 804, defendant must first make good faith effort to secure witness for trial).³

Here, Defendants intentionally chose an expert knowing the expert was

on vacation throughout the time period set for trial. Dr. Li's expertise was not so specialized that Defendants were could to timely obtain and designate another expert for trial, especially when Defendants had, by the most conservative measure, at least five months to do so.

The Defendants intentionally procured Dr. Li knowing he was on vacation at the time of trial and Rule 804 does not provide for accommodations under such circumstances. In fact, Rule 804 contains an express provision that a witness whose absence was procured by a party is not "unavailable." Dr. Li was not "unavailable" as intended by the rule, thus, the Chancellor abused her discretion in accommodating his out-of-time testimony.

2. The court's order permitting Li to testify out of time prejudiced Plaintiffs.

Permitting Dr. Li to testify out of time prejudiced Plaintiffs.¹²⁶ Plaintiffs were entitled to the assistance of their experts during the trial and expert assistance in this matter was especially important because Plaintiffs' allegations are scientifically based. *Malek v. Fed. Ins. Co.*, 994 F.2d 49 (2d Cir. 1993). Defendants provided notice of Dr. Evans who testified at trial and in the presence of Plaintiffs' experts who Plaintiffs' counsel consulted for purposes of Dr. Evans' cross-examination. The

¹²⁶ Here the Chancellor ignored Dr. Li in her ruling other than her acknowledgement that "the Defendant's two experts, while qualified, did not have the research knowledge and imminent publications that Plaintiff's experts did" (XVI 2251) and where the Chancellor found that Petitioners have proven that Midazolam "does not elicit strong analgesic effects and the inmate being executed may be able to feel pain from the administration of the drugs" to the contrary to Dr. Li's testimony, the prejudice Plaintiffs suffered from the admission of his testimony is difficult to cite. *Id*.

Chancellor's accommodation of the Defendants' witness problem deprived Plaintiffs of the ability to competently cross-examine of Dr. Li

VIII. Should this Honorable Court engage in any *de novo* factual review, the testimony of Dr. Roswell Lee Evans and Dr. Feng Li should be given no weight; the Chancellor should have excluded their testimony pursuant to *McDaniel v. CSX* and Tennessee Rules of Evidence 702 and 703.

The Chancellor in her Findings of Fact and Conclusions of Law, made virtually no mention of the Defendants' experts, Dr. Roswell Lee Evans and Dr. Feng Li. Order, XVI 2229-78 (established by nearly complete omission). Dr. Evans' opinion regarding compounding (which is not at issue in this appeal, and which was an area, as a pharmacist he was qualified to opine on) was mentioned approvingly. XVI 2263-64. The only other time Defendants' experts were mentioned was at the end of a long footnote detailing the qualifications of Plaintiffs' "four well-qualified and imminent experts." XVI 2251. After devoting a full paragraph to describe the qualification of each of Plaintiffs' experts, the Chancellor observed, "[t]he Defendants' two experts [who she did not name], while qualified, did not have the research knowledge and imminent publications that Plaintiffs' experts did." *Id.*, fn. 7. The testimony, opinions, and conclusions of Dr. Evans and Dr. Li (outside of Dr. Evans' on compounding) do not appear in her opinion.

None of the Chancellor's legal conclusions relied on the testimony of Dr. Evans or Dr. Li (again, with the exception of her finding on compounding). Thus, as they were irrelevant, it might seem unnecessary to further examine their credentials (or lack thereof). However, to the extent that this Honorable Court believes it proper to engage in any *de novo* factual analysis, appellants feel it prudent to explain why that *de novo* review should pay no regard to the defense experts.¹²⁷

a. Tennessee Rules of Evidence 702 and 703.

Expert scientific opinion testimony is only admissible under certain circumstances. As a predicate, the proponent of the opinion testimony must be "qualified as an expert by knowledge, skill, experience, training, or education." State v. Ferrell, 277 S.W.3d 372, 378 (Tenn. 2009); 94th Aero Squadron of Memphis, Inc. v. Memphis-Shelby Cnty. Airport Auth., 169 S.W.3d 627, 640 (Tenn. Ct. App. 2004); Tenn. R. Evid. 104(a), 702. An expert who is so qualified may provide opinion testimony if it will "substantially assist the trier of fact to understand the evidence or to determine a fact in issue." Tenn. R. Evid. 702. However, "[t]he court shall disallow testimony in the form of an opinion or inference if the underlying facts or data indicate a lack of trustworthiness." Tenn. R. Evid. 703. The Tennessee Supreme Court has taken the "substantially assist" and "trustworthiness" requirements from Rules 702 and 703 and combined them into an analysis of the "reliability" of the expert opinion. Brown v. Crown Equip. Corp., 181 S.W.3d 268, 274-75 (Tenn. 2005); McDaniel v. CSX Transp., Inc., 955 S.W.2d 257, 263-65 (Tenn. 1997).¹²⁸ In making these determinations, the Tennessee Supreme Court notes that

¹²⁷ If this Honorable Court sees no need to reweigh the evidence or to consider the testimony of Drs. Evans and Li, then the following sections of this brief can be skipped.

¹²⁸ The "substantially assist" prong also considers whether the subject matter of the opinion is one for which expert testimony is needed, or whether it is a matter that is within the common-sense understanding of the fact finder. *See Mabry v. Board of*

Rule 702 requires that the opinion "substantially assist" the trier of fact, unlike the federal rule, which merely requires that it "assist;" thus Tennessee requires that the "probative force of the testimony must be stronger before it is admitted in Tennessee." *State v. Scott*, 275 S.W.3d 395, 410 (Tenn. 2009); *McDaniel*, 955 S.W.2d at 264.

b. Defendants' proffered experts were unqualified.

Tennessee has long recognized that an expert's qualifications are a

"preliminary question for the trial judge." Ferrell, 277 S.W.3d at 378; 94th Aero

Squadron, 169 S.W.3d at 640. As the Tennessee Supreme Court held in Scott:

When assessing the admissibility of expert testimony, the trial court must first determine whether the witness is qualified by knowledge, skill, experience, training, or education to express an opinion within the limits of his or her expertise. This determination hinges upon whether the proposed expert's qualifications authorize him or her to give an informed opinion upon the fact or issue for which his or her testimony is being proffered.

Scott, 275 S.W.3d at 402 (citing State v. Stevens, 78 S.W.3d 817, 834 (Tenn. 2002)).

