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# IN THE SUPREME COURT OF MISSISSIPPI

Cause No. 2016-DR-962-5CT

THOMAS EDWIN LODEN, JR., Petitioner

FILED
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VS.

STATE OF MISSISSIPPI, Respondent

## SUCCESSIVE PETITION FOR POST-CONVICTION RELIEF

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#### STATE OF MISSISSIPPI, Respondent

# SUCCESSIVE PETITION FOR POST-CONVICTION RELIEF

COMES NOW the Petitioner THOMAS EDWIN LODEN, JR., by and through Petitioner's attorneys of record, and files this Successive Petition for Post-Conviction Relief. The claims in this Petition are in two categories. First, Mr. Loden seeks enforcement of the statutory boundaries of the State of Mississippi's authority to execute the death sentence upon him. Specifically, because Miss. Code Ann. § 99-19-51 requires that lethal injection executions be accomplished by the use of an "ultra short-acting barbiturate or other similar drug," the Mississippi Department of Corrections cannot lawfully execute Mr. Loden using midazolam, which is neither an "ultra short-acting barbiturate" nor an "other similar drug."

#### PRESERVATION OF ISSUES

Miss. Code Ann. § 99-39-21 (6), requires the petitioner to allege in his petition such facts as are necessary to demonstrate that his claims are not procedurally barred under that section. These claims are not barred for the following reasons:

<sup>&</sup>lt;sup>1</sup> Mr. Loden's verification is attached as Exhibit 1.

Post-conviction proceedings are for the purpose of bringing facts not known at the time of judgment to the Court's attention. *Williams v. State*, 669 So.2d 44, 52 (Miss. 1996); *Smith v. State*, 477 So.2d 191, 195 (Miss. 1985); *see also* Miss. Code Ann. § 99-39-5. Furthermore, post-conviction proceedings afford the Court an opportunity "to review those matters which, in practical reality, could not or should not have been raised at trial or on direct appeal." Miss. Code Ann. § 99-39-3 (2); *see also Brown v. State*, 798 So.2d 481 (Miss. 2001). Post-conviction proceedings also afford a petitioner an opportunity to ask a reviewing court to reconsider issues raised on direct appeal in light of intervening decisions of the Mississippi Supreme Court and the United States Supreme Court. Miss. Code Ann. § 99-39-27 (9).

Petitioner Loden's Claim for Relief involves the revised execution protocol promulgated by the Mississippi Department of Corrections on July 28, 2015. Under this new protocol, MDOC plans to use lethal injection drugs that are not permitted by Miss. Code Ann. § 99-19-51. This Court has jurisdiction to consider, in a successive petition, a convicted prisoner's challenge to his sentence on grounds it exceeds the statutory limits of lawful punishment. *Rowland v. State*, 98 So. 3d 1032, 1036 (Miss. 2012) ("the State is without authority or right to impose a sentence illegally or without due process"); *Ivy v. State*, 731 So.2d 601, 603 (Miss. 1999) (same). The claims raised in this petition implicate "fundamental rights" — particularly the right not to be punished except in accordance with the authority granted to the Department of Corrections by the Legislature. *Id.* 

In *Jordan v. Fisher*, No. 14-cv-295-HTW-LAA, a Federal civil action brought under 42 U.S.C. § 1983, Loden seeks to challenge the July 2015 protocol as exceeding the authority conferred on MDOC by Section 99-19-51. The MDOC successfully persuaded the Fifth Circuit

<sup>&</sup>lt;sup>2</sup> The July 28, 2015 Notice of Change of Lethal Injection Protocol is attached as Exhibit 2

that there was no Federal jurisdiction over Loden's statutory-grounded claim:<sup>3</sup>

Our sister circuit has concluded that state post-conviction relief petitions satisfy a prisoner's right to seek proper enforcement of a state's method-of-execution law. *Pavatt v. Jones*, 627 F.3d 1336, 1341 (10th Cir. 2010). We agree. Mississippi provides an adequate forum for the vindication of Plaintiffs' rights that arise from state law. Mississippi's post-conviction relief statute explicitly empowers prisoners to challenge their sentence as "imposed in violation of the . . . Constitution or laws of Mississippi." Miss. Code Ann. § 99–39–5(1). If Plaintiffs wish to protest that Mississippi's revised lethal injection protocol is an unlawful deviation from Mississippi's laws, Mississippi's courts are the appropriate venue for their suit.

Jordan v. Fisher, 2016 WL 3512637 at \*5 (5th Cir., June 27, 2016).4

This Court has long recognized that "where fundamental rights are violated, procedural rules give way to prevent a miscarriage of justice." *Gray v. State*, 549 So. 2d 1316, 1321 (Miss. 1989). Moreover, "errors affecting fundamental constitutional rights are excepted from the procedural bars of the [Uniform Post-Conviction Collateral Relief Act]." *Rowland v. State*, 42 So. 3d 503, 506 (Miss. 2010). Loden has the fundamental right not to suffer cruel or unusual punishment, and therefore, there is no procedural impediment to this Court's review of the merits of the claim.<sup>5</sup>

<sup>&</sup>lt;sup>3</sup> Other claims raised by Loden relating to MDOC's lethal injection protocol are still pending in Federal District Court. *Jordan v. Fisher*, 2016 WL 3512637 at \*1 n.3.

<sup>&</sup>lt;sup>4</sup> Having succeeded in convincing the Fifth Circuit to vacate the preliminary injunction on grounds, among others, that Mr. Loden could raise a claim seeking enforcement of the terms of Section 99-19-51 in a state post-conviction petition, the State of Mississippi is judicially estopped from denying this Court's jurisdiction to consider Claim I of this Petition. See Clark v. Neese, "131 So.3d 556, 559 ¶21 (Miss. 2015) ("[t]he purpose of judicial estoppel is to prevent parties from knowingly taking a position in one court that is contrary to a position that party has asserted in, and that has been accepted by, another court").

<sup>&</sup>lt;sup>5</sup> It is also worth noting that there are no time bars to the filing of an otherwise viable successive petition. *Doss v. State*, 19 So. 3d 690, 695 (Miss. 2009).

#### PROCEDURAL HISTORY

### A. Procedural History of Loden's Capital Prosecution

Thomas E. Loden, Jr. was arrested on June 23, 2000 in Itawamba County, Mississippi on charges of capital murder, rape and four counts of sexual battery of Leesa Marie Gray. Loden was a 37-year old, married father, and an active United States Marine Corp. Sergeant, who had served honorably for 18 years and been highly decorated, including a medal for valor in combat during the Gulf War. He had never been arrested before.

On September 21, 2001, Thomas Edwin Loden, Jr. pled guilty to four counts of sexual assault, rape, and capital murder, and was sentenced to death in the Circuit Court for Itawamba County, Mississippi by Circuit Judge Thomas Gardner. Loden's motion to vacate his guilty plea pursuant to Mississippi Code Annotated Sections 99-39-1 et seq., was denied. The Mississippi Supreme Court affirmed the judgment on direct appeal. *Loden v. State*, 971 So. 2d 548 (Miss. 2007), *cert. denied*, *Loden v. Mississippi*, 555 U.S. 831 (2008).

The Mississippi Supreme Court denied Loden's petition for post-conviction relief and denied his request for an evidentiary hearing. *Loden v. State*, 43 So. 3d 365 (Miss. 2010),

Loden filed a Petition for a Writ of Habeas Corpus in the United States District Court for the Northern District of Mississippi. The district court denied Loden's Petition and request for an evidentiary hearing on September 18, 2013. The court granted a certificate of appealability on the following claims of ineffective assistance of counsel: the development of mitigation evidence, Loden's guilty plea and the waiver of jury sentencing, defense counsel's litigation of the case, the cumulative effect of trial counsel's performance, and the performance of appellate counsel. Loden filed a Notice of Appeal on October 17, 2013. Loden filed a motion to amend the Judgment, which was denied.

Loden thereafter filed an amended Notice of Appeal on February 26, 2014. The Fifth Circuit Court of Appeals affirmed Loden's conviction and sentence. *Loden v. McCarty*, 778 F3.484 5th Cir. (Miss.), Feb. 13, 2015. On June 29, 2015, Loden filed a Petition for Writ of Certiorari with the United States Supreme Court which was denied on November 2, 2015. *Loden v. Fisher*, 136 S.Ct. 402, U.S., Nov. 02, 2015.

#### B. Lethal Injection Litigation

On May 20, 2015, Mr. Loden, moved to intervene in a complaint for preliminary and permanent injunctive relief pursuant to 42 U.S.C. § 1983 against officials of the Mississippi Department of Corrections. The Complaint alleges violations of Plaintiffs' rights to due process, to be free from cruel and unusual punishment, and for access to the courts and to petition the government for the redress of grievances under the First, Eighth, and Fourteenth Amendments to the United States Constitution. Of the five claims for relief pled in the Complaint, Count II challenges, under the Eighth and Fourteenth Amendments and Mississippi statutory law, the use of any anesthetic that is not an "ultra short-acting barbiturate or other similar drug" as required by Miss. Code Ann. § 99-19-51.

At the time of the filing of the complaint in intervention in May 2015, MDOC's execution protocol called for the serial administration of three drugs to put a prisoner to death. The first drug, pentobarbital, is intended to sufficiently anesthetize the prisoner so that he is both unconscious and insensate when the executioner injects the second and third drugs. The second drug, vecuronium bromide, paralyzes all of the prisoner's voluntary muscles, including those used for respiration, but does not suppress sensation, consciousness, cognition, or the ability to feel pain and

<sup>&</sup>lt;sup>6</sup> Loden's Complaint in Intervention is attached to this Petition as Exhibit 3. The motion to intervene was granted on July 20, 2015. Ex. 3-A.

suffocation. The third drug, potassium chloride, disrupts the electrical signals in the heart, paralyzes the cardiac muscle, and kills the prisoner by cardiac arrest.

In May 2015, pentobarbital sodium active pharmaceutical ingredients (API) – the raw ingredients used in compounding injectable pentobarbital – were the only drugs in the possession of MDOC for use as the first drug in its lethal injection protocol. Thus, Count Π of the Complaint alleged, among other things, that compounded pentobarbital was not an "ultra short-acting barbiturate or other similar drug," and was thus outside the punishment prescribed by the state legislature. Plaintiffs moved for a preliminary injunction on June 3, 2015 with respect to Counts I through III of their complaint. The relief requested on Count Π of the Complaint was "that this Court enter a Preliminary Injunction enjoining the Defendants during the execution of the Plaintiffs, including any intervening party to this suit, from: A. administering any anesthetic that is not in the statutorily-mandated class of "ultra short-acting barbiturates."

At 6:38 p.m. on July 28, 2015, the night before the hearing in Federal Court on the motion for preliminary injunction, MDOC filed into the federal record a new execution protocol. The only change was a significant one – the addition of the following language: "In the event of the unavailability of a sufficient quantity of Pentobarbital from available sources, a sufficient quantity of Midazolam will be acquired and administered in the place of Pentobarbital." Ex. 2.

Not only is midazolam not an ultra short-acting barbiturate, it is not a barbiturate at all. Rather, it is a benzodiazepine, an entirely different class of drugs from that authorized by Mississippi law. Moreover, the substitution of midazolam was an about-face from representations made by the state in a hearing in state court on March 2, 2015, that midazolam was "not an option" for Mississippi.<sup>7</sup>

<sup>&</sup>lt;sup>7</sup>. See Exhibit 4, partial transcript of March 2, 2015 hearing in *Roderick & Solange MacArthur Justice Center v. Miss. Dep't of Corrections*, at 54.

On August 26, 2015, the Federal Court issued a preliminary injunction against the use of either compounded pentobarbital or midazolam.<sup>8</sup> The court's grant of preliminary injunctive relief relied on its finding that

[P]laintiffs have shown a substantial likelihood in prevailing, at least, on their claim that Mississippi's failure to use a drug which qualifies as an "ultra short-acting barbiturate or other similar drug" as required by Miss. Code Ann. § 99-19-51 violates Mississippi statutory law and the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution.

#### Exhibit 5.

Aggrieved by the injunction, MDOC appealed. It specifically challenged the jurisdiction of the Federal Court to order MDOC to follow state statutory law. The Fifth Circuit agreed, and vacated the injunction:

Plaintiffs argue that they have a liberty interest created by state law, specifically § 99–19–51, and that it prevents the state from executing them using any drugs other than "an ultra short-acting barbiturate or other similar drug" as the first drug in a three-drug cocktail. However, even if the revised lethal injection protocol does not conform to § 99–19–51, "a mere error of state law is not a denial of due process."

Jordan v. Fisher, 2016 WL 3512637 \*4 (June 27, 2016).

The Fifth Circuit, following MDOC's assertions, invited Loden to file his claim that midazolam is not authorized as the first lethal injection drug under Mississippi law in a successive state post-conviction petition:

Our sister circuit has concluded that state post-conviction relief petitions satisfy a prisoner's right to seek proper enforcement of a state's method-of-execution law. *Pavatt v. Jones*, 627 F.3d 1336, 1341 (10th Cir.2010). We agree. Mississippi provides an adequate forum for the vindication of Plaintiffs' rights that arise from state law. Mississippi's post-conviction relief statute explicitly empowers prisoners to challenge their sentence as "imposed in violation of the ... Constitution or laws of Mississippi." Miss. Code Ann. § 99–39–

<sup>&</sup>lt;sup>8</sup> The order granting preliminary injunction is attached as Exhibit 5.

5(1). If Plaintiffs wish to protest that Mississippi's revised lethal injection protocol is an unlawful deviation from Mississippi's laws, Mississippi's courts are the appropriate venue for their suit.