"To give expert testimony, one must be particularly skilled, learned or experienced in a science, art, trade, business, profession or vocation. The expert must possess a thorough knowledge upon which he testifies that is not within the

Prof'l Responsibility of Supreme Court, 458 S.W.3d 900, 909 (Tenn. 2014) (holding expert in law was not appropriate expert, as "his knowledge of the disciplinary process would have hardly 'substantially assisted' a trial judge, who is an expert in law himself."); *State v. Farmer*, 380 S.W.3d 96, 104-105 (Tenn. 2012)(whether an injury creates a "substantial risk of death" is outside of a juror's common-sense understanding, and is an appropriate subject for expert testimony). In this case the pharmacological and physiological properties of complex pharmaceuticals were plainly outside the common-sense understanding of jurists and lawyers.

general knowledge and experience of the average person." *State v. Ayers*, 200 S.W.3d 618, 621 (Tenn. Crim. App. 2005) (quoting *Otis v. Cambridge Mut. Fire Ins. Co.*, 850 S.W.2d 439, 443 (Tenn. 1992)). A qualified expert should have "some special as well as practical acquaintance with the immediate line of inquiry." *Martin v. Sizemore*, 78 S.W.3d 249, 273 (Tenn. Ct. App. 2001); *Bradford v. City of Clarksville*, 885 S.W.2d 78, 83 (Tenn. Ct. App. 1994).

> 1. Dr. Roswell Lee Evans qualifications; he was qualified to testify about compounding, but he had no relevant experience, professional expertise, research interest, or basis of knowledge to testify about Midazolam, or to offer an opinion on its efficacy as an anesthetic.

Dr. Evans is a Pharm.D. He is not a Ph.D. Though he has lived in Alabama for the past 24 years, he is not licensed in Alabama. XLV 2061. He is only licensed in the State of Georgia, but he has not practiced there since 1970. *Id.* 2034; Ex. 141, *Evans CV*, at Vol. 16, p. 2268-69. When Dr. Evans received his Pharm.D, in 1972, the degree only required 18 months of post-graduate education. XLV 2059. Midazolam wasn't on the market in 1972. *Id.* The last time Evans was in an operating room (other than as a patient) was in 1972, as a graduate student.

Since 1994, the majority of Evans' professional time (85%) has been devoted to administrative tasks. XLV 2121. He spent very little time teaching (at most two hours a week). *Id.* 2122. Prior to being hired to testify for the state of Florida in 2014, Evans has not studied Midazolam for lethal injection, nor has he researched it. *Id. Id.*

Evans has never been present when Midazolam was administered. *Id.* He has no experience in prescribing Midazolam, indeed he is not allowed to prescribe medications. *Id.* 2060. Evans has never researched, published, or presented on the subject of Midazolam. He did present lectures regarding Xanax (generic name alprazolam) at places such as "The Ozark Society" and the "Black Hills Winter Seminar" in the 1980's and he did write an article about Xanax in 1992. *Id.* 2062-2064. Xanax is administered orally. *Id.* 2064. Evans is not a pharmacologist. XLV 2058.

2. Dr. Feng Li's is not qualified to provide an opinion on pain and suffering in living humans: he has spent his career examining dead humans.

Dr. Li is a forensic pathologist. He is not a pharmacologist. XLVIII 42. He is not a member of any organization that deals with pharmacology. XLVIII 43. He is not an anesthesiologist. XLVIII 42. He is not familiar with the American Society of Anesthesiology. XLVIII 43. He has never administered Midazolam. XLVIII 43-44. He has not seen Midazolam administered. He graduated from medical school in China in 1983. XLVIII, 42; Ex. 149, *Li CV*, at Vol. 19 2752.¹²⁹

Dr. Li has never conducted research on pharmaceuticals. XLVIII 44; Ex. 149. Dr. Li has never published an article about any pharmaceutical. XLVIII 44; Ex. 149. Dr. Li has never presented a lecture about pharmaceuticals. XLVIII 44; Ex. 149. Dr. Li does not have an H-Index –in fact he does not know what an H-Index is. XLVIII 45.

¹²⁹ Thought Dr. Li identified Ex. 149 as his current CV on direct examination. On cross-examination he stated that it was not current. XLVIII 45. Defendants did not provide the Court with an updated CV. According to Dr. Li, any additions to his CV are not relevant to the issues before the Court.

Dr. Li has spent his entire professional career as a medical examiner. Ex. 149, at Vol. 19 2752. Dr. Li has never conducted an autopsy on person who overdosed from Midazolam. XLVIII 46. Dr. Li testified that he cannot tell from an autopsy whether the decedent was aware of pain prior to their death. XLVIII 47.

3. Neither defense experts' qualifications met the standard for admissibility.

Under the less-demanding federal standards, multiple federal courts have excluded expert testimony from unqualified experts. In *Mancuso v. Consolidated Edison Company of New York, Inc.*, 967 F. Supp. 1437 (S.D.N.Y. 1997), the district court declined to consider expert testimony from an individual who had no "specialized knowledge of the scientific issues...as a result of training or experience," but instead, after being hired, had "subsequently attempted, with dubious success, to qualify himself as such by a selective review of the relevant literature." *Id.* at 1443.

In Newell Rubbermaid, Inc. v. Raymond Corp., 676 F.3d 521, 526 (6th Cir. 2012), the Sixth Circuit affirmed the exclusion of a forensic engineer who had sought to testify that a particular forklift was defectively designed, despite having no relevant experience with that model forklift and only limited experience in driving forklifts from other manufacturers: "An expert who presents testimony must 'employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 527 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)) (alteration in original).

A. Pharmacists, like Dr. Evans, are regularly found not to be

qualified to testify regarding pharmacology or medical matters.

At least four federal courts have excluded testimony from pharmacists who

attempted to offer opinions on pharmacological and/or medical issues. In Dellinger

v. Pfizer Inc., No. 5:03CV95, 2006 WL 2057654, at *8 (W.D.N.C. July 19, 2006) a

court excluded a pharmacist offered to establish a "pharmacological link between

Neurotonin and pneumonia and/or pancreatis":

Keeys is not a doctor and has a degree in pharmacy—not pharmacology. Without a degree in pharmacology, Keeys is not qualified to render a relevant or reliable pharmacological opinion regarding the effects of Neurontin.

In addition to a lack of professional training in pharmacology, Keeys readily admits that he has no specialized knowledge of, or experience with, pancreatitis or pneumonia. Furthermore, Keeys never performed independent research on the pharmacologic design, efficacy or mechanism of Neurontin. For these reasons, Keeys' opinion lacks the necessary background and expertise to qualify him as an expert witness on the issue of causation. Therefore, Keeys' opinion is inadmissible under Fed. R. Evid. 702.

Id. (internal citations deleted).