Id. at \*5.

The remainder of Loden's claims, which do not rely on Mississippi statutory law, were remanded back to the Federal District Court. Loden's civil action on these Federal claims is still pending. *Jordan v. Fisher*, 2016 WL 3512637 at \*1 n.3; *Jordan v. Fisher*, No. 14-cv-295-HTW-LAA (S.D. Miss.).

#### CLAIM FOR RELIEF

# MDOC'S EXECUTION PROTOCOL VIOLATES MISSISSIPPI'S STATUTE PRESCRIBING THE METHOD OF EXECUTION

#### A. The Clear Command of the Statute

Thomas Loden was "sentenced to suffer death by administration of a substance or substances in the manner required by law." The language of Mississippi's statute prescribing the method of execution is clear: "[t]he manner of inflicting the punishment of death shall be by continuous intravenous administration of a lethal quantity of *an ultra short-acting barbiturate or other similar drug* in combination with a chemical paralytic agent." Miss. Code Ann. § 99-19-51 (emphasis added). Notably, while the Attorney General vigorously advocated for an amendment to this statute during the 2016 legislative session, the amendment enacted by the Legislature and

<sup>&</sup>lt;sup>9</sup> For the Court's reference, the Amended Complaint in the Federal civil action is attached as Exhibit 6.

<sup>&</sup>lt;sup>10</sup> Mr. Loden's September 21, 2001 sentencing order is attached as Exhibit 7

<sup>&</sup>lt;sup>11</sup> By contrast, the Oklahoma statute at issue in *Glossip v. Gross* 135 S. Ct. 2726 (2015) merely specified that the state execute its prisoners using some form of lethal injection. Okla, Stat. Ann. tit. 22, § 1014 (West).

signed into law by the Governor retained the requirement of an "ultra short-acting barbiturate or other similar drug." <sup>12</sup>

The unambiguous nature of the statutory language controls the selection of drugs for lethal injection executions in Mississippi. This Court has recognized that the judiciary has "no right to add anything to or take anything from a statute, where the language is plain and unambiguous. To do so would be entrenching upon the power of the Legislature. Neither have the Courts authority to write into the statute something which the Legislature did not itself write therein." *Sheppard v. Mississippi State Highway Patrol*, 693 So. 2d 1326, 1328 (Miss. 1997) (citations omitted). "This Court does not decide what a statute should provide, but determines what it does provide." *Palermo v. LifeLink Foundation, Inc.*, 152 So. 3d 1099, 1105 ¶13 (Miss. 2014), *citing Lawson v. Honeywell Intern., Inc.*, 75 So. 3d 1024, 1027 (Miss. 2011). *See also Miss. Dep't of Revenue v. Mississippi Power Co.*, 144 So. 3d 155, 162 ¶26 (Miss. 2014) (same). "If the words of a statute are clear and unambiguous, the Court applies the plain meaning of the statute and refrains from using principles of statutory construction." *Palermo*, 152 So. 3d at 1105, *quoting Lawson*, 75 So. 3d at 1027.

MDOC, an administrative agency of the Executive Branch, is constitutionally barred from establishing or modifying punishments set forth by the Mississippi Legislature. Article IV § 33 of the Mississippi Constitution provides that "the legislative power shall be vested in a Legislature." Because the power to define crimes and prescribe punishments is a legislative power, the vesting clause prevents the legislature from delegating that power to another branch. *Howell v. State*, 300 So. 2d 774, 780 (Miss. 1974). In other words, only the legislature can define crimes and prescribe punishments. *Howell*, 300 So. 2d at 781; *Winters v. State*, 473 So. 2d 452, 456 (Miss. 1985); *Jones v. State*, 122 So. 3d 698, 702 (Miss. 2013). Thus, the delegation of authority to define crimes and

<sup>&</sup>lt;sup>12</sup> See http://billstatus.ls.state.ms.us/2016/pdf/history/SB/SB2237.xml (last reviewed July 4, 2016).

prescribe punishments to an executive branch agency would violate both the legislative vesting clause and the provisions of the Mississippi Constitution that require the separation of powers. Miss. Const. Art. I §§ 1, 2; Art. IV § 33; *Howell* at 781 (holding that the delegation of power to an administrative agency to increase punishment was unconstitutional). *See also Miss. Dep't of Revenue*, *supra*, 144 So. 3d at 161 ¶27 ("the MDOR may not promulgate rules that alter or amend or negate the effect of a statute and may not overstep its authority by creating regulations inconsistent with the controlling statutes").

Loden has the right to enforcement of this statutory command. *Rowland v. State*, 98 So. 3d 1032, 1036 (Miss. 2012) ("the State is without authority or right to impose a sentence illegally or without due process"); *Ivy v. State*, 731 So.2d 601, 603 (Miss. 1999) (same). The claims raised in this petition implicate "fundamental rights" — particularly the right not to be punished except in accordance with the authority granted to the Department of Corrections by the Legislature. *Id.* 

# B. Midazolam is not an "Ultra Short-Acting Barbiturate or Other Similar Drug."

The expert affidavit of Craig Stevens, Ph.D., establishes that midazolam is not an "ultra short-acting barbiturate or other similar drug." Dr. Stevens is a Professor of Pharmacology, a full-time faculty member in the department of Pharmacology and Physiology at the College of Osteopathic Medicine, a unit of the Oklahoma State University, Center for Health Sciences campus in Tulsa, Oklahoma. He received his Ph.D. in Pharmacology from the Mayo Clinic, in Rochester, Minnesota.

<sup>&</sup>lt;sup>13</sup> Dr. Stevens' Affidavit is attached as Exhibit 8. His report, attached to the affidavit, is attached as Ex. 8-A. Dr. Stevens' curriculum vitae (CV) is attached as Exhibit 8-B.

Dr. Stevens works part-time as a litigation consultant/expert witness on cases involving pharmacological issues. He has consulted in both civil and criminal cases, working with both the prosecution or plaintiff and the defendant. With regard to the pharmacological issues of lethal injection, he has consulted with state departments of corrections as well as with attorneys representing condemned inmates.

Dr. Stevens was asked to investigate the use as a lethal injection drug, and specifically whether midazolam can be characterized as an "other similar drug" to an ultra short-acting barbiturate, such as thiopental (the original first drug used in the Mississippi three drug lethal injection protocol).

Dr. Stevens framed the inquiry in two parts: a comparison of the pharmacological nature of midazolam and thiopental and a comparison of midazolam and thiopental in terms of the effect that each drug have on consciousness.

#### 1. The Pharmacological Distinction Between Midazolam and Thiopental

Dr. Stevens introduced the pharmacological comparison of the two drugs (the ultra short-acting barbiturate thiopental and the benzodiazepine midazolam) as follows:

Each drug has a unique chemical (atomic) structure and exerts a unique profile of pharmacological effects. **Drugs are classified both by their chemical structures and by their therapeutic uses.** Drugs that have very similar chemical structures are grouped together based on that structure. Drugs that have similar therapeutic uses are also grouped together by their therapeutic or pharmacological effects.

Pharmacological equivalency is present when two or more drugs exhibit the same or closely similar pharmacological properties. It is a working principle used by physicians who often substitute drugs due to drug allergies or for reasons of cost. Pharmacological equivalency is also the guiding principle for the FDA to accept a generic version of the same branded drug (e.g. Walgreen's ibuprofen, the generic form, is pharmacologically equivalent to Advil®, the branded formulation of ibuprofen. See Meredith 2003, Borgheini 2003).

**Pharmacological substitution** is the act of using one drug in the place of another. It is axiomatic that in order to maintain the same pharmacological and therapeutic effect of two drugs, the drug that is substituted must have pharmacological equivalency to the new drug.

There is no question that midazolam and thiopental are different drugs. The key question in substituting drugs for lethal injection is one of a pharmacological nature: Does midazolam have pharmacological equivalency to thiopental such that a valid pharmacological substitution can be made?

Exhibit 8-A at 3-4 (emphasis added).

#### a. Pharmacological Classification of Midazolam and Thiopental

Dr. Stevens first considered the **pharmacological classification** of Midazolam, a benzodiazepine, and Thiopental, an ultra short-acting barbiturate, with reference to their respective chemical structures:

Midazolam belongs to the class of drugs called benzodiazepines and thiopental is a member of the barbiturate class of drugs (Brenner and Stevens, 2013). The chemical structure of midazolam and thiopental are shown in the first row of Table 1 . . . to provide an accessible first exposure to the differences between the two drugs. The untrained eye clearly recognizes that midazolam and thiopental do not have similar structures and are not close analogs.

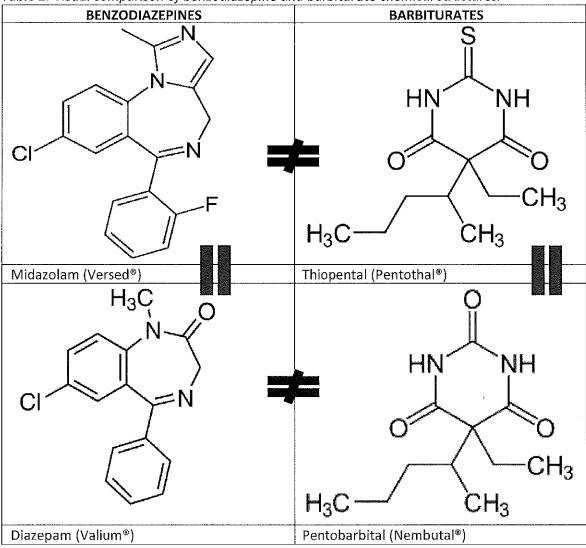
The second row in Table 1... shows examples of other drugs from the same class of drugs as midazolam and thiopental. Most notably, at the center of the benzodiazepines there is 7-sided ring with two nitrogen atoms (N) attached to a 6-sided ring with one chloride atom (Cl).

Quite differently, the two barbiturates do not contain such a core structure and instead consist of a single 6-sided ring containing two nitrogen atoms. The non-expert can see that the benzodiazepine, midazolam is similar to diazepam (Valium®), and the barbiturate, thiopental, is a close analog of pentobarbital (Nembutal®).

Exhibit 8-A(Stevens' Affidavit) at 3-5 (emphasis added).

The Table is reproduced below:

Table 1. Visual comparison of benzodiazepine and barbiturate chemical structures.



Dr. Stevens concludes that "[t]here is an irrefutable difference between midazolam and thiopental at the atomic level . . . Table 1 shows that pharmacological equivalency by consideration of chemical structures is NOT met when employing midazolam as a substitute for thiopental." *Id.* at 5 (emphasis added).

#### b. Mechanism of Action of Midazolam and Thiopental

Dr. Stevens then looks to the different mechanisms by which midazolam and thiopental operate on the central nervous system. After a complex discussion of the mechanisms of both drugs on the GABAA receptor-chloride ion channel, Dr. Stevens concludes that "a large body of pharmacological research on the mechanisms of action of midazolam and thiopental clearly demonstrates that benzodiazepines, like midazolam, and barbiturates, such as thiopental, do NOT exhibit pharmacological equivalency with regard to their detailed mechanism of action." Exhibit 8-A at 6.

#### c. Partial versus Full Agonist

Next, Dr. Stevens elucidates the distinction between a partial agonist like midazolam and a full agonist like Thiopental. Both drugs are "agonists," that is, drugs that bind to a target receptor and the receptor does something, like open an ion channel. But as Dr. Stevens explains:

Agonists are further subdivided into partial agonists and full agonists. As their name suggests, full agonists produce a full pharmacological effect and partial agonists only produce a partial pharmacological effect. The difference between one drug being a partial agonist and another drug being a full agonist arises from the two drugs differing mechanism of action.

As noted above, midazolam, like all benzodiazepines, increases the frequency (not the duration) of ion channel opening only when GABA is present. As GABA is a neurotransmitter synthesized by inhibitory brain neurons, the amount of GABA released onto GABAA receptors is limited. Because midazolam depends on the co-activation of GABA to produce its effects, midazolam effects on the brain is therefore also limited. In this regard, midazolam is a partial agonist.

Thiopental, to the contrary, does not need co-activation by GABA to produce its effects. In this regard, the neuronal inhibition produced by barbiturates is not limited. In this regard, **thiopental is a full agonist**.

Dr. Stevens then concludes:

In summary, the fact that midazolam is a partial agonist, and that thiopental is a full agonist, arises directly from their mechanisms of action as barbiturates can act in the absence of GABA and increase the inhibition of brain neurons whereas midazolam and other benzodiazepines are limited with their effect only when GABA is present and thus cannot inhibit neurons as much as barbiturates. This pharmacological fact, demonstrates that pharmacological equivalency is NOT met by substitution of a barbiturate with a benzodiazepine. The ceiling effect of a midazolam and other benzodiazepines, and the lack of ceiling effect with the use of thiopental and other barbiturates, is beyond controversy and taught to all medical and pharmacology students.

Exhibit 8-A at 8 (emphasis in original).