Two different federal district courts have excluded the same proffered

expert-Dr. James O'Donnell, Pharm. D.-from offering expert opinion testimony

on the pharmacological effects of medications.¹³⁰ In Newton v. Roche Labs., Inc.,

243 F. Supp. 2d 672 (W.D. Tex. 2002), Dr. O'Donnell was offered to testify that

Accutane is pharmacologically capable of causing schizophrenia. Pointing out

¹³⁰ Roswell Lee Evans is also a Pharm.D. Though he has not been engaged in the practice of pharmacy for years and does not hold a pharmacy license his state of residence. Dr. Evans has been in academic administration for nearly thirty years.

O'Donnell's "lack [of] appropriate pharmacological training relevant to the issues"

presented, the court explained its reasons for excluding him as follows:

O'Donnell admits that he took just one course related to pharmacology during his year-long Pharm. D. program. . . . [H]e has no expertise in what causes psychosis, including schizophrenia, or in any field of science relevant to plaintiffs' claims (such as psychiatry, psychology, dermatology, neurology, biology, biochemistry, or epidemiology). Not only does O'Donnell lack appropriate pharmacological training relevant to the issues in this case, he concedes that he has not performed even basic "bench or clinical research" on Vitamin A or Accutane. He has conducted no serious scientific research independent of this litigation. See Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir.), *cert. denied*, 516 U.S. 869, 116 S. Ct. 189, 133 L.Ed.2d 126 (1995) ("One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying."). Instead, O'Donnell's opinion in this case is based solely on an incomplete review of existing literature (mainly limited to anecdotal case reports), certain FDA documents, and a small subset of the spontaneous adverse event reports produced in an earlier litigation. As one Court of Appeals has put it, an individual's "review of literature" in an area outside his field does "not make him any more qualified to testify as an expert ... than a lay person who read the same articles." United States v. Paul, 175 F.3d 906, 912 (11th Cir. 1999).

Id. at 677–78 (some internal citations and footnotes deleted). Two years later, another district court followed the *Newton* court's lead, when O'Donnell was offered as an expert on the inadequacy of a drug label's warning about withdrawal risks of Paxil. *Devito v. Smithkline Beecham Corp.*, No. CIV.A. 02-CV-0745NPM, 2004 WL 3691343, at *7 (N.D.N.Y. Nov. 29, 2004). The *Devito* court characterized O'Donnell as merely possessing "the sort of 'litigation-drive[n] expertise' which courts have eschewed." *Id.* at *7. "O'Donnell is *not* a pharmacologist. Therefore, he cannot, as he
does in his 'expert report,' opine to a 'reasonable pharmacological certainty,' that plaintiff is experiencing 'withdrawal toxicity reactions from Paxil[.]' Clearly, allowing a pharmacist/nutritionist such as O'Donnell to testify in that way would run afoul of the rule that an expert must stay 'within the reasonable confines of his subject area[.]." *Id.* (internal citations omitted).

Finally, in the unreported opinion of *Wehling v. Sandoz Pharm. Corp.*, 162 F.3d 1158 at *3-4 (4th Cir. 1998) (table), the Fourth Circuit upheld the exclusion of a pharmacist who intended to testify about the interaction within the human body between Clorazil and the benzodiazepine, Klonopin: "Without prior training, education, or experience in the field, McBay's review of the literature, after he was retained as an expert witness in this suit, was insufficient to qualify him as an expert on the issues in dispute." *Id.* at 4.

4. Accordingly, the testimony from Dr. Evans and Dr. Li should be given no weight, should there be a *de novo* review of the evidence.

The above body of law strongly supports the conclusion that neither Dr. Li nor Dr. Evans was qualified to proffer expert opinions on the capacity of Midazolam to render an inmate insensate to noxious stimuli, and/or on the pain and suffering that would be caused by Tennessee's three-drug lethal injection protocol. Dr. Li is a pathologist whose specialty is the cause of death, who displays no meaningful knowledge of how Midazolam operates, or what the noxious effects of vecuronium bromide or potassium chloride could be. Dr. Evans is a pharmacist who has spent much of last three decades in administration, has not published any relevant articles in peer-reviewed journals, has not conducted relevant research, and whose past involvement with benzodiazepines was related to their use as psychiatric/anxiety medications, not as surgical sedatives.

Neither defense expert had any real world experience with any issue in dispute. Moreover, both engaged in a "litigation-driven," incredibly selective reading of a small portion of the relevant scientific literature, while ultimately relying as the final source of their opinions on the "package insert" that comes with every prescription for commercially manufactured Midazolam. This type of reading does not make them "any more qualified to testify as an expert ... than a lay person who read the same [package insert]." *Paul,* 175 F.3d at 912; *Newton,* 243 F. Supp. 2d at 678. Moreover, neither the package insert, the FDA, nor the manufacturers of Midazolam indicate that it is appropriate for use as a general anesthetic. For these reasons, this Honorable Court should conclude that neither of Defendants' experts are qualified to provide an expert opinion under Rule 702.

c. Defendants' proffered experts are not reliable.

In *McDaniel*, this Court announced the Tennessee standard for the admissibility of opinion testimony from qualified experts:

Tennessee Rules of Evidence 702 and 703 impose a duty upon trial courts to determine whether scientific evidence will substantially aid the trier of fact and whether the underlying facts and data relied on by the expert witness indicate a lack of trustworthiness. The trial court must further determine whether the reasoning or methodology underlying the scientific evidence is sufficiently valid and reliable, and whether it can properly be applied to the facts at issue. In making this determination, the trial court should focus on the principles and methodology underlying the science, and not on the conclusions of experts. The trial court is not required to determine that the principles and methodology employed are generally accepted by the scientific community. The court needs only to determine that the principles and methodology are scientifically valid and reliable.

955 S.W.2d at 258.

The *McDaniel* court provided a "non-exclusive list of factors to determine

reliability":

(1) whether scientific evidence has been tested and the methodology with which it has been tested;

(2) whether the evidence has been subjected to peer review or publication;

(3) whether a potential rate of error is known;

(4) whether, as formerly required by *Frye*, the evidence is generally accepted in the scientific community; and

(5) whether the expert's research in the field has been conducted independent of litigation.

Id. at 265.

Here, Defendants' proffered experts did nothing more than conduct limited

research and then draw conclusions not supported by the research they cite.

1. Defendants' proffered experts' opinions were based on speculation, not science.

Subsequent to McDaniel, this Honorable Court further defined the reliability

analysis to include "four general inter-related components: (1) qualifications

assessment, (2) analytical cohesion, (3) methodological reliability, and (4)

foundational reliability. *Scott*, 275 S.W.3d at 402. Methodological reliability is somewhat tautological as it "focuses upon the reliability of the methodology employed by the expert." *Id.* at 403. Foundational reliability, however, is more concretely defined:

The foundational inquiry has two steps. The first step is to assess the expert's field or discipline itself by focusing on the reliability of the studies, articles, and data that compose the field and that provide the underlying foundation for the expert's testimony. The second step is to analyze the reliability of the underlying facts or data upon which the expert's opinion is predicated.