#### d. Comparing the Therapeutic Uses of Midazolam and Thiopental

Dr. Stevens then compared the therapeutic uses of the two drugs at issue in this case. "As noted above, while both benzodiazepines and barbiturates act on the GABAA receptor, they do so in very different ways. Because of the difference in their mechanism of action, the clinical use of benzodiazepine and barbiturate drugs are for different therapeutic reasons." Exhibit 8-A at 8. He illustrated this comparison with the table reproduced below:

Therapeutic Use	Benzodiazepines	Barbiturates
Anxiety disorders	YES, alprazolam, diazepam,	YES but only for 'sedation' with
	lorazepam	butabarbital
Panic Disorder	YES, alprazolam, clonazepam	NO
Acute Alcohol Withdrawal	YES, diazepam	NO
Skeletal Muscle Spasm	YES, diazepam	NO
Seizure Disorders	YES, clonazepam, diazepam	YES, pentobarbital (IV), phenobarbital
		(IV), thiopental (IV)
Preoperative Sedation	YES, midazolam (IM/IV)	YES, pentobarbital (IV), secobarbital
Outpatient Sedation	YES, midazolam (IV)	NO
Anesthesia Induction	YES, midazolam (IV)	YES, thiopental (IV)
Sole Anesthesia (brief)	NO	YES, thiopental (IV)
Sedation for Intubated Ptx	YES, midazolam (IV cont.)	NO
Co-Anesthesia (Adjunct)	YES, midazolam (IV)	YES, thiopental (IV)
Insomnia (short-term)	NO	YES, butabarbital, secobarbital,
, , ,		pentobarbital (IV)
Induce Coma in Brain Trauma	NO	YES, thiopental (IV)
Psychiatric Use (Narcoanalysis)	NO	YES, thiopental (IV)

Dr. Stevens summarizes his analysis of the comparison in therapeutic uses as follows:

The demonstration that benzodiazepines and barbiturates, and more specifically midazolam and thiopental, have different therapeutic uses shows that pharmacological equivalency of barbiturates and benzodiazepines is NOT met considering the criteria of approved therapeutic uses. Most importantly, midazolam was not approved for use as a Sole Anesthetic. In contrast, thiopental, was approved as a Sole Anesthetic for brief procedures.

Exhibit 8-A at 9 (emphasis in original).

e. Comparison of DEA Scheduling of Midazolam and Thiopental
Dr. Stevens then looked to the difference in the way federal narcotics agencies schedule
midazolam and Thiopental:

Midazolam and pentobarbital are controlled substances according to the DEA, as promulgated by the Controlled Substances Act of 1970. The DEA places dangerous drugs into five schedules, with Schedule I drugs being the most dangerous drugs with no approved medical use. Schedule II-V are drugs with medical uses but with decreasing danger of abuse and dependence. Midazolam, as with most of the other benzodiazepines like diazepam (Valium®) and lorazepam (Ativan®) are placed into Schedule IV.

Thiopental is deemed a more dangerous drug than midazolam as thiopental is a Schedule III controlled substance. This is evidence that midazolam is deemed safer to use by the DEA, with less evidence of abuse and drug dependence than thiopental. Simply put, the DEA decision to schedule midazolam and thiopental differently reflects the DEA finding that midazolam and thiopental do NOT exhibit pharmacological equivalency in causing drug dependence and abuse.

*Id.* (emphasis in original).

# f. Summary of Pharmacological Comparisons Between the Benzodiazepine Midazolam and the Ultra Short-Acting Barbiturate Thiopental

Dr. Stevens helpfully summarized the critical factual inquiry in this case as follows:

There is no pharmacological equivalency between midazolam and thiopental using the criterion of chemical structures for benzodiazepines and barbiturates.

There is no pharmacological equivalency when examining the different mechanisms of action of benzodiazepines (midazolam) and barbiturates (thiopental).

There is no pharmacological equivalency between the magnitude of pharmacological effects produced by benzodiazepines (partial agonists) and barbiturates (full agonists). In particular, it is well-known that midazolam has a ceiling effect that is not present in thiopental.

There is little pharmacological equivalency when examining the different therapeutic uses of benzodiazepines and barbiturates, or between midazolam and thiopental.

There is no pharmacological equivalency in the drug abuse and dependence properties of midazolam and thiopental as confirmed by the different scheduling of these drugs by the DEA.

Exhibit 8-A at 10.

#### 2. The Functional Comparison of the Effects of Thiopental and Midazolam on

#### Consciousness

In addition to the strictly pharmacological comparison between the ultra short-acting barbiturate thiopental and the benzodiazepine midazolam, Dr. Stevens also compares the two drugs in terms of the effect that each has on consciousness. Ex. 8-A at 24-26.

He explains, "[s]cientific models of consciousness rely on the measurement of activity in different areas of the brain and the known functions associated with them . . . consciousness is correlated to activity in brain association areas and therefore unconsciousness is correlated to lack of activity in these brain association areas." Ex. 8-A at 24. Dr. Stevens testifies that, unlike

thiopental, midazolam does not decrease activity in the brain functions in sufficient degree to ensure the level of anesthetic depth associated with loss of consciousness:

- i. Studies show a link between unconsciousness, anesthesia, and decreased activity in brain association areas.
- ii. Thiopental and other barbiturate anesthetics decrease activity in these brain association areas, and are potent in decreasing the BIS value which is associated with depth of anesthesia<sup>14</sup>.
- iii. There are few studies of midazolam's depth of anesthesia because midazolam cannot produce the same anesthetic effects as thiopental on the brain, and midazolam is less potent in reducing BIS values<sup>15</sup>.
- iv. Scientific studies show that a cautious and conservative approach is warranted in positing an 'anesthetic' action of midazolam, as a significant number of patients are found to be under-anesthetized and conscious during surgery even when using the strongest general anesthetic agents are used.

#### Ex. 8-A at 26.

Thus, not only is midazolam not similar to thiopental from a pharmacological perspective, it also does not produce the same result on consciousness as does thiopental. In short, midazolam, unlike thiopental, does not produce the depth of anesthesia scientifically associated with unconsciousness.

<sup>&</sup>lt;sup>14</sup> According to Dr. Stevens, BIS (bispectral analysis) is a measurement of the depth of general anesthesia using EEG recordings of the frontal lobe brain and computer processing. BIS values range from 100 (completely awake and alert) to 0 (coma and total EEG burst suppression). BIS values under 60 correlate to the depth of anesthesia associated with lack of awareness. Ex. 8-A at 25.

<sup>&</sup>lt;sup>15</sup> In fact, multiple studies based on BIS support the finding that midazolam does not induce general anesthesia. "BIS values of in the range of 77-92 were reported after repeated IV doses of midazolam in a surgical outpatient study. In surgery patients, the lowest BIS score for IV midazolam was 65." Ex. 8-A at 25. This is above the BIS cutoff of 60 which is the threshold of "awareness during anesthesia." Id.

# C. Conclusion: Midazolam is not "similar" to an "ultra short-acting

#### barbiturate."

Dr. Stevens' overall conclusion bears quoting in full:

The fact that thiopental is not pharmacologically equivalent to midazolam is evidenced by midazolam and thiopental failing the tests of equivalency detailed in §2A-F<sup>16</sup>; the supporting fact that lethal levels of thiopental are obtained after a 2 gram IV bolus dose as calculated in §3B and that midazolam produces a ceiling effect and does not produce a fatal blood level after 500 mg bolus IV dose as shown in §4E; and the supporting fact that midazolam does not produce general anesthesia nor a depth of anesthesia equal to thiopental in clinical studies detailed in §5A-C.

. . . .

It is therefore my opinion, to a reasonable degree of scientific certainty, that . . . midazolam is not an "other similar drug" to an ultra short-acting barbiturate . . .

Ex. 8-A at 27.

Given this extensive analysis, Petitioner Loden has met his burden to establish that midazolam is not an "ultra short-acting barbiturate or other similar drug" as required by Miss. Code Ann. § 99-19-51. MDOC does not have authority to inject a condemned prisoner with midazolam in place of thiopental or another "ultra short-acting barbiturate."

<sup>&</sup>lt;sup>16</sup> These internal references are to the sections of Dr. Stevens' report (Ex. 8-A). They are retained in the quote for the Court's easy reference.

# D. At a Minimum, Loden is Entitled to an Evidentiary Hearing on this Claim.

This Court has long held that if a petition for post-conviction relief "presents a claim procedurally alive substantially showing denial of a state or federal right, the petitioner is entitled to an in court opportunity to prove his claims." *Neal v. State*, 525 So. 2d 1279, 1281 (Miss. 1987). *See also Batiste v. State*, 184 So. 3d 290, 294 ¶12 (Miss. 2016) (same).

Given the extensive expert testimony by Dr. Stevens, Petitioner Loden has far exceeded the requirements under the Post-Conviction Act and this Court's jurisprudence for an evidentiary hearing. Thus, unless this Court grants judgment for Loden as a matter of law, this petition should be remanded to the Circuit Court of Lee County, Mississippi, for an evidentiary hearing on the issue of whether midazolam is an "ultra short-acting barbiturate or other similar drug" as mandated by Section 99-19-51.

#### PRAYER FOR RELIEF

Thomas Edwin Loden, Jr., is entitled to an order forbidding the Mississippi Department of Corrections from using any drug which is not "an ultra short-acting barbiturate or other similar drug," including midazolam, in his execution. At a minimum, he is entitled to an "in-court opportunity to prove" that midazolam is not an "ultra short-acting barbiturate or other similar drug."

Respectfully Submitted:

Stacy Ferraro, MSB No. 100263 239 N. Lamar Street, Suite 604

StayFerraro

Jackson, MS 39201

(601) 576-2322 (p)

(601) 576-2319 (f)

lifestoryms@gmail.com

#### **CERTIFICATE OF SERVICE**

I hereby certify that I have served this Petition on the Office of the Attorney General, by electronic mail to Jason Davis, Special Assistant Attorney General, jdavi@ago.state.ms.us, and by mail delivery to Post Office Box 220, Jackson MS 39205.

This the day of July, 2016.

#### IN THE SUPREME COURT OF MISSISSIPPI

,	Cause No	·	<u></u>		

## THOMAS EDWIN LODEN, JR., Petitioner

VS.

#### STATE OF MISSISSIPPI, Respondent

#### SUCCESSIVE PETITION FOR POST-CONVICTION RELIEF

#### **EXHIBITS**

- 1. Verification of Thomas Edwin Loden, Jr.
- 2. Notice of Change of Lethal Injection Protocol
- 3. Complaint in Intervention in Jordan v. Fisher, No. 3:15-cv-295-HTW
- 4. Excerpts from Transcript of Oral Argument in *The Roderick & Solange MacArthur Justice Center v. Mississippi Department of Corrections* (Chancery Ct. Hinds Cty.) (March 2, 2015)
- 5. Order Granting Preliminary Injunction in Jordan v. Fisher
- 6. First Amended Complaint in Jordan v. Fisher
- 7. Order Sentencing Petitioner Loden to Death
- 8. Expert Testimony of Dr. Craig Stevens

### VERIFICATION

#### STATE OF MISSISSIPPI COUNTY OF SUNFLOWER

PERSONALLY APPEARED BEFORE ME, the undersigned authority in and for the jurisdiction aforesaid, the within named THOMAS EDWIN LODEN, Jr., who, being by me first duly sworn, deposed and said:

- 1. My name is THOMAS EDWIN LODEN, JR. I am a prisoner (No. K8126) incarcerated on Unit 29 of the Mississippi State Penitentiary at Parchman.
- 2. I am currently under sentence of death on a conviction of capital murder from the Circuit Court of Itawamba County, Mississippi.
- 3. My attorneys have researched and prepared a Petition for Post-Conviction Relief related to the lethal injection protocol by which the Mississippi Department of Corrections intends to execute me.
- 4. I have reviewed the Petition for Post-Conviction relief. Because the facts alleged in the Petition relate to the drugs and other aspects of MDOC's lethal injection protocol, I have no personal knowledge of the facts set forth in the claim for relief. However, based on the allegations of the Petition, that I believe that I am entitled to the relief sought in the Petition.
  - 5. Further, affiant sayeth naught.

THIS the 29 day of 5006, 2016.

EXHIBIT 1

before me ;

2016. my commission experies: KATHRYN M. MCINTYRB

Feb:28, 2020

#### IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI NORTHERN DIVISION

RICHARD JORDAN and RICKY CHASE,

Plaintiffs

THOMAS EDWIN LODEN, JR.

Proposed Intervenor

VS.

No. 3:15-ev-00295-HTW-LRA

MARSHALL L. FISHER, Commissioner, Mississippi Department of Corrections, in his Official Capacity; EARNEST LEE Superintendent, Mississippi State Penitentiary, in his Official Capacity; THE MISSISSIPPI STATE EXECUTIONER, in his Official Capacity; and UNKNOWN EXECUTIONERS, in their Official Capacities Defendants

#### NOTICE OF LETHAL INJECTION PROTOCOL CHANGE

COME NOW Defendants Marshall Fisher, Commissioner of the Mississippi Department of Corrections, ("MDOC"), and Earnest Lee, Superintendent of the Mississippi State Penitentiary at Parchman, the Mississippi State Executioner and Unknown Executioners (collectively referred to as "MDOC" or the "State Defendants") in their official capacities and file this Notice of Lethal Injection Protocol Change.

The State Defendants had previously announced that in the event the Mississippi Department of Corrections (MDOC) amended its lethal injection protocol to include a drug other than sodium thiopental or pentobarbital that notice would be provided to the Court. See Docket # 25.

Accordingly, notice is now given that MDOC has amended its lethal injection protocol on this day,



July 28, 2015 to allow for the administration of 500 milligrams<sup>1</sup> of midazolam as the anaesthetic and first drug administered in the protocol. This change is a direct result of the pressure by death penalty opponents to limit and/or stop the production of drugs for use in executions. This pressure has resulted in the unavailability of both sodium thiopental and pentobarbital.<sup>2</sup> Thus, MDOC has now amended its lethal injection protocol to include the use of 500 milligrams of midazolam as the first drug in its protocol. See Exhibit A. Change to Protocol and Exhibit B. Amended Injection Protocol.

THIS the 27th day of July, 2015.