Id.

The Court in *Scott* additionally required that "an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 402-3. The Court enunciated a crucial distillation of these principles in *McDaniel*. "The court...must assure itself that the opinions are based on relevant scientific methods, processes, and data, and not upon an expert's mere speculation." *McDaniel*, 955 S.W.2d at 265.

Thus, ultimately, the inquiry focuses on whether the expert's proffered opinion is an intellectually rigorous one based on scientific methodology, or merely the product of litigation-driven speculation.

2. Ipse dixit expert opinions are not reliable, not admissible, and have been frowned on since the time of Pythagoras and Cicero.

In *Scott*, this Court eloquently explained why an expert's opinion should not be admitted, merely because he or she is an expert: *Ipse dixit* assertions were insufficient to support the contentions of the Pythagoreans,⁴ and they remain so with regard to appeals to the authority of a modern expert as a sole basis for admission. Just because an expert is speaking does not make what he or she is saying sufficiently reliable to be admitted into evidence as expert testimony. The courts "must analyze the science and not merely the qualifications [of the expert]."

FN 4: The literal translation of the Latin phrase "ipse dixit" is "he himself said it." It refers to dogmatic statements—"something said but not proved." The first prominent historical use of the expression ipse dixit is attributed to Cicero's critique of adherents of Pythagoras. "Nor am I in the habit of commending the custom of which we hear in connection with the Pythagoreans, of whom it is said that when they affirmed anything in argument, and were asked why it was so, their usual reply was 'the master said it,' 'the master' being Pythagoras, and the force of preconceived opinion being so great as to make authority prevail even without the support of reason."

Scott, 275 S.W.3d at 402 (internal citations deleted).

Scott's holding is consistent with that of the United States Supreme Court: "Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). In Joiner, the Supreme Court upheld the exclusion of two expert witnesses, who concluded that the plaintiff had incurred lung cancer from PCBs, when the experts had reached their conclusion based on (1) animal studies involving massive doses of daily applications of PCBs to infant mice; (2) studies which reached a contrary conclusion: "there were apparently no grounds for associating lung cancer deaths and exposure in the plant;" and the rate of cancer was "not statistically significant," (3) one study that did not involve PCBs at all, and (4) a single study, which found a statistically significant increase in cancer, but involved subjects exposed to multiple carcinogens. *Id.* at 518-10.

In *State v. Stevens*, 78 S.W.3d 817 (Tenn. 2002), this Court upheld the exclusion of a crime scene reconstructionist, who wished to testify that the murder scene was consistent with a sexually motivated assault: "we cannot allow an individual's guilt or innocence to be determined by such opinion evidence connected to existing data only by the *ipse dixit* of the expert." *Id.* at 835.

In *Brown v. Crown Equipment Corp.*, 181 S.W.3d 268 (Tenn. 2005), this Court cautioned trial courts against using an expert's qualifications "as the sole basis of reliability," as doing so "would result in a reconsideration of the Rule 702 requirement that the expert witness be qualified by knowledge, skill, experience, training, or education to express an opinion within the limits of the expert's expertise. As a result, the expert testimony would become "perilously close to being admissible based upon the *ipse dixit* of the expert." *Id.* at 274.

Respectfully, Plaintiffs submitted highly-credentialed experts who did not rely on *ipse dixit* at all, whereas Defendants submitted two pleasant gentlemen who claimed that their ability to read a package insert is somehow greater than that possessed by this Honorable Court. Indeed, Dr. Evans most paradoxically claimed to be able to draw conclusions based on the research papers of Dr. Greenblatt, that were contrary to the conclusions reached by Dr. Greenblatt in those papers. Dr. Evans and Dr. Li both ask this Honorable Court to accept their opinions on the efficacy of Midazolam, not based on science, let alone Midazolam's mechanism of

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action, but because they are experts. They asked the court to accept their nonsensical conclusion that while Midazolam cannot bring someone to a plane of general anesthesia, it can bring them beyond general anesthesia straight to coma.¹³¹

Dr. Li explicitly testified at trial that, although he is unable to point to specific studies or science to support his conclusions, he is an expert pathologist and at some undefined point read something (beyond the package insert) that supported his opinion that enough Midazolam would render a patient sufficiently insensate to pain that the second two drugs could be administered without suffering.¹³² Albeit, he was unsure of what suffering, if any, the second two drugs would cause.¹³³ Dr. Li,

¹³¹ Madeleine L'Engle wrote a charming series of books, beginning with "A Wrinkle in Time." In these books, specially skilled humans (and stars that take on human form) can warp time and space, so that they can jump from Point A straight to Point Q, bypassing points B through V. It is interesting fiction. However, it is unlikely that Dr. Evans or Dr. Li has mastered these fictional skills.

¹³² Dr. Li claimed to rely on phantom sources. He stated that he did not include all of his sources in his report, and when challenged to name any additional authority for his testimony, he was unable to name them. XLVIII 48 ("I don't want to list everything I have or I know."); XLVIII 121 ("some sources are listed, some **sources I don't list** as a result of too many references to put in. So as I said, today, and in the past, I cannot list everything I studied or researched on. I can only put **certain most important** as I said, I mean, in the report.")(emphasis added); XLVIII 122 ("I cannot explain everything I have."); XLVIII 125 ("I cannot list everything I have."); XLVIII 156 ("I don't want to list them all."); XLVIII 160 ("I mean I don't list it here."); XLVIII 169 ("I cannot list everything I have or everything I know in this declaration.").

¹³³ Contrary to every other expert and the Chief Justice of the United States Supreme Court in *Baze*, Dr. Li maintains that an injection of potassium chloride without anesthesia would not be painful. XLVIII 48.

ultimately, acknowledged that whatever it was he read, he may have read it during medical school, in China, in the 1980s.¹³⁴

3. Defendants' proffered experts relied on warnings on package inserts, which are of no significance.

Defendants' experts' testimony that Plaintiffs will not experience pain as a result of Protocol B largely rests on the Midazolam package insert, which warns of the risk of coma, from which they extrapolate that if a normal dose of Midazolam can occasionally cause a coma, then a large enough dose will always cause a coma, and ultimately death.¹³⁵ The full warning reads: "The manifestations of Midazolam overdosage reported are similar to those observed with other benzodiazepines, including sedation, somnolence, confusion, impaired coordination, diminished reflexes, coma and untoward effects on vital signs." Aside from the unscientific absurdity of Defendants' experts conclusion—which is akin to reading the label on a box of Cheerios, which says "Can Help Lower Cholesterol" and concluding that six boxes of Cheerios a day will eliminate all cholesterol—the experts' reliance on the package insert was also legally unsound.

¹³⁴ Dr. Greenblatt was responsible for the original studies on the efficacy of Midazolam, which were done in the early 1980's. Thus, what experience Dr. Li would have had with Midazolam in 1980's Communist China has never been explained. When confronted with his apparent lack of sources, Dr. Li resorted to invocations of "common knowledge" as the basis of his opinions. XLVIII 129; XLVIII 159-60

¹³⁵ The FDA package insert for Tylenol lists coma as a possible side effect of overdose. No one would suggest using a massive quantity of Tylenol as the first drug in a three drug protocol.

First, "the FDA regulations on warnings provide that a causal relationship need not have been proved" before warnings are added to drug labels." *Newton.*, 243 F. Supp. 2d at 683; *see also Nozinch v. Johnson and Johnson, Inc.*, No. 09-02105 DKV, 2011 WL 13124085, at *7-10 (W.D. Tenn. July 6, 2011). This is because, under federal regulations, a medication's label must "include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6)(i). Thus, the fact that Midazolam's package insert warns of a risk of coma is not proof that there is a causal connection between Midazolam and coma. Second, a package insert that fails to adequately warn of any possible risk (however remote) can lead to a lawsuit when the 1 in 1,000,000 risk actually occurs—and even if the specific pharmaceutical is not responsible for the tragic result.¹³⁶ Thus, not only are drug manufacturers legally required to place warnings

¹³⁶ See, e.g. Rheinfrank v. Abbott Labs., Inc., 680 F. App'x 369, 370 (6th Cir. 2017) (suit for inadequate packaging that allegedly failed to warn of danger of birth defects caused by Depakote; defendant ultimately prevailed); Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378, 391 (6th Cir, 2013) (discussion of multiple cases alleging failure to provide additional warnings); Marsh v. Genentech, Inc., 693 F.3d 546, 548 (6th Cir. 2012) (Defendant, allegedly, knew of dangerous side effects that it concealed from the public and did not include in the drug's label; motion to dismiss for failure to state a claim granted and upheld); Smith v. Wyeth, Inc., 657 F.3d 420, 423 (6th Cir. 2011) (plaintiffs alleged that their long-term use of generic metoclopramide caused tardive dyskinesia, and manufacturers failed to provide adequate warnings on the product's label; case dismissed); Barnes v. Kerr Corp., 418 F.3d 583, 590 (6th Cir. 2005) (plaintiffs claimed that manufacturer failed to include warnings about the dangers of exposure to mercury in dental fillings); Boggs v. DuPont Pharm., 865 F.2d 1267 (6th Cir. 1989) (plaintiffs contended that DuPont's package insert inadequately warned of the danger of necrosis of the skin following the use of Coumadin).

in package inserts before a causal relationship has been proven, but doing so is also a wise business decision to avoid litigation.

In *Newton*, cited above for the district court's holding that Dr. O'Donnell was unqualified to testify, the court found another of the plaintiff's expert opinions unreliable because it was based in large part on a package insert:

Dr. Rossiter claims to rely on two things to conclude that [plaintiff's] schizophrenia was induced by her use of Accutane: (1) the temporal association between [plaintiff's] Accutane use and her illness; and (2) the Physician's Desk Reference and package insert warnings supplied by Roche Labs. Neither of these bases is sufficiently reliable. As Defendants point out, the Fifth Circuit has rejected expert testimony that relies "substantially on the temporal proximity between exposure and symptoms." Defendant contends further that the warning label should not be considered a "reliable" source for Dr. Rossiter's opinion. FDA-approved warnings to physicians generally are not evidence of causation. Indeed, the FDA regulations on warnings provide that "a causal relationship need not have been proved" before warnings are added to drug labels.

Newton, 243 F. Supp. 2d at 683 (internal citations deleted).

In contrast to Plaintiffs' experts, Defendants experts' cite no relevant literature (in the case of Dr. Li), or only cite to a small and selective body of science, which, paradoxically includes the published writings of Dr. Greenblatt (in the case of Dr. Evans). Neither of Defendants' proposed experts could explain how Midazolam's pharmacological properties can render an inmate insensate to pain. Instead, both experts relied on a small number of anecdotal reports of fatalities

Plaintiffs' counsel note that the above string cite only contains cases from the Sixth Circuit Court of Appeals. Running a national Westlaw search for: *adv: ((package product) +s (label insert)) /s (insufficient missing failure inadequate) /s warning* in All States and All Federal results in 769 hits as of July 2, 2018 at 1:15 p.m.

and/or coma involving Midazolam (the majority of which, they conceded, involve other drugs, including fentanyl). Based on these reports, the experts concluded that larger doses of Midazolam would be fatal (and thus, for some reason, would render an inmate insensate prior to death). They also relied on package inserts, which include a warning that coma is possible. Their "science" is significantly less rigorous than that rejected in *Newton* and *Nozinch*. Ultimately, they simply speculated about the possible impact of large doses of Midazolam; they did not engage in any scientific methodology at all (unless extrapolating that "more must mean stronger" qualifies as science); the data upon which they relied is anecdotal; and their conclusions were thus fatally flawed and should have been found to be inadmissible.

VIII. We cannot "wantonly and freakishly" impose a method of execution on inmates prior to deliberative appellate review of a fulsome trial record; to do so violates Due Process, the Law of the Land and the promise of *Gregg v. Georgia*.

In *Gregg v. Georgia* the United States Supreme Court asserted the crucial role that "meaningful appellate review" would play in assuring that death sentences would not be imposed in a "freakish" manner. *Gregg v. Georgia*, 428 U.S. 153, 195, 96 S. Ct. 2909 (1976). In *Lewis v. Jeffers*, we were reminded that "the Eighth and Fourteenth Amendments cannot tolerate the infliction of a sentence of death under legal systems that permit this unique penalty to be...wantonly and...freakishly imposed." *Lewis v. Jeffers*, 497 U.S. 764, 774, 110 S. Ct. 3092 (1990). However, it appears that the determination of whether inmates may constitutionally suffer a torturous death will be made on a time schedule more suited for the small claims

courts of General Sessions. Affording so little time for deliberative process and legal analysis, inevitably will lead to violation of the 14th Amendment and Article I, § 8.

a. The record is over 15,000 pages in length; this Honorable Court has virtually no time available to review it, while counsel for appellants (and appellees) have too-little time to prepare helpful and thoughtful briefings.