Respectfully submitted

JIM HOOD ATTORNEY GENERAL STATE OF MISSISSIPPI

By: s/ Jason L. Davis

Jason L. Davis, MSB No. 102157

Paul E. Barnes, MSB No. 99107

Wilson Minor, MSB No. 102663

SPECIAL ASSISTANT ATTORNEYS GENERAL

ATTORNEYS FOR DEFENDANTS

OFFICE OF THE ATTORNEY GENERAL P.O. Box 220 Jackson, MS 39205 Telephone: (601) 359-3680 Telefax: (601) 359-3796 jdavi@ago.state.ms.us

<sup>&</sup>lt;sup>1</sup>See Glossip v. Gross, U.S. , 135 S.Ct. 2726, L.Ed.2d , 2015 WL 2473454 (2015). This dose of midazolam specifically held to be constitutional and not in violation of the Eighth Amendment.

<sup>&</sup>lt;sup>2</sup>See Dkt. # 25 and # 36.

#### CERTIFICATE OF SERVICE

This is to certify that I, Jason L. Davis, Special Assistant Attorney General for the State of Mississippi, have electronically filed the foregoing document with the Clerk of the Court using the ECF system which sent notification of such filing to the following:

James W. Craig Emily M. Washington 4400 South Carrollton Ave. New Orleans, LA 70119

This the 28th day of July, 2015.

s/ Jason L. Davis

# EXHIBIT A.

# Case 3:15-cv-00295-HTW-LRA Document 38-1 Filed 07/28/15 Page 2 of 2

# MISSISSIPPI DEPARTMENT OF CORRECTIONS POLICY/SOP REQUEST FORM

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SOP 01.01.01, Form 1 Revised: 06/01/2014

# EXHIBIT B.

#### Confidential

#### **INJECTION PREPARATION**

- Open execution room and injection room
   Inventory and inspect IV equipment, syringes and drugs
   Inspect gurney and straps
- > Prepare drugs, fill syringes and place IV saline bags in position

	CONTENTS OF SYRINGES	
LABELED/MARKED		QUANTITY
#1	Sodium Pentothal, 2.0 Gm. (four 500 mgm vials dissolved in the least amount of diluent possible to attain complete, clear suspension)  Or	I Syringe
	In the event of an unavailability of a sufficient quantity of sodium pentothal from available sources, a sufficient quantity of pentobarbital will be acquired and administered in the place of sodium pentothal. The pentobarbital will be administered in the same serial order as sodium pentothal:  Pentobarbital 5.0 Gm. (two 50 ml vials in the least amount of diluents possible to attain complete, clear suspension).	2 Syringes
	Or	
	In the event of the unavailability of a sufficient quantity of Pentobarbital from available sources, a sufficient quantity of Midazolam will be acquired and administered in the place of Pentobarbital. The Midazolam will be administered in the same serial order as Pentobarbital (Two 50 cc syringes totaling 500 MG).	2 Syringes
/ N/S	Normal Saline, 10 – 15 cc.	2 Syringes

#### Confidential

#2	Pavulon, 50 mgm per 50 cc. (five 10cc. Ampules of 10 mgm each in each syringe	3 Syringes
	In the event of unavailability of a sufficient quantity of pavulon from available sources, a sufficient quantity of vecuronium bromide will be acquired and administered in the place of pavulon. The vecuronium bromide will be administered in the same serial order as pavulon. Vecuronium Bromide 40mg/40cc. 20mg/20cc in each syringe followed by a flush of 50cc of saline injected into the line.	2 syringes
#3	Potassium Chloride, 50 milequiv. Per 50 cc (five 10 cc. Ampules of 10 milequiv. Each in each syringe))	3 Syringes

#### PRE-EXECUTION INVENTORY AND EQUIPMENT CHECK

Members of the injection team shall conduct an equipment check of all materials necessary to perform the execution.

The inventory shall be conducted not less than twenty-four (24) hours and not more than ninety-six (96) hours, of the scheduled execution.

An inventory checklist shall be completed, dated and initialed by the injection team.

Expiration and/or sterilization dates of all applicable items shall be checked on an individual item.

Outdated items (e.g., Normal Saline bags) shall be replaced immediately

Sterilized packs bearing a sterilization date in excess of thirty (30) days shall be replaced or resterilized immediately.

On the evening of the execution, members of the injection team shall enter the injection room at least one (1) hour prior to the scheduled time of the execution. They shall immediately re-inventory the supplies and equipment to insure that all is in readiness and if applicable, obtain replacement items for the Medical Facility.

### IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI NORTHERN DIVISION

RICHARD JORDAN and RICKY CHASE,	) )
Plaintiffs,	) )
THOMAS EDWIN LODEN, Jr.	) )
Intervenor v.	) ) ) Civil Action No )
MARSHALL L. FISHER, Commissioner, Mississippi Department of Corrections, in his Official Capacity; EARNEST LEE, Superintendent, Mississippi State Penitentiary, in his Official Capacity; THE MISSISSIPPI STATE EXECUTIONER, in his Official Capacity; and UNKNOWN EXECUTIONERS, in their Official Capacities,	
Defendants.	) ) . <u>)</u>

### INTERVENOR'S COMPLAINT FOR PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF UNDER THE FEDERAL CIVIL RIGHTS ENFORCEMENT ACT OF 1871 (42 U.S.C. §1983)

### NATURE OF ACTION

1. This action is brought pursuant to 42 U.S.C. § 1983 and Mississippi law for violations and threatened violations of Intervenor Thomas Edwin Loden, Jr.'s rights to due process and to be free from cruel and unusual punishment under the First, Eighth, and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14, 24, and 28 of the Mississippi Constitution.



- 2. Under the direction of the Defendants named herein, the Mississippi Department of Corrections ("MDOC") intends to execute Mr. Loden with compounded drugs that may be counterfeit, expired, contaminated, and/or sub-potent, creating a substantial risk of serious harm to the Mr. Loden. The decision of the Defendants to use compounded drugs, specifically a compounded anesthetic that has not been tested or approved by the United States Food and Drug Administration ("FDA") and the production of which was not under the supervision or regulation of the FDA, substantially risks that Mr. Loden may be conscious throughout his execution and will experience a torturous death by suffocation and cardiac arrest.
- 3. Further the decision of the Defendants to use compounded pentobarbital as the first drug in a three-drug lethal injection series impermissibly violates the directive of the Mississippi legislature that death sentences be executed by the continuous intravenous administration of "an ultra short-acting barbiturate or other similar drug."
- 4. The entirety of the lethal injection protocol promulgated by MDOC is not at issue in this lawsuit. Rather, this civil action challenges the use of compounded drugs, including but not limited to compounded pentobarbital, in lethal injection executions conducted by MDOC. Further this civil action specifically challenges the use of compounded pentobarbital in a three-drug lethal injection procedure. Lastly this civil action challenges MDOC's intent to have the raw ingredients for pentobarbital compounded into an injectable solution on the grounds of the Mississippi State Penitentiary at Parchman, where there is no pharmacy suitable for compounding sterile drugs. MDOC first ordered compounded drugs for purposes of lethal injection executions on May 20, 2012. That purchase instituted a policy, practice, or custom of using compounded drugs in MDOC executions.

5. Mr. Loden seeks permanent injunctive relief to prevent the Defendants from inflicting cruel and unusual punishment upon him during his execution, and otherwise violating his federal and state constitutional rights. Mr. Loden seeks preliminary injunctive relief to preserve the status quo pending this Court's final adjudication of this civil action.

### JURISDICTION AND VENUE

- 6. Mr. Loden's claims arise under the Constitution and laws of the United States, as well as under the Constitution and laws of the State of Mississippi. This Court has original federal question jurisdiction over those claims arising under the Constitution and laws of the United States pursuant to 28 U.S.C. §§ 1331, 1343. This Court has supplemental jurisdiction over those claims arising under the Constitution and laws of the State of Mississippi pursuant to 28 U.S.C. § 1367(a).
- 7. This Court has the authority to grant declaratory and injunctive relief under 28 U.S.C. § 2201-2202 and FED.R.CIV.P. 57 and 65. The federal rights asserted by Mr. Loden are enforceable under 42 U.S.C. § 1983.
- 8. Venue is proper in the Southern District of Mississippi under 28 U.S.C. §§ 1391(b)(1) and 1391(c)(2). With respect to Section 1391(b)(1), Defendant Marshall Fisher, Commissioner, Mississippi Department of Corrections, in His Official Capacity, is located in Jackson, Hinds County, Mississippi. With respect to Section 1391(c)(2), all Defendants in this action are required to be served with process by service on the Attorney General of Mississippi in Jackson, Hinds County, Mississippi, pursuant to Miss.R.Civ.P. 4(D)(5), incorporated through FED.R.Civ.P. 4(e)(1).

### **PARTIES**

- 9. The Intervenor, Thomas Edwin Loden, Jr., is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Thomas Edwin Loden, Jr., filed for relief under the MDOC Administrative Remedy Program on December 15, 2014. The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on January 1, 2015.
- 10. Defendant Marshall L. Fisher is the Commissioner of the Mississippi Department of Corrections.
- 11. The MDOC is the state agency charged with the incarceration, care, custody, and treatment of all state prisoners, including prisoners sentenced to death. Miss. Code Ann. §§ 47-5-10(a); 47-5-23.
- 12. Commissioner Fisher is the chief executive, administrative, and fiscal officer of MDOC, establishes the general policy of MDOC, and oversees the administration of all affairs within MDOC. Miss. Code Ann. §§ 47-5-20(a); 47-5-23; 47-5-24(1).
- 13. As the Commissioner of the MDOC, Mr. Fisher must perform "[a]II duties and necessary acts pertaining to the execution of a convict . . . except where such duties and actions are vested in the state executioner." Miss. Code Ann. § 99-19-13. See also Miss. Code Ann. § 99-19-55.
- 14. Commissioner Fisher is responsible for ensuring that all prisoners committed to the custody of MDOC are treated in accordance with the United States and Mississippi Constitutions.

- 15. At all relevant times, Commissioner Fisher has been acting under the color of law and as the agent and official representative of MDOC, pursuant to MDOC's official policies and procedures. Commissioner Fisher is sued in his official capacity only.
- 16. Defendant Earnest Lee is the Superintendent of the Mississippi State Penitentiary in Parchman, MS, the prison that houses all male death row inmates, and the prison where all executions take place in the State of Mississippi. Miss. Code Ann. § 99-19-55(1).
- 17. Superintendent Lee is responsible for implementing MDOC's policies and procedures governing executions, managing the preparations for an execution, and for turning over the execution site to the State Executioner to perform the execution.
- 18. Superintendent Lee is also responsible for protecting the constitutional rights of all persons incarcerated at the Mississippi State Penitentiary in Parchman, and/or transported to Parchman for an execution.
- 19. At all relevant times, Superintendent Lee has been acting under color of law and as the agent and official representative of the Mississippi State Penitentiary and MDOC. He is sued in his official capacity only.
- 20. The State Executioner of the State of Mississippi is appointed by the Governor and shall supervise and inflict the punishment of death pursuant to Miss. Code Ann. § 99-19-53. The name of the State Executioner is withheld from the public by the State of Mississippi.
- 21. The names of Defendants Unknown Executioners are unknown to Plaintiffs, but they include the State Executioner, his or her designee, and members of the State Execution Team. On information and belief, the Unknown Executioners will participate in the process of the execution by virtue of their roles in designing, implementing, carrying out, and/or

supervising the lethal injection process, including the procurement and storage of lethal injection drugs and materials. Miss. Code Ann. § 99-19-53, 99-19-55(2).

22. At all relevant times, Defendants State Executioner and Unknown Executioners have been acting under the color of law. There are sued in their official capacities only.

#### FACTUAL ALLEGATIONS

### A. MISSISSIPPI'S THREE-DRUG LETHAL INJECTION PROTOCOL

- 23. In Mississippi, the manner of execution for individuals sentenced to death is "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.
- 24. MDOC's lethal injection protocol calls for the serial administration of three drugs to put a prisoner to death.
- 25. The first drug, pentobarbital, a short-acting or intermediate-acting barbiturate, is intended to sufficiently anesthetize the prisoner so that he is both unconscious and insensate when the executioner injects the second and third drugs, vecuronium bromide<sup>2</sup> and potassium chloride, respectively.
- 26. Pentobarbital is not "an ultra short-acting barbiturate or other similar drug" as required by Mississippi law.

<sup>&</sup>lt;sup>1</sup> MDOC's most recent protocol, promulgated in March 2012, calls for the use of Sodium Pentothal as the first drug in the series, but provides for the use of pentobarbital "[i]n the event of an unavailability of a sufficient quantity of sodium pentothal from available sources." As discussed *infra*, Sodium Pentothal is no longer available to MDOC. Sodium Pentothal is the trademarked name for sodium thiopental. The MDOC's execution protocols have never expressly authorized or referenced the use of compounded drugs in executions.

<sup>&</sup>lt;sup>2</sup> The March 2012 protocol calls for the use of pavulon as the second drug in the series, but provides for the use of vecuronium bromide "[i]n the event of unavailability of a sufficient quantity of pavulon from available sources."

- 27. The second drug, vecuronium bromide, is a neuromuscular blocking agent that paralyzes all of the prisoner's voluntary muscles, including the muscles used for respiration, but does not suppress sensation, consciousness, cognition, or the ability to feel pain and suffocation. It is used by the MDOC to be the "chemical paralytic agent."
- 28. There is no legitimate penological justification for the use of a neuromuscular blocking agent or other chemical paralytic agent in an execution by lethal injection.
- 29. Neuromuscular blocking agents are not necessary to produce death, and do not diminish the prisoner's awareness or ability to feel pain.
- 30. Over eighty executions have been accomplished in other jurisdictions in the United States without the use of a neuromuscular blocking agent or other chemical paralytic agent. In each of these executions, the prisoner died.
- 31. The only purpose of the neuromuscular blocking agent in Mississippi's lethal injection protocol is to mask the gasping and physical convulsions produced by injection of the final drug, potassium chloride.
- 32. The neuromuscular blocking agent is thus used to make the execution appear serene and peaceful where the State may have in fact failed to sufficiently anesthetize the prisoner against pain and suffering.
- 33. The third and final drug in Mississippi's lethal injection protocol is potassium chloride a chemical that disrupts the electrical signals in the heart, paralyzes the cardiac muscle, and kills the prisoner by cardiac arrest.
- 34. Provided that a lethal dose of the barbiturate is administered, there is no legitimate penological justification for the use of potassium chloride in an execution by lethal injection.

- 35. Over eighty executions have been accomplished in other jurisdictions in the United States without the use of potassium chloride. In each of these executions, the prisoner died.
- 36. The humaneness and constitutionality of the three-drug lethal injection process hinges on whether the entire dose of the anesthetic (the first drug) is administered correctly, and whether the drug is sufficiently potent, pure, and rapid in onset to ensure that the prisoner is unconscious and insensate so he does not feel the torturous effects of the second and third drugs. If the first drug administered fails to work as intended, the execution will be torturous for the prisoner.

## B. KNOWN RISKS OF THE DRUGS, USED IN THE MISSISSIPPI LETHAL INJECTION PROTOCOL

- 37. The drugs used in Mississippi's lethal injection protocol have known and documented risks about which the Defendants are, or should be, aware.
- 38. The first risk is associated with the administration of vecuronium bromide, the drug currently stockpiled by MDOC to serve as the paralytic agent required by the Mississippi statute and protocol.
- 39. Vecuronium bromide causes the paralysis of all voluntary muscles, including the lungs and diaphragm.
- 40. If vecuronium bromide is administered to a prisoner who is still conscious and able to feel pain, he will suffocate to death while experiencing the agonizing and conscious urge to breath.

- 41. Thus, if a prisoner is injected with the paralytic agent vecuronium bromide before he is fully anesthetized and before he is rendered insensate, he will experience conscious paralysis and suffocation.
- 42. However, because the prisoner is completely paralyzed and unable to talk, move, or make facial expressions as a result of being paralyzed, his agony will be completely masked and concealed to observers.
- 43. The second known risk associated with the drugs used in the Mississippi lethal injection protocol is associated with the third and final drug in the series, potassium chloride.
- 44. There is no medical dispute that the injection of potassium chloride into an individual who has not been adequately anesthetized will cause excruciating pain.
- 45. Potassium chloride induces an intense burning sensation throughout the blood vessel walls running through a prisoner's body. If a prisoner is not fully anesthetized prior to the injection of potassium chloride, then he will consciously experience the agony of cardiac arrest.
- 46. The two risks set forth in paragraphs 38 to 45 above create a substantial risk of severe pain and serious harm, particularly where MDOC will not be administering an FDA-approved,<sup>3</sup> ultra short-acting barbiturate in sufficient dosage and potency to ensure that the prisoner is completely anesthetized prior to the injection of the paralytic agent and of potassium chloride.
- 47. There is no penological justification for the use of a paralytic agent and potassium chloride in an execution by lethal injection. Executions by lethal injection may be carried out

<sup>&</sup>lt;sup>3</sup> As used in this Complaint, the term "FDA-approved" includes both the drug itself (i.e. that the drug's formula is approved for distribution to consumers) and the process for manufacturing the drug. An "FDA-approved" drug thus refers to the specific batch or supply of a medication after manufacture.

through the use of a single-drug, anesthetic-only injection, a protocol now used in most executions nationwide and which has proven effective in executing over eighty prisoners to date.

48. An execution conducted by MDOC which continues to use a three-drug protocol, thereby refusing to adopt the feasible and readily implemented alternative of a single-drug injection of an FDA-approved, ultra short-acting barbiturate (which significantly reduces the substantial risks of severe pain and serious harm posed by the use of a chemical paralytic agent and potassium chloride), violates the Eighth Amendment.

RECENT HISTORY OF LETHAL INJECTION EXECUTIONS IN OTHER STATES DEMONSTRATES THE SEVERITY OF THE RISK OF EXTREME PAIN AND TORTURE WHERE THE POTENCY AND DOSAGE OF THE ANESTHETIC IS INSUFFICIENT.

- 49. Reflecting their revulsion against the use of their medications to execute prisoners in the United States, many pharmaceutical manufacturers have ceased production of drugs commonly used in American executions, have refused to sell them to corrections departments that may use them in executions, or have conditioned the sale of such drugs on "end-user agreements" which forbid the resale or use of the drugs for purposes of lethal injection executions.
- 50. Last month, the American Pharmacists Association, the largest association of pharmacists in the United States, voted to adopt a policy which discourages "pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care." Just a week prior to this announcement, the top trade group representing compounding pharmacists in the United States, the International Academy of Compounding Pharmacists, similarly "discourag[ed] its members from participating in the preparation, dispensing, or distribution of compounded medications for use in legally authorized executions."

### Sodium Thiopental

- 51. Hospira, Inc., the American manufacturer of the anesthetic sodium thiopental, stopped making sodium thiopental in 2011, after the drug's use in executions interfered with Hospira's ability to enter into manufacturing contracts in Europe. Hospira elected to stop making the drug entirely because it could not prevent the drug from getting into the hands of corrections' departments. Although sodium thiopental is manufactured in other countries, the FDA has not approved its importation into the United States.
- 52. Some states including Georgia resorted to violating federal law in order to procure sodium thiopental. Georgia illegally imported the drug from an English pharmaceutical distributor that operated out of the back of a driving school in London.
- 53. In May of 2011, the United States Drug Enforcement Agency ("DEA") seized the illegal sodium thiopental from the Georgia Department of Corrections; however Georgia had already executed two individuals with the illegal substance.
- 54. The compromised drug used in these Georgia executions failed to perform its necessary function of rendering the prisoners unconscious and insensate, causing the two prisoners to experience significant and unnecessary pain and suffering.
- 55. Thus, when Brandon Rhode was executed in September 2010 with the illegally-imported sodium thiopental, his eyes remained open for the entirety of his execution, indicating consciousness during the process.
- 56. Similarly, when Emmanuel Hammond was executed in January 2011 with the illegally-imported sodium thiopental, his eyes also remained open, and he grimaced and appeared to be trying to communicate throughout his execution.

- 57. Mississippi's lethal injection protocol calls for the use of Sodium Pentothal (a trademarked name for sodium thiopental) as the first drug in its series (except in the event of the unavailability of a sufficient quantity of the drug).
- 58. On information and belief, the last execution in Mississippi using Sodium Pentothal as the anesthetic drug given first in the three-drug series was on July 21, 2010. Since that time Mississippi has been unable to legally obtain Sodium Pentothal for use in executions.

### Nembutal: Pentobarbital Sodium Manufactured by Lundbeck

- 59. Where Sodium Pentothal is unavailable for use as the first drug in the series, the Mississippi execution protocol allows the administration of pentobarbital in its place.
- 60. There is only one manufacturer of FDA-approved injectable pentobarbital sodium, sold under the name-brand Nembutal.
- 61. In July 2011, Lundbeck, the manufacturer of Nembutal, announced that it would no longer sell the drug to departments of corrections, and required purchasers of its drug to enter into end-user agreements by which they agreed not to sell or transfer the drugs to prisons in states that still use capital punishment.
- 62. In December 2011, Lundbeck sold the rights to Nembutal to Akorn, Inc. and, as part of the agreement, Akorn agreed to maintain the restricted distribution program.
- 63. Any Nembutal sold prior to the July 2011 agreement would have expired no later than November 2013.
  - 64. The last time MDOC purchased Nembutal was on March 23, 2011.
  - 65. Any unused drugs from MDOC's purchase of Nembutal have expired.
- 66. By the March 23, 2011 transaction, MDOC purchased 12 units of Nembutal (50 mg/mL). It is unclear from the receiving report disclosed by MDOC what total volume of Nembutal was purchased.

- 67. Upon information and belief, the supply of Nembutal obtained by MDOC in March 2011 was utilized by MDOC in executions conducted in May 2011, and in executions conducted between February and June 2012.<sup>4</sup>
  - 68. The State of Mississippi has not executed any prisoner since June 20, 2012.
- 69. Consequently, Mississippi no longer has any legally-obtained, FDA-approved, and unexpired pentobarbital to use in executions.

### Experimentation with Anesthetics Previously Not Used in Executions

- 70. Due to this nation-wide shortage of FDA-approved sodium thiopental and pentobarbital for use in executions, some states (including Florida, Ohio, Arizona, and Oklahoma) have executed prisoners with drugs never previously used for lethal injection.
- 71. In Florida, Ohio, and Arizona executions using these experimental drugs caused the prisoners to remain conscious for an unacceptable length of time.
- 72. Since October 2013, Florida has executed prisoners using a three-drug protocol featuring midazolam hydrochloride, a paralytic agent, and potassium chloride. William Happ's execution in Florida the first using this new series took twice the amount of time as prior executions, and he continued to make body movements after he was injected with an untested drug, midazolam hydrochloride.
- 73. In January 2014, Dennis McGuire's execution in Ohio (using a two-drug injection of midazolam and hydromorphone) took twenty-six (26) minutes, and he gasped for air and gagged throughout the execution signs that he was being suffocated to death.

<sup>&</sup>lt;sup>4</sup> As discussed *infra*, MDOC did not purchase any additional legally-obtained, FDA-approved, and unexpired pentobarbital after March 2011. Rather in May 2012, MDOC purchased the active pharmaceutical ingredients ("API") to compound pentobarbital. This supply was not received by MDOC until June 13, 2012, according to receiving reports disclosed by MDOC. The State of Mississippi has only conducted one execution – that of Gary Simmons on June 20, 2012 – since this date of receipt. Upon information and belief, MDOC utilized Nembutal still in its possession from the March 2011 purchase in the execution of Mr. Simmons. As such MDOC's current supply of pentobarbital sodium API has never been used in any execution in the state.

- 74. The same protocol (midazolam and hydromorphone) was later used in Arizona's execution of Joseph Wood in July 2014, with even more troubling results. Mr. Wood gasped and gulped in the death chamber as prison officials injected 15 doses of lethal injection chemicals into his body for *nearly two hours* before he was pronounced dead.
- 75. Florida's three-drug protocol featuring midazolam hydrochloride was subsequently tried by Oklahoma in April 2014 with torturous results in the botched execution of Clayton Lockett. Mr. Lockett was observed writhing on the execution table and attempting to speak, even after having been declared unconscious.

### Experimentation with Compounded Drugs

- 76. Some states have responded to the unavailability of Nembutal by turning to the "gray market" of unregulated compounded drugs and unregulated active pharmaceutical ingredients ("API") to obtain compounded pentobarbital for use in executions.
- 77. This type of pharmacy compounding is a deviation from the traditional practice of pharmacy compounding, which involved the mixing of small batches of drugs in response to a physician's prescription to meet the unique needs of an individual patient when an FDA-approved drug is not suitable for the patient.
- 78. Compounded drugs are not FDA-approved and have not been evaluated for effectiveness and safety. Until recently, the FDA did not regulate compounded drugs and compounding pharmacies at all, and even now, the FDA does not have regulatory authority over all compounding pharmacies.
- 79. Compounded drugs are created without producing the data on safety and efficacy that the FDA requires for new drugs, and without the requirement that they follow good manufacturing practice regulations (GMPs) which insure their identity, strength, quality and

purity. Thus the FDA has noted "quality problems with various compounded drugs, including sub-potency, super-potency, and contamination."

- 80. State regulation of compounding pharmacies varies substantially, but no state regulates compounding pharmacies in a manner that would replicate the FDA's regulation of pharmaceutical manufacturers. Without unified standards and regulations there is no way to guarantee that drugs from a compounding pharmacy are what they purport to be and are safe and effective.
- 81. In recent years, a substandard compounding drug industry has emerged wherein compounding pharmacies create and market copies of FDA-approved drugs for general distribution. These drugs are developed and sold without the testing required by the FDA to ensure that the drugs are potent, pure, safe, and effective.
- 82. Additionally, there is a significant risk that compounded drugs are manufactured with counterfeit or substandard ingredients purchased from a range of manufacturers that operate outside of FDA supervision and regulation.
- 83. For these reasons, among others, the FDA has called the proliferation of compounded drugs a "troubling trend" because it has resulted in individuals taking harmful, contaminated, counterfeit, sub-potent, and/or super-potent drugs.
- 84. This is not a speculative risk. The 2012 outbreak of fungal meningitis caused by contaminated steroid injections from a compounding pharmacy in New England drew national attention to the regulatory vacuum within which compounding pharmacies operate, and the substandard and harmful products that these pharmacies can market to the public. Two senior executives of the New England pharmacy have since been indicted on charges of racketeering

and murder. The compounded drugs responsible for the meningitis outbreak had been "tested" and found potent by a laboratory purporting to be "independent."

- 85. Further, Oklahoma executed Michael Lee Wilson with compounded pentobarbital on January 9, 2014. After Mr. Wilson spoke his final words, and after the executioner administered the first drug, Mr. Wilson spoke again and stated: "I feel my whole body burning."
- 86. The burning sensation relayed by Mr. Wilson during his execution is consistent with an excruciatingly painful reaction to the injection of contaminated pentobarbital.