The publicly available Technical Record, including transcripts, is 11,718 pages long. I to LI. There are another 2,804 bate-stamped pages of exhibits. Exhibits Vol. 1-19. Additionally, there are 92 pages of underseal pleadings and orders, and 956 pages of underseal technical record. This totals well-over 15,000 pages of information that this Honorable Court has only been able to review (without benefit of any briefing), beginning August 22, 2018. Briefing that will illuminate this record will be completed on September 28, 2018, five-days before oral argument, and less than two-weeks prior to the next scheduled execution.

The first brief (this brief) is due September 6, 2018, a mere two-weeks after the filing of the 15,000+ page record, and only six-weeks after the issuance of the 49-page Order that is the primary (but not only) subject of appeal. Appellees have two-weeks to file a responsive briefing, and then appellants will have only one-week to correct any errors or misstatements made by appellee.¹³⁷

Thus, the briefing that this Honorable Court will turn to for legal analysis and factual development will have been prepared on an incredibly rushed schedule.

¹³⁷ On this compressed time-schedule, it would seem inevitable that both sides will find errors, typos, omissions and mistakes in the opposition pleadings.

Appellants' counsel sincerely hope that their late night efforts have produced a wellreasoned and beneficial legal product, but the reality is that—even if this brief is factually compelling and legally illuminating—it would have been better (and much more concise) had time pressures not been so pressing. The greatest harm will be the argument that was overlooked, or assigned to three lawyers and finished by none, or inadvertently dropped in the rush of late-night edits.

This schedule can be compared to the traditional schedule afforded litigants in less complex litigation: a full 30-days are permitted simply to file appeal.¹³⁸ *Tenn.R.App.P. 4.* Ideally the record is then filed in 45-days (though, as we are all aware extensions are frequently requested and granted). *Tenn.R.App.P. 25(a).* The appellant's first brief is then due 30-days thereafter, appellee's response 30-days more, and appellant's reply after 14-days—again if the inevitable extensions are not requested and granted. *Tenn.R.App. 29.* On that traditional schedule, the first brief would not have been due until early November, at the earliest, and briefing would not have been finished until early 2019. Oral argument would have been in the Spring of 2019. Instead, our oral argument is scheduled before the record would have been filed in a traditional case. Crucially, this Honorable Court would have been given months following oral argument to consider arguments, review the applicable law, and study the evidentiary record. *E.g. West v. Schofield*, 519 S.W.3d 550 (Tenn. 2017) (lethal injection challenge argued October 6, 2016, opinion issued

¹³⁸ Due to responsibility to living plaintiffs whose executions are imminent, appellants could not wait those 30-days before filing notice.

March 28, 2017). Sadly, if an opinion is to be issued prior to the next execution, this Honorable Court will have all of one-week to complete that crucially important precedent.

b. *Gregg v. Georgia* ended the ban on executions mandated by *Furman*, however, *Gregg* relied on the promise that appropriate due process protections would ensure that "death sentences are not imposed...in a freakish manner."

For the reasons that have been set-forth many times previously, Tennessee's present method of execution is plainly "freakish."¹³⁹ The United States Supreme Court in *Gregg v. Georgia* attempted to remove such freakishness from the execution process, and to bring a manner of rationality and dignity to such proceedings. *Gregg v. Georgia*, 428 U.S. 153, 195, 96 S. Ct. 2909 (1976). One factor that the *Gregg* court examined was whether a "further safeguard of meaningful appellate review is available to ensure that death sentences are not imposed capriciously or in a freakish manner." *Id.* Moreover, *Gregg* reiterated that methods of execution "must not involve the unnecessary and wanton infliction of pain." *Id.* at 173 (citing *Furman v. Georgia*, 408 U.S. 238, 392-93, 92 S. Ct. 2726 (1972)).

Yet, here, the determination of whether Tennessee's three-drug protocol will cause the wanton infliction of pain will be made in roughly the same time that this

¹³⁹ On this compressed time-schedule, appellants' counsel has not fully researched the legal meaning of "freakish." Rather, appealing to common-sense word usage, it is suggested that an execution process that is akin to drowning someone in blood, burying them alive, and then setting them on fire would not only be torturous and barbaric (and inhumane and sadistic), but freakish as well.

Court usually takes to issue an order in response to a two-page motion to expand the record. This violates the spirit of *Gregg* and devalues human life.

c. Meaningful appellate review is constitutionally required.

This Honorable Court has long asserted that meaningful appellate review is constitutionally required, pursuant to the 14th Amendment and Article I, § 8. *State v. Trent*, 533 S.W.3d 282, 295-96 (Tenn. 2017) ("record must be sufficient for meaningful appellate review"); *Am. Heritage Apartments, Inc. v. Hamilton Cty. Water & Wastewater Treatment Auth.*, 494 S.W.3d 31, 50 (Tenn. 2016) (trial court decision lacked "sufficient specificity to allow for meaningful appellate review); *State v. Curry*, 988 S.W.2d 153, 157 (Tenn. 1999) (need for meaningful appellate review when determining eligibility for diversion); *House v. State*, 911 S.W.2d 705, 711 (Tenn. 1995) (a full and fair hearing includes meaningful appellate review)

In *Parker v. Dugger*, the United States Supreme Court reaffirmed the principal of *Gregg*: "[w]e have emphasized repeatedly the crucial role of meaningful appellate review in ensuring the death penalty is not imposed arbitrarily or irrationally. 498 U.S. 308, 321, 111 S. Ct. 731 (1991). In *Dugger* the Court condemned the Supreme Court of Florida's affirmance of a death penalty when Florida's decision was "neither based on a review of the individual record in this case nor in reliance on the trial judge's findings based on that record, but in reliance on some other nonexistent findings." *Id.*

The United States Supreme Court has repeatedly held that, in civil cases, the Due Process clause requires meaningful appellate review of punitive damage

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awards. *Honda Motor Co. v. Oberg*, 512 U.S. 415, 420, 114 S. Ct. 2331 (1994); *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 20 111 S.Ct. 1032 (1991). The Supreme Court's reasoning was best articulated by Justice Breyer (joined by O'Connor and Souter) in *BMW of North America:*

The reason flows from the Court's emphasis in *Haslip* upon the constitutional importance of legal standards that provide "reasonable constraints" within which "discretion is exercised," that assure "meaningful and adequate review by the trial court whenever a jury has fixed the punitive damages," and permit "appellate review [that] makes certain that the punitive damages are reasonable in their amount and rational in light of their purpose to punish what has occurred and to deter its repetition." ...

This constitutional concern, itself harkening back to the Magna Carta, arises out of the basic unfairness of depriving citizens of life, liberty, or property, through the application, not of law and legal processes, but of arbitrary coercion...Requiring the application of law, rather than a decisionmaker's caprice, does more than simply provide citizens notice of what actions may subject them to punishment; it also helps to assure the uniform general treatment of similarly situated persons that is the essence of law itself.