## C. Mississippi's Decision to Use Compounded Drugs in Lethal Injection Executions

- 87. Because MDOC can no longer obtain the FDA-approved form of pentobarbital, the Defendants, jointly and/or severally, have obtained pentobarbital sodium API for use in lethal injections from a compounding pharmacy in Grenada, Mississippi that otherwise markets its expertise in herbal supplements.
- 88. On or around May 20, 2012, MDOC purchased \$3,150 worth of pentobarbital sodium from H&W Compounding Pharmacy d/b/a Brister Brothers ("Brister Brothers"), a compounding pharmacy in Grenada, MS. According to a receiving report disclosed by MDOC, this supply was received by the Department on June 13, 2012. Brister Brothers purchased the pentobarbital sodium API from Professional Compounding Centers of America, Inc. ("PCCA"), in Houston, Texas.

<sup>&</sup>lt;sup>5</sup> MDOC also purchased vecuronium bromide and potassium chloride from the Brister Brothers pharmacy but this supply expired in 2014 and has since been destroyed. MDOC has subsequently purchased new supplies of vecuronium bromide and potassium chloride (reported to expire in fall 2015). MDOC refuses to disclose the provider of its current supply of vecuronium bromide and potassium chloride. This failure to disclose the identity of lethal injection drug suppliers is the subject of ongoing litigation between the MacArthur Justice Center and MDOC under the Mississippi Public Records Act. A chancery court has ordered the disclosure of the identity of the drug supplier but MDOC has appealed this ruling to the Mississippi Supreme Court.

- 89. Upon information and belief, Defendants did not purchase Nembutal or another sterile, injectable pentobarbital from Brister Brothers on or around May, 20, 2012 or at any time thereafter.
- 90. Specifically Defendants purchased 70 grams of raw materials or active pharmaceutical ingredients ("API") from Brister Brothers.
- 91. Upon information and belief, these 70 grams were packaged as 14 vials containing 5 grams each.
- 92. Defendants have not purchased any additional pentobarbital sodium API since May 20, 2012. Of the 14 vials purchased on this date, MDOC only has nine (9) vials remaining in its custody.
- 93. The 70 grams of pentobarbital sodium API which Defendants purchased from Brister Brothers were not compounded prior to the shipment from Brister Brothers to the grounds of the Mississippi State Penitentiary at Parchman. Thus, the pentobarbital will have to be compounded before its use in any execution in Mississippi.
- 94. According to the records of the Mississippi State Board of Pharmacy, there is no registered or licensed pharmacy at the Medical/Dental Facility at Parchman (Mississippi State Department of Health License No. 11-317). Drugs administered to prisoners are kept in the Drug Room at the Medical/Dental Facility at Parchman.
- 95. According to the MDOC's Chemical Supply Inventory, drugs used for lethal injection are not kept in the Drug Room, but at Unit 17, the building where death-sentenced prisoners were once incarcerated, and which is now used exclusively to house a condemned prisoner the days before his scheduled execution and to house the death chamber where he will

- be executed. The nine (9) vials of pentobarbital sodium API in MDOC's possession is set to expire on May 20, 2015.
- 96. Upon information and belief, MDOC has never used this supply of pentobarbital sodium API in an execution.
- 97. Upon information and belief, Defendants have not yet compounded the raw pentobarbital. There is no public record of MDOC sending the raw pentobarbital to a compounding pharmacy. Additionally, an affidavit executed by Special Assistant Attorney General Jim Norris on March 10, 2014 describes the pentobarbital sodium as being in a "powder" form.
- 98. Upon information and belief, the Defendants intend to compound the pentobarbital on the grounds of the Mississippi State Penitentiary at Parchman; or in the alternative, the Defendants intend to send the raw pentobarbital to a yet undisclosed location to prepare the drug for an execution.
- 99. If Mississippi proceeds with their executions, Mr. Loden will be among the first prisoners in Mississippi to be executed with compound pentobarbital.
  - D. CONSTITUTIONAL, PHARMACEUTICAL, AND MEDICAL RISKS PRESENTED BY DEFENDANTS' USE OF COMPOUNDED PENTOBARBITAL
- 100. Because Mississippi will use a three-drug formula in its executions, the humaneness and the constitutionality of the procedure depends entirely on the first drug working as intended and deeply anesthetizing the prisoner.
- 101. When compounded pentobarbital is used as the first drug in the three-drug formula, risks are introduced to the execution procedure which serve no valid penological purpose. Compounded drugs are not FDA-approved, so they carry no guarantees of the identity, purity, or potency of the drug.

- 102. Compounding pharmacies such as Brister Brothers generally do not have the facilities to test chemicals for identity, potency, purity, and contamination.
- 103. It is not possible for testing of API to eliminate the risks posed by impurities, contaminants, particulate matter, and/or an improper pH balance. Testing only provides a very provisional indication of an API's suitability for compounding given the unknowns about the chemical's integrity, storage, and custody in the timeframe from testing to pharmacy compounding and use.
- 104. Testing of non-sterile API by laboratories contracting with a distributor has proven unreliable. Poorly regulated, if regulated at all, contract-testing laboratories are supposed to test compounded drugs for safety and effectiveness. Too often, however, these laboratories are themselves substandard, and many are established to serve the financial interests of the pharmacies for which they are doing the testing. Five laboratories that test compounded drugs have had enforcement actions taken against them by the FDA.
- 105. Where the compounded pentobarbital is in any way sub-optimal, it poses a substantial risk of serious harm to the condemned prisoner either by inflicting pain and suffering itself or by failing to adequately anesthetize the prisoner, who then would experience conscious paralysis and the pain of potassium chloride, followed by cardiac arrest.
- 106. Moreover, each injection of compounded pentobarbital used in executions in Mississippi will be a new product, so the effectiveness of one dose does not demonstrate the effectiveness of the next.

### The Questionable Integrity of the Materials in the Possession of the Defendants

107. The integrity of the MDOC's supply of sodium pentobarbital API has not been verified, and these ingredients could very well be counterfeit, contaminated, or substandard.

- 108. The Defendants have not revealed the source of the active pharmaceutical ingredients that were used or will be used to make the compounded drug.
- 109. PCCA's source for the pentobarbital sodium API is not a matter of public record and is unknown to Mr. Loden.
- 110. On information and belief, Defendants themselves do not know the source of the pentobarbital sodium API sold by PCCA to Brister Brothers, and from Brister Brothers to MDOC.
- 111. PCCA expressly disclaimed any warranties in its sale of pentobarbital sodium API to Brister Brothers.

### The Questionable Process for the Compounding of Mississippi's Execution Drugs

- 112. The Defendants refusal to disclose critical facts surrounding the compounding process is also problematic.
- 113. In order to properly and safely compound the raw ingredients for pentobarbital into a sterile injectable, the compounding must be done in a sterile compounding laboratory with very specific and sophisticated physical requirements.
- 114. Under State law, a pharmacy or medical facility must be registered with the Mississippi State Board of Pharmacy in order to manufacture pentobarbital or another controlled substance. The pharmacy or facility cannot manufacture any controlled substance not authorized by its registration. Miss. Code Ann. §41-29-125, 41-29-141(2). Manufacture, in this context, includes compounding. Miss. Code Ann. §41-29-105(q).
- 115. As stated above, the State Board of Pharmacy does not list the Medical/Dental Facility at Parchman as a facility with a licensed pharmacy. The State Board of Pharmacy does

not list the Medical/Dental Facility at Parchman as a facility registered to compound controlled substances.

- 116. There are a limited number of compounding laboratories in Mississippi, and MDOC has not revealed to Mr. Loden where or how they intend to compound the raw pentobarbital.
- 117. The compounding of sodium pentobarbital API or any other drug on the grounds of the Mississippi State Penitentiary creates substantial risks that a drug so manufactured may be contaminated during compounding, and/or the compounding process may be flawed, resulting in the production of a sub-potent and ineffective drug.

### The Risk That the Pentobarbital Is Degraded or Expired

- 118. The expiration dates for FDA-approved drugs are based on rigorous testing in a controlled and regulated environment. The same testing is not performed on compounded drugs, resulting in an unacceptable risk that the drug may be degraded and sub-potent by the time it is used, and unable to perform its designated anesthetic function.
- 119. According to the March 10, 2014 affidavit of MDOC attorney Jim Norris and records from PCCA, the batch of pentobarbital sodium API held by MDOC has an expiration date of May 20, 2015. The risk of sub-potency and/or degradation of the API (and ultimately of any pentobarbital compounded therefrom) is greatly increased when a drug has passed its expiration date.
- 120. Even a small level of contamination or small deviation in the preparation process will, over time, lead to increasing deterioration of the quality of the batch. Because the MDOC's batch of pentobarbital is at the brink of its expiration date, a small problem with the initial preparation may well have progressed, over time, into a severe problem that will cause an

anomaly or botch. Any contamination, sub-potency, or super-potency in the original preparation may be enhanced as the batch ages closer to its expiration date.

121. Other records provided by MDOC indicate that the vecuronium bromide possessed by the Defendants will expire on October 1, 2015, and the potassium chloride possessed by the Defendants will expire on September 1, 2015.

### The Risk of Counterfeit API

- 122. One of the purposes of FDA regulation is to ensure that the drugs and narcotics used by Americans are true and genuine. The risk of counterfeit or "watered-down" drugs is a substantial part of the FDA's justification for prohibiting Americans from purchasing narcotics and drugs from foreign pharmacies or sources.
- 123. Because Defendants have not procured the drugs for lethal injections from an FDA-approved source, there is a risk that the materials which Defendants claim to be pentobarbital, vecuronium bromide, and potassium chloride are, in fact, nothing of the sort. The materials in Defendants' possession may be "watered-down" or wholly counterfeit.

### Compounded Pentobarbital Is Not an Ultra Short-Acting Barbiturate

124. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

- 125. Unable to obtain Sodium Pentothal or Nembutal, MDOC has now purchased pentobarbital sodium API to be compounded into an injectable solution to be used as the first drug in the three-drug series.
- 126. Compounded pentobarbital is not an ultra short-acting barbiturate like Sodium Pentothal. Rather pentobarbital is classified as a short- or intermediate-acting barbiturate.
- 127. This classification system refers to the rate of onset and length of duration for a given class of barbiturates. Those barbiturates classified as ultra short-acting have the fastest rate of onset, producing their anesthetic effect more quickly than all other classes of barbiturates. By contrast, short- or intermediate-acting barbiturates have a slower rate of onset than those barbiturates classified as ultra short-acting, taking longer to produce any anesthetic effect upon injection.
- 128. As there is substantial risk that compounded pentobarbital may be sub-potent, the onset rate of compounded pentobarbital would be even slower than that of FDA-approved pentobarbital.
- 129. An understanding of this classification system is of the utmost importance when a barbiturate is planned for use as the first drug in three-drug protocol for execution by lethal injection. Where the first drug does not act swiftly and effectively to anesthetize the prisoner such that he is both unconscious and insensate *before* the executioner injects the second and third drugs, there is a substantial risk of severe pain and suffering.
- 130. It was with this understanding in mind that the Mississippi legislature specifically directed the use of an ultra short-acting barbiturate for use in lethal injections. Furthermore any chemical which does not mirror the ultra short-acting property of the drug class explicitly prescribed for use by the statute cannot be considered an "other similar drug."

- 131. The current MDOC execution protocol does not account for the difference between an ultra short-acting barbiturate and other classes of barbiturates. The protocol simply substitutes pentobarbital for Sodium Pentothal with no other changes to the procedure.
- 132. According to execution logs produced by MDOC, the intervals between the administration of the anesthetic and paralytic drugs have not been lengthened as a result of substituting pentobarbital for the ultra short-acting barbiturate required by the Mississippi statute.

### Summary of Risks Presented by Defendants' Conduct

- 133. For the reasons set forth above, there is a high risk that either: (a) the Defendants intend to use a degraded form of compounded pentobarbital for the execution of Mr. Loden; (b) the Defendants have obtained only the raw ingredients for pentobarbital and intend to compound the pentobarbital at the Mississippi State Penitentiary; or (c) the Defendants have devised some other unknown and heretofore untested method of making pentobarbital.
- 134. The administration of pure and potent pentobarbital is the crucial step in the execution process to ensure that a condemned prisoner does not consciously experience the agonizing pain of live suffocation and cardiac arrest.
- 135. Defendants' decision to use a non-FDA-approved form of pentobarbital made with unknown and potentially contaminated or counterfeit ingredients is nothing short of human experimentation and presents an unacceptable risk that Plaintiffs will experience unnecessary pain and suffering if and when they are executed.
- 136. Defendants' decision to use a new and experimental lethal injection protocol without adequate assurances that the pentobarbital is manufactured according to accepted pharmaceutical practices and with pure and potent ingredients presents an unacceptable risk that

MDOC will attempt to execute Mr. Loden with an expired, contaminated, degraded, or subpotent form of pentobarbital, resulting in the infliction of cruel and unusual punishment.

### Defendant's Policy of Secrecy

- 137. On November 20, 2014 and February 20, 2015, the MacArthur Justice Center submitted public records requests to MDOC pursuant to Miss. Code Ann. § 25-65-1 et seq., wherein counsel for Plaintiffs Jordan and Chase requested documents and correspondence pertaining to MDOC's lethal injection protocol, and where and how MDOC procured its lethal injection drugs.<sup>6</sup>
- 138. In response to the November 20 request, MDOC provided 10-pages of heavily-redacted documents, stating that MDOC would not disclose any information that could identify the supplier or manufacturer of their lethal injection drugs out of fear that such disclosure of public information would negatively affect MDOC's supply of such drugs.
- 139. MDOC's failure to comply with the Mississippi Public Records Act and disclose public records related to their supply of lethal injection drugs is currently the subject of litigation between the MacArthur Justice Center and MDOC. The trial court has ruled in favor of the MacArthur Justice Center, ordering MDOC to provide un-redacted records as to their purchase of lethal injection drugs, awarding attorneys' fees, costs, and expenses, and denying a stay of this ruling pending appeal. MDOC has filed for appeal with the Mississippi Supreme Court.

<sup>&</sup>lt;sup>6</sup> The MacArthur Justice Center had submitted another request to MDOC on February 7, 2014, similarly requesting public documents pertaining to MDOC's lethal injection protocol and lethal injection drugs. After receiving records redacted for the identity of the supplier of MDOC's lethal injection drugs, the MacArthur Justice Center filed suit against MDOC for violations of the Mississippi Public Records Act (filed March 3, 2014). This lawsuit was ultimately mooted when the MacArthur Justice Center was able to determine the identity of MDOC's lethal injection drug supplier – the Brister Brothers – through information make publically-available by the MDOC on the state's Transparency website (as operated by the Department of Finance and Administration pursuant to the Mississippi Accountability and Transparency Act of 2008).

- 140. In response to the February 20 request, MDOC has again provided redacted records, claiming the ongoing litigation between the MacArthur Justice Center and MDOC as the basis for the denial.
- 141. Importantly, in the records provided on April 14, 2015, in response to the February 20 request, MDOC has reducted *even more* information from records which have previously been made available to the MacArthur Justice Center. Specifically, MDOC has reducted the month from records as to the date of purchase of the pentobarbital sodium API, and has provided records of the six (6) executions carried out by Mississippi in 2012 in response to an inquiry about the disposition of five (5) vials of the pentobarbital sodium API that have left the possession of the MDOC since June 2012.
- 142. By these calculated redactions of documents produced in response to a specific request for information about the use, disposal, or transfer of MDOC's pentobarbital sodium API, MDOC seeks to mislead the public to believe that the pentobarbital sodium API which has left MDOC's possession was used in the executions the state conducted in 2012. This is impossible given the fact known through records MDOC previously disclosed that the API was not in MDOC's possession until *after* five (5) of the six (6) executions carried out in 2012 had already occurred.<sup>7</sup>
- 143. The MacArthur Justice Center was previously able to identify the supplier of MDOC's lethal injection drugs through its own investigation, see footnote 6 supra, but MDOC has since purchased new vecuronium bromide and potassium chloride (the second and third drugs in the execution series), and the identity of the supplier of these drugs is unknown. MDOC

<sup>&</sup>lt;sup>7</sup> The April 13, 2015 MDOC Public Records Act response was also inconsistent with the statement of counsel for the MDOC in a March 2, 2015 hearing in the chancery court case brought by the MacArthur Justice Center against MDOC, see footnote 5. Counsel asserted then that the unaccounted for pentobarbital sodium API had been destroyed because it had passed its expiration date. All documents produced by MDOC, however, demonstrated that all of the sodium pentobarbital API purchased from Brister Brothers had the same expiration date – May 20, 2015.

maintains a policy of secrecy with regard to where and from whom they purchase lethal injection drugs, and how and where those drugs are prepared for use in executions.

- 144. States continue to have difficulty purchasing pentobarbital in any form.

  Consequently, Defendants may change their protocol or purchase different drugs or active pharmaceutical ingredients from different manufacturers before the next scheduled execution.
  - 145. No execution is currently scheduled in the State of Mississippi.
- 146. Upon information and belief, Defendants have not compounded the pentobarbital sodium API into a sterile injectable form, and if Mr. Loden is scheduled for an execution before the May 20, 2015 expiration date, his execution will be the first in which Defendants use this compounded pentobarbital.
- 147. Defendants have failed to disclose any information as to their ability to or history of successfully compounding the pentobarbital sodium API in their possession into a sterile injectable form for use in executions. Defendants have also failed to disclose what information, if any, they have researched, gathered, or relied upon to evaluate the efficacy or effect of this new drug when used for an execution.
- 148. Defendants' failure to disclose the manufacturer of the active pharmaceutical ingredients deprives Mr. Loden of any means to assess the purity of the API from which the injectable form of pentobarbital has or will be made; whether the API has been diluted with any substances which could impact the potency of the final product; whether the API is contaminated with either particulate foreign matter or a microbial biohazard that could lead to a severe allergic or neurotoxic reaction upon injection and several other similar issues.
- 149. Defendants will not disclose to Mr. Loden where and when they plan to compound the drug, or the training and qualifications of the individuals who will participate in

and supervise the compounding process. Mr. Loden has no way to assess the qualifications of the compounding pharmacy, whether the facility is actually equipped to make sterile injectable drugs such as pentobarbital, or whether the facilities are equipped to conduct any testing on the identity and/or purity of the API.

150. Defendants' policy of secrecy, and their failure to disclose the manufacturer of the API it purchased from Brister-Brothers, and where, how, and when they intend to try to compound the API into a sterile injectable form of pentobarbital violates Mr. Loden's' right to be free from cruel and unusual punishment, to due process, and to access to the courts.

### CLAIMS FOR RELIEF

Count I: Use of Compounded Pentobarbital in a Three-Drug Lethal Injection Protocol Violates Intervenor's Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

- 151. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 150.
- 152. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is among the ultra short-acting barbiturates authorized by the Mississippi lethal injection statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 153. Defendants also no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of the Mississippi statute.
- 154. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Mr. Loden's right to be free from cruel and unusual punishment and to due

process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claim II infra.

- 155. Defendants plan to use a compounded form of pentobarbital made from active pharmaceutical ingredients of unknown origin that may be counterfeit, contaminated, or ineffective.
- 156. In the alternative, Defendants intend to compound the drug by some other means pursuant to an unknown process and protocol, and by individuals with unknown qualifications.
- 157. The Eighth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, and the corresponding provisions of the Mississippi Constitution, prohibit the infliction of unnecessary pain in the execution of a death sentence.
- 158. Because it is nearly impossible to determine with certainty whether a prisoner will suffer serious and needless pain and suffering during an execution, the question of whether a particular execution procedure will inflict such pain and suffering involves an inquiry as to whether the prisoner is subject to a substantial or intolerable risk of serious harm.
- 159. Such a substantial or intolerable risk of serious harm may occur when a state lacks a clear protocol for lethal injection, when experience with the procedure demonstrates that there are foreseeable problems, or when it is known that the drugs intended for use in lethal injections will very likely result in the prisoner suffering intense pain that an alternative procedure would not cause.
- 160. The Defendants' decision to use a previously untried form of pentobarbital created with unknown and unregulated ingredients through an unknown and unregulated compounding process creates a substantial and intolerable risk that the pentobarbital will be

counterfeit, contaminated, degraded, expired, or sub-potent, resulting in the infliction of cruel and unusual punishment.

- 161. The Defendants' untried and untested drugs create a substantial risk that Plaintiffs will suffer unnecessary and excruciating pain either by the injection of the compounded pentobarbital causing a painful reaction itself, or by the compounded pentobarbital failing to work, resulting in a torturous death by life suffocation and cardiac arrest.
- 162. Thus, Mississippi's planned use of compounded pentobarbital as the first drug in a three-drug series, which is completed with the intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to Thomas Edwin Loden Jr.
- 163. There is a feasible alternative which could substantially reduce the risk of severe pain and serious harm presented by the continuous intravenous administration of compounded pentobarbital in combination with a chemical paralytic agent and potassium chloride.
- 164. The use of an FDA-approved, ultra short-acting barbiturate in a single-drug protocol is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure. Other jurisdictions have already moved towards the use of a single-drug anesthetic-only protocol.
- 165. Defendants' refusal to adopt this alternative for the execution of Thomas Edwin Loden, Jr., in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of execution, constitutes cruel and unusual punishment prohibited by the Eighth Amendment.
- 166. To the extent that Defendants' refusal to adopt the single-drug anesthetic-only barbiturate technique is based on the requirements of Miss. Code Ann. §99-19-51, that part of the

statute which requires the use of a "chemical paralytic agent" in executions should be held unconstitutional as contrary to the Eighth Amendment.

- 167. For the reasons set forth above, Defendants are deliberately indifferent to Mr. Loden's constitutional rights.
- 168. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count I.

Count II: Failure to Use an Ultra Short-Acting Barbiturate or Other Similar Drug as Directed by Mississippi Statute Violates Intervenor's Right to be Free from Cruel and Unusual Punishment and Right to Due Process under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

- 169. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 168.
- 170. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.
- 171. Intervenor, Thomas Edwin Loden, Jr. has a liberty interest created by the requirement of an "ultra short-acting barbiturate or other similar drug" in Section 99-19-51. This interest is protected from arbitrary deprivation by the Due Process Clause of the Fourteenth Amendment.

- 172. Prior to 2011, Defendants used Sodium Pentothal (also known as sodium thiopental) as the first drug in a three-drug lethal injection protocol. Sodium Pentothal is classified as an ultra short-acting barbiturate. This classification is based on the drug's speed of onset and duration of effect. Use of an ultra short-acting barbiturate in Mississippi's execution protocol is necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs.
- 173. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. As a result, MDOC has amended its protocol to allow for the use of pentobarbital as the first drug in the three-drug series where Sodium Pentothal is unavailable.
- 174. Pentobarbital even in its FDA-approved form is never classified as an ultra short-acting barbiturate. Rather it is classified as a short- or intermediate-acting barbiturate. This classification recognizes the slower speed of onset of pentobarbital when compared to an ultra short-acting barbiturate.
- 175. While the Mississippi statute provides for use of an "ultra short-acting barbiturate or other similar drug," pentobarbital is not sufficiently similar to an ultra short-acting barbiturate as to be considered an "other similar drug" within the meaning of a statute. This is true even for FDA-approved pentobarbital, let alone for compounded pentobarbital made from unknown active pharmaceutical ingredients, as MDOC intends to now use.
- 176. MDOC's decision to use compounded pentobarbital as the first drug in its upcoming executions is in clear violation of Miss. Code Ann. § 99-19-51. As such this decision violates Mr. Loden's right, guaranteed by the Eighth Amendment to the United States Constitution and Article 3, Section 28 of the Mississippi Constitution, be free from cruel and unusual punishment.

- 177. MDOC's decision to use compounded pentobarbital as the first drug in its upcoming executions further violates Mr. Loden's right, guaranteed by the Fourteenth Amendment to the United States Constitution and Article 3, Section 14 of the Mississippi Constitution, to not be executed except in accordance with Section 99-19-51. Mississippi law provides no adequate post-deprivation remedy for the harm that will be caused by Defendants' denial of Mr. Loden's right to be executed only with the use of an ultra short-acting barbiturate.
- 178. For the reasons set forth above, MDOC's failure to use an ultra short-acting barbiturate as required by Miss. Code Ann. §99-19-51 creates an unacceptable risk of severe pain and serious harm in violation of the Eighth Amendment.
- 179. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count II.
- Count III: Mississippi's Continued Use of a Three-Drug Protocol in the Face of Evolving Standards of Decency Which Require Abandonment of the Use of a Chemical Paralytic Agent and Potassium Chloride, Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution
- 180. Mr. Loden re-alleges and incorporates by reference the allegations contained in paragraphs 21 to 180.
- 181. "The basic concept underlying the Eighth Amendment is nothing less than the dignity of man . . . . The Amendment must draw its meaning from the evolving standards of decency that mark the progress of a maturing society." *Atkins v. Virginia*, 536 U.S. 304, 311-312 (2002) (quoting Trop v. Dulles, 356 U.S. 86 (1958)). The United States Supreme Court has repeatedly looked to legislation enacted by the states as the "clearest and most reliable objective evidence of contemporary values," *id.* at 312 (quoting Penry v. Lynaugh, 492 U.S. 302, 331

- (1989)), relying on such legislative evidence of evolving trends to narrow the classes of those individuals we seek to punish through the death penalty and to determine the suitability of those methods and protocols by which we carry out such sentences.
- 182. Defendants can no longer purchase Sodium Pentothal, as detailed supra.

  Defendants have not used Sodium Pentothal in an execution since 2010.
- 183. Defendants have amended their lethal injection protocol to provide for the use of pentobarbital in the event that Sodium Pentothal is unavailable. In executions conducted in 2011 and in 2012, MDOC used pentobarbital as the first drug in its three-drug lethal injection protocol, in place of Sodium Pentothal.
- 184. On information and belief, all eight (8) of these executions used the FDA-approved form of pentobarbital, marked as Nembutal and purchased by MDOC in March 2011.
- 185. Defendants no longer possess an FDA-approved form of pentobarbital. Instead Defendants have purchased pentobarbital sodium API to be compounded into injectable pentobarbital for use in upcoming lethal injections.
- 186. Mississippi's decision to continue use of a three-drug lethal injection protocol, particularly one employing pentobarbital, runs contrary to the trend towards single-drug, anesthetic-only protocols employed successfully by other states in recent years.
- 187. All other states which have conducted executions in 2014 and 2015 have completely abandoned the use of pentobarbital (compounded or otherwise) in a multi-drug lethal injection protocol. No state has used pentobarbital in a three-drug protocol this year (with 13 executions having been conducted by five states to date). Only Oklahoma used pentobarbital in a three-drug protocol in 2014, accounting for just two (2) of the 35 executions conducted by seven (7) states last year.

- 188. Furthermore Oklahoma itself has since moved away from the use of pentobarbital in its three-drug series, for while the state conducted two executions with pentobarbital in January 2014, Oklahoma conducted its third execution in 2014 using an alternate drug as the first drug in its three-drug series.<sup>8</sup>
- 189. The chart below summarizes this evolving trend away from the use of three-drug lethal injection protocols, particularly those involving pentobarbital. The execution methods, protocols, and drugs (as contained in the chart) track the lethal injection statutes propagated by state legislatures, as well as the lethal injection protocols propagated and implemented by state departments of corrections.