BMW of N. Am., Inc. v. Gore, 517 U.S. 559, 587–88, 116 S. Ct. 1589 (1996) (Breyer, J, concurring).

Appellants' counsel do not disagree that BMW and Honda Motors should be entitled to meaningful appellate review of any punitive damages assessed against them. Counsel simply ask that their clients be afforded the same level of constitutional due process.

CONCLUSION

For all of the foregoing reasons, Plaintiffs' request this Court, at a minimum:

1) reverse the judgment of the Chancery court; and/or

2) find that the July 5, 2018 lethal injection protocol violates the 8th amendment to the United States Constitution and/or Article 1, §16 of the Tennessee Constitution because it constitutes cruel and unusual punishment; and/or

3) find that the Chancery Court erred in failing to consider Plaintiffs' second alternative lethal injection protocol: a two-drug protocol which eliminates the paralytic; and/or

4) find Defendants waived the pleading requirement of a known, feasible, and readily available alternative by refusing to produce the only source of information regarding Defendants' efforts to obtain Pentobarbital; and/or

5) find that the July 5, 2018 lethal injection protocol violates the 8th amendment to the United States Constitution and/or Article 1, §16 of the Tennessee Constitution because it constitutes torture; and/or

6) find that the conduct of Defendants in choosing to use midazolam as a part of three-drug protocol violates Plaintiffs' substantive due process rights under the United States and/or Tennessee Constitutions; and/or

7) find the Chancery Court erred, based on an erroneous interpretation of state secrecy laws related to executions, by denying discovery requests that were designed to discover evidence of the availability of Pentobarbital to the State of Tennessee where it is known that the states of Texas and Georgia continue to use Pentobarbital in executions; and/or

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8) find that Tennessee's secrecy statute excuses Plaintiffs from the burden to establish the availability of an alternative lethal injection protocol; and/or

9) find that the denial of a telephone, visual access, and a second attorney in the observation room during an execution will prevent Plaintiffs from accessing the court, and that e the TDOC's general counsel's admission that the reason for the denial of telephone access is to prevent the inmates from calling the courts because the court might interrupt the execution violates Plaintiffs' federal and state constitutional rights to access the courts; and/or

10) find that the chancery court erred in dismissing Plaintiffs' claim that the Protocol violates their right to dignity because it does not reflect evolving standards of decency as required by Article 1, § 16 of the Tennessee Constitution and the Eighth Amendment of the United States Constitution.

11) find that the chancery court erred in dismissing Plaintiffs' claim that the Protocol violates the dignity of man by using lethal injection chemicals that are prohibited by state statutes for use in non-livestock animal euthanasia in violation of Article 1, § 16 of the Tennessee Constitution and the Eighth Amendment of the United States Constitution; and/or

12) find that the Chancery Court erred in denying Plaintiffs' pre-trial motion to amend their complaint to add an as-applied challenge to the use of the secret Drug Supplier who was unlicensed to compound Midazolam and therefore unqualified to provide instruction on how to prepare and store compounded Midazolam; and/or

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13) find that the Chancery Court erred in reconsidering her order excluding the testimony of Dr. Feng Li who Defendants engaged knowing that he would be out of town during the trial and whose late testimony delayed the adjudication of the trial where Defendants had been on notice for months that the protocol would be challenged and in fact knew three months before Plaintiffs that they were going to use this highly problematic protocol; and/or

14) find that the Chancery Court erred in failing to exclude Defendants' witnesses under *McDaniel v. CSX Transportation Inc.*, 955 S.W.2d 257 (Tenn. 1997); and/or

15) enter final judgment in favor of the plaintiffs. Alternatively,

16) vacate the execution date of Edmund Zagorski and reset the appellate schedule in this matter to permit new briefing and a more deliberative appellate process; and/or

17) if this Court finds that the Chancery Court failed to make sufficient fact findings, remand the case for directions for further proceedings.

Respectfully Submitted,

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I. <u>CERTIFICATE OF SERIVCE</u>

I, Kelley J. Henry, hereby certify that a true and correct copy of the foregoing document was electronically filed and sent to the following via email on this the 6th day of September, 2018, to:

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IN THE SUPREME COURT OF TENNESSEE AT NASHVILLE ZUIT NOV 29 PM 4:04

APPELLATE COURT CLERK NASHVILLE

STATE OF TENNESSEE V. STEPHEN MICHAEL WEST

Circuit Court for Union County No. 415A

No. M1987-000130-SC-DPE-DD¹

ORDER

On November 6, 2010, this Court reset the execution date for Stephen Michael West to November 30, 2010, pending an evidentiary hearing and ruling in a declaratory judgment action filed by Mr. West challenging the constitutionality of Tennessee's three-drug protocol for lethal injection. On November 22, 2010, the trial court entered an order granting a declaratory judgment to Mr. West. To date, no appeal has been lodged.

Also on November 22, 2010, Mr. West filed in this Court a "Motion to Vacate or Further Modify Court's Order Scheduling Mr. West's Execution." A transcript of the trial court's ruling was included with the filing, but not a transcript of the evidence. On November 24, 2010, the State filed a response in opposition to Mr. West's Motion and attached to the response a copy of a revised protocol. Later that same day, this Court denied Mr. West's motion to vacate or further modify his execution date because the revised protocol appeared to address the basis of the trial court's conclusion that the previous protocol was unconstitutional. However, we specified that the denial of Mr. West's motion was without prejudice to his ability to seek further relief in this or any other court.

On November 26, 2010, Mr. West filed in this Court a motion to reconsider or in the alternative a renewed motion to vacate or further modify the order scheduling his execution for November 30, 2010. Mr. West forcefully asserts that reconsideration is warranted because he was not afforded an opportunity to reply to the State's response and to address

¹Mr. West styled his motion *Stephen Michael West et al. v. Gayle Ray et al.*, and referred to the number of the declaratory judgment action pending in the Chancery Court for Davidson County. As previously stated, to date no appeal has been lodged in the declaratory judgment action. Because Mr. West's motion asks this Court to modify a scheduled execution, it is more properly filed under the style of the order initially setting Mr. West's execution, listed above.

the trial court on the issues of whether the revised protocol eliminates the constitutional deficiencies in the prior protocol and whether the revised protocol is constitutional. In support of his motion, Mr. West has submitted the transcript of the testimony presented at the two-day hearing in the trial court. This Court has now received and fully reviewed the motion and the transcript.

The evidence presented in this case differs from the evidence presented in *Abdur 'Rahman v. State*, 181 S.W.3d 292 (Tenn. 2005). The inmate's primary challenge to the three-drug protocol in *Abdur 'Rahman* was that the inclusion of pancuronium bromide in the three-drug protocol rendered the protocol unconstitutional. We determined that the use of the pancuronium bromide did not undermine the constitutionality of the protocol because it was preceded by the administration of a dose of sodium thiopental sufficient to render the inmate unconscious. *Abdur 'Rahman v. State*, 181 S.W.3d at 307-08. The inmate in *Abdur 'Rahman* did not produce evidence that the required dose of sodium thiopental would fail to render the inmate unconscious.

Proper administration of an adequate amount of sodium thiopental is essential to the constitutionality of Tennessee's three-drug protocol. Chief Justice Roberts has noted that "[i]t is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride." *Baze v. Rees*, 553 U.S. 35, 53 (2008). Echoing Chief Justice Roberts, the trial court in this case found that Tennessee's lethal injection protocol was unconstitutional because it "allows . . . death by suffocation while the prisoner is conscious." Following this finding, the trial court also determined feasible and readily available alternative procedures existed to insure unconsciousness and to negate any objectively intolerable risk of severe suffering or pain.²

After the trial court's findings and conclusions, on November 24, 2010, the State revised its three-drug execution protocol to include a process to assess the consciousness of the inmate following the administration of the sodium thiopental and to provide for the administration of additional sodium thiopental should the inmate be conscious following the administration of the first dose of the drug.

²The trial court stated:

It appears to this Court that there are feasible and readily available alternative procedures which could be supplied at execution to insure unconsciousness and negate any objectively intolerable risk of severe suffering or pain. This Court should not say or find which of those it would recommend, but I think the Court's finding of fact regarding the ways – the various ways that unconsciousness can be checked should be left to the State.

The principles of constitutional adjudication and procedural fairness require that decisions regarding constitutional challenges to acts of the Executive and Legislative Branches be considered in light of a fully developed record addressing the specific merits of the challenge. The requirement of a fully developed record envisions a trial on the merits during which both sides have an opportunity to develop the facts that have a bearing on the constitutionality of the challenged provision. Mr. West is correct that the trial court has not been given the opportunity to consider in the first instance whether the revised protocol eliminates the constitutional deficiencies the trial court identified in the prior protocol and whether the revised protocol is constitutional.

Upon due consideration, Mr. West's Motion is GRANTED, and his November 30, 2010 execution is stayed. Additionally, the State is directed to file a motion in the trial court presenting for determination in the first instance the issues of whether the revised protocol eliminates the constitutional deficiencies the trial court identified in the prior protocol and whether the revised protocol is constitutional. *See* Tenn. R. Civ. P. 52.02; 59.04. The trial court shall afford the parties an opportunity to submit argument or evidence on the revised protocol. The trial court shall render its final, appealable judgment expeditiously, but in no event later than ninety (90) days from the date of the entry of this Order.

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

The stay granted herein shall remain in effect throughout the pendency of any appeal of the trial court's final judgment in the declaratory judgment action and until the State files a motion to reset the execution date pursuant to Tennessee Supreme Court Rule 12.4.

The final resolution of the issues in this case impacts the scheduled executions of Billy Ray Irick, Edmund Zagorski, and Edward Jerome Harbison. Accordingly, entered contemporaneously herewith are orders staying the executions of Mr. Irick, Mr. Zagorski, and Mr. Harbison.

It is so ORDERED.

PER CURIAM

• April 19, 2000

- June 1, 2003

(TN) Robert Glen Coe execution Abdur'Rahman v. Sundquist–

(Ex. 106):

- "The State cop-catted," using what the majority of other states were doing."
- "[T]he State's use of [a paralytic] is 'gilding of the lily" or, stated in legal terms, arbitrary." (p.13)
- June 28, 2006
- Feb. 1, 2007
- April 30, 2007

(TN) Sedley Alley execution

- Executive Order- cut and paste job
- New 3-drug protocol adopted (after 1-drug protocol was recommended)



- May 9, 2007
- (TN) Philip Workman execution September 19, 2007

Hon. Judge Trauger (Ex. 108): Harbison v. Little -

- Tennessee Protocol Committee's recommendation of using a oneexecutioners were not adequately trained; (4) administration of knowingly disregarded an excessive risk by failing to follow the unconstitutional because (1) there is a substantial risk inmate holding 3-drug protocol using sodium thiopental as first drug drug protocol using sodium thiopental, adequately training will not be unconscious when second and third drugs are executioners, and implementing appropriate safeguards. administered; (2) there was no consciousness check; (3) the drugs was not adequately monitored; (5) the State
- (TN) Daryl Holton execution Sept. 12, 2007



- Feb. 4, 2009
- Dec. 2, 2009

• November 22, 2010

(TN) Cecil Johnson execution

(TN) Steve Henley execution

- West v. Ray Chancellor Bonneyman (Ex. 109)
- holding 3-drug protocol using sodium thiopental as first drug unconstitutional because it "allows suffocation while the prisoner is conscious" (p.10)
- check even though the "protocol committee appears to have been finding that the State had not incorporated a consciousness well aware of the necessity" for it (pp. 21-26)
 - "[T]his Court cannot find a justification for not checking on . . . unconsciousness." (p.38)
- Revised lethal injection protocol • November 24, 2010



- September 27, 2013 H
- Jan. 16, 2014
- Feb. 26, 2014
- April 29, 2014
- July 23, 2014
- June 25, 2015

- Revised lethal injection protocol
- (OH) Dennis McGuire execution
- (FL) Paul Howell execution (Sonya Rudenstine; Ex. 22)
- (OK) Clayton Lockett execution (Dean Sanderford; Ex. 36)
- (AZ) Joseph Wood execution (Dale Baich, Julie Hall, Robin Konrad, Ex. 27)
- Revised lethal injection protocol



• Dec. 8, 2016

Jan. 18, 2017

• April 27, 2017

• July 26, 2017

• Sept. 13, 2017

- Jan. 21, 2016 (AL) Christopher Brooks execution (Terri Alang, Leslie Smith)
 - (AL) Ronald Bert Smith execution (Spencer Hahn)
 - (VA) Ricky Gray execution (Elizabeth Peiffer)
 - (AR) Kenneth Williams execution (Eric Motylinski)
 - (OH) Ronald Phillips execution (Carol Wright, Ex. 24)
 - (OH) Gary Otte execution (Carol Wright, Ex. 24)



• Oct. 19, 2017

(AL) Torrey McNabb execution
(Christine Freeman)
Revised lethal injection protocol (Ex. 1)
Revised lethal injection protocol (Ex. 2)

July 5, 2018

Jan. 8, 2018