	3-drug sodium thiopental	1-drug sodium thiopental	3-drug pentobarbital	1-drug pentobarbit al	3-drug midazolam	2-drug midazolam	Other	Total
2010	34	9	1	0	0	Ö	2	46
	TX, LA, OK, FL, MS, VA, AL, GA, AZ	OH, WA	OK				VA, UT	
2011	7	1	31	4	0	0	0	4.3
	AL, GA, MO, TX, AZ	он	OK, TX, SC, MS, AL, AZ, GA, DE, VA, FL, ID	ОН				
2012	0	0	21	22	0	0	0	43
			OK, TX, MS, FL, DE	AZ, OH, ID, TX, SD				
2013	0	Ó	12	24	2	0	1	39
			OK, FL, AL	TX, GA, OH, AZ, MO	FL		VA	
2014	0	0	2	22	9	2		35
			ок	TX, MO, GA	FL, OK	OH, AZ		
2015	0	0	0 .	11	2	0	0	13 (to date)
				GA, TX, MO	FL, OK			(

<sup>&</sup>lt;sup>8</sup> Oklahoma executed Clayton Lockett on April 29, 2014 using a three-drug series of midazolam hydrochloride, followed by a paralytic agent and potassium chloride. This botched execution further documented the substantial risk of serious harm posed by the use of a three-drug protocol. The lethal injection protocol implemented by Oklahoma in September of 2014 provides for four (4) different lethal injection procedures, but does not include a three-drug series featuring pentobarbital as one of these procedures.

- 190. The trend towards abandonment of the three-drug protocol is evidence of the evolving standards of decency which inform the Eighth Amendment. From 2010 to 2012, of the 132 executions conducted nationwide, over 70 percent (94 executions) were conducted using a three-drug protocol. Yet since 2013, just three states have conducted executions using a three-drug protocol, a total of 27 executions (31 percent) of the 87 conducted nationwide. Only 14 of these 87 executions used pentobarbital in a three-drug series (16 percent of executions nationwide).
- 191. Put another way, forty-seven of the fifty states punish murder without undertaking the risk of conscious, torturous pain and suffocation which is raised by the use of a chemical paralytic agent and potassium chloride in the three-drug protocol.
- 192. It follows that use of the three-drug protocol by Mississippi constitutes cruel and unusual punishment in violation of the Eighth Amendment.
- 193. Defendants continued use of a pentobarbital-based three-drug lethal injection protocol, when other states have abandoned this method in favor of a single-drug, anesthetic-only protocol, violates Mr. Loden's right to be free from cruel and unusual punishment as guaranteed by the United States and Mississippi Constitutions.
- 194. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count III.

# Count IV: Violation of Intervenor's Right to Notice of the Defendants' Method of Execution under the Fourteenth Amendment to the United States Constitution and Article 3, Section 14 of the Mississippi Constitution

195. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 194.

- 196. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 197. Defendants also no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of Mississippi statute. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Plaintiffs' rights to be free from cruel and unusual punishment and to due process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claims *supra*.
- 198. Defendants have obtained active pharmaceutical ingredients from a compounding pharmacy to try to manufacture a sterile injectable form of pentobarbital.
- 199. Defendants have not disclosed where they have compounded, or where they intend to compound the raw ingredients to try to make a sterile injectable form of pentobarbital.
- 200. Defendants have not disclosed the training or qualifications of the individuals responsible for trying to compound the raw ingredients to make a sterile injectable form of pentobarbital.
- 201. Upon information and belief, Defendants intend to execute Mr. Loden with drugs or ingredients that have never been used before in an execution in Mississippi.
- 202. Under the due process clauses of the United States and Mississippi Constitutions, Mr. Loden is entitled to notice of the Defendants' intended method of execution, including information about the drugs Defendants have obtained and the steps by which these API will be compounded into a sterile injection to be used in executions.

- 203. Defendants' failure to disclose the manufacturer of the active pharmaceutical ingredients it purchased to make pentobarbital, and Defendants' failure to disclose how, where, and when they intend to try to compound the raw ingredients into a sterile injectable form of pentobarbital violates Mr. Loden's right to due process under the United States and Mississippi Constitutions.
- 204. For the reasons set forth above, Defendants are deliberately indifferent to Mr. Loden's constitutional rights.
- 205. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count IV.

# Count V: Violation of Intervenor's Right of Access to the Courts under the First and Fourteenth Amendment to the United States Constitution and Article 3, Section 14 and 24 of the Mississippi Constitution

- 206. Mr. Loden realleges and incorporates by reference the allegations contained in paragraphs 21 to 205.
- 207. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 208. Defendants also no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of Mississippi statute. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Plaintiffs' rights to be free

from cruel and unusual punishment and to due process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claims *supra*.

- 209. Due to the unavailability of FDA-approved pentobarbital, Defendants have changed their lethal injection protocol by substituting a compounded form of pentobarbital for the FDA-approved drug Nembutal.
- 210. Defendants have purchased the active pharmaceutical ingredients for pentobarbital, and already have, or will in the future, devise a way to try to compound the active pharmaceutical ingredients to create a sterile injectable form of pentobarbital.
- 211. Defendants have asserted that the identity of the manufacturer and supplier of lethal injection drugs is confidential for fear the disclosure of such information would forestall MDOC's ability to obtain lethal injection drugs in the future. MDOC will not tell MacArthur Justice Center or Intervenor who manufactured the active pharmaceutical ingredients, where the drugs have been or will be compounded, and the training and qualifications of the individuals who have or will compound the drugs. This information is necessary in order for Mr. Loden to more fully determine the risks associated with Defendants' lethal injection drugs.
- 212. Mr. Loden possesses a right to file a legal challenge to enjoin their executions if Defendants' execution procedure presents a substantial risk of serious harm, in violation of the Eighth and Fourteenth Amendments to the United States Constitution.
- 213. Mr. Loden also possesses a right under the First and Fourteenth Amendments to the United States Constitution and Article 3, Section 24 of the Mississippi Constitution to have a reasonable opportunity to present legal claims implicating fundamental constitutional rights to the courts.

- 214. Defendants' policy of secrecy prevents Mr. Loden from accessing all of the relevant information he needs to mount an Eighth Amendment challenge to Defendants' lethal injection protocol, and thus violates his right of access to the courts.
- 215. For the reasons set forth above, Defendants are deliberately indifferent to Mr. Loden's constitutional rights.
- 216. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count V.

#### PRAYER FOR RELIEF

WHEREFORE, Mr. Loden requests that this Court:

- Grant a declaratory judgment that pentobarbital is not "an ultra-short acting barbiturate or other similar drug" and is therefore not permitted for lethal injection executions in Mississippi;
- Grant preliminary and permanent injunctive relief to enjoin the Defendants, their
  officers, agents, employees, and all persons acting in concert with them from
  executing Mr. Loden with pentobarbital, which is not an ultra-short acting
  barbiturate;
- 3. Grant a declaratory judgment that the words "in combination with a chemical paralytic agent" in Miss. Code Ann. §99-19-51 violate the Eighth and Fourteenth Amendment to the United States Constitution;
- 4. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden with compounded drugs;

- 5. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden with drugs that have passed their expiration date;
- 6. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden with a three-drug series which includes a chemical paralytic agent and potassium chloride;
- 7. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden until such time as Defendants can demonstrate the integrity and legality of any and all controlled substances they intend to use for Mr. Loden's execution;
- 8. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden without providing full and complete information about the drugs that Defendants intend to use in their execution, within sufficient time for Mr. Loden to raise any statutory or constitutional challenges to the use of said drugs.
- 9. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Mr. Loden until such time as Defendants can demonstrate that measures are in place to allow for Mr. Loden's execution in a manner that

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complies with the Eighth and Fourteenth Amendments to the United States Constitution;

- 10. Award costs and attorney's fees pursuant to 42 U.S.C. §1988; and
- 11. Grant any such other relief that this Court determines to be just and proper in these premises.

Respectfully submitted, THOMAS EDWIN LODEN, Hr.

By:

/s/ Stacy Ferraro

Stacy Ferraro

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# **CERTIFICATE OF SERVICE**

I certify that I have served a copy of the foregoing motion on the following via the Court's ECF system on this the 20th day of May, 2015.

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> /s/ Stacy Ferraro Stacy Ferraro

## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI NORTHERN DIVISION

RICHARD JORDAN and RICKY CHASE,

Plaintiffs,

THOMAS EDWIN LODEN, Jr.

Intervenor

v.

Civil Action No. 3:15-cv-00295

MARSHALL L. FISHER, Commissioner,
Mississippi Department of Corrections, in
his Official Capacity; EARNEST LEE,
Superintendent, Mississippi State
Penitentiary, in his Official Capacity;
THE MISSISSIPPI STATE EXECUTIONER,
in his Official Capacity; and UNKNOWN
EXECUTIONERS, in their Official Capacities,

Defendants.

## Order

This matter comes before the Court on Thomas Edwin Loden, Jr.'s Motion to Intervene (doc. no. 14). Having fully considered the matter, the Court finds the motion well taken and the Motion should be **GRANTED**.

SO ORDERED this the 20th day of July, 2015.

s/ HENRY T. WINGATE HENRY T. WINGATE United States District Judge



IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE RODERICK & SOLANGE MAY 22 2015

PLAINTIFF

MACARTHUR JUSTICE CENTER CHANCERY CLERK

RY CLEAN CARR, CHANCERY CLEAR

NO. G2014-1885

MISSISSIPPI DEPARTMENT OF CORRECTIONS

DEFENDANT

TRANSCRIPT OF PROCEEDINGS HAD IN THIS CAUSE BEFORE THE

IN THE FIFTH CHANCERY COURT DISTRICT OF MISSISSIPPI ON THE 2ND DAY OF MARCH 2015

HONORABLE DENISE OWENS, CHANCELLOR

APPEARANCES!

REPRESENTING THE PLAINTIFF:

JIM CRAIG, ESQUIRE CO-DIRECTOR RODERICK & SOLANGE MACARTHUR JUSTICE CENTER 4400 S. CARROLLTON AVENUE NEW ORLEANS, LA 70119

REPRESENTING THE DEFENDANT:

PAUL ELDRIDGE BARNES, ESQUIRE ALISON ELIZABETH O'NEAL, ESQUIRE JASON LEWIS DAVIS, ESQUIRE OFFICE OF THE ATTORNEY GENERAL POST OFFICE BOX 220 JACKSON, MISSISSIPPI 39205-0220

EXHIBIT 4

 test -- go head, Your Honor.

THE COURT: Well, I do understand that, you know, you said it's really effectively

impossible to get the pentobarbital. So, it's impossible to execute someone here now --

MR. BARNES: At this time, the protocol that Mississippi -- that has been approved uses the three-drug protocol. If we change the protocol, it will, of course, be challenged by the plaintiffs, and so --

THE COURT: But has that happened in other

aware, there are no other responsive documents, whether -- whatever plaintiff might make of that, notwithstanding, it's our understanding that the 10 pages of documents which MDOC produced are the documents in its possession, custody or control responsive to their most recent request. One moment, Your Honor.

(PAUSE IN THE PROCEEDINGS)

MR. BARNES: Your Honor, I'd just like to conclude, at least this portion of the argument. I certainly would be willing to answer any other — any questions the court might have and provide the court with any other argument after Mr. Craig discusses the confidential financial information exemption further; but again, this is an issue of utmost importance to the state. The public has an interest in the enforcement of the laws and if the court gets to the balancing test — go head. Your Honor.

 states that seem to have the same problem?

MR. BARNES: I'll let Mr. Davis speak to that.

MR. DAVIS: Let me make sure I understand your question, Your Honor.

THE COURT: I mean, I understand that -- I mean, you're saying it's really virtually impossible to get the pentobarbital to execute the person, but does that mean you're not going to execute or would you change the protocol like they have in other states?

MR. DAVIS: Well, you would -- obviously if you couldn't get the one, you'd have to come up with another --

THE COURT: I mean, so, the state --

MR. DAVIS: -- but the other states have been doing that, and that's what we've been seeing in the press lately is the change to the drug -- and Your Honor may be familiar with it -- midazolam, and that's the one that Ohio utilized and that Oklahoma, I believe.

THE COURT: I guess my question goes: You could still carry on your duty even if you're unable to get the pentobarbital?

MR. DAVIS: Well, our statute says ultra short-acting barbiturate or other similar drug. We are already limited. We've already -- if we lose pentobarbital, that's two down from that.

THE COURT: So, you'd have to change the

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protocol for executions.

MR. BARNES: Absolutely, Your Honor.

THE COURT: But you would change the protocol? Is that --

MR. DAVIS: Provided we could find a suitable drug, Your Honor. Counsel would state for the court that based on my years of doing this and what I'm seeing with the use of midazolam and counsel for the state is not interested in using that right now and that's not an option for this counsel at this point which means that you've got to find something else and there's a whole process that would be involved in trying to find an alternative anesthetic. And I don't know —— I'm not a doctor, so I don't know what the classes what the —— how many are left, but there aren't very many that are in that ultra short—acting category that we can utilize.

THE COURT: Okay.

MR. BARNES: And, Your Honor, just one moment. I was going to say that -- and it's also -- you know, I've had to educate myself somewhat about this and Mr. Davis, you know, has educated me a great deal, but obviously he hasn't taught me everything. It's my understanding that when veterinarians put animals to sleep, they use pentobarbital and almost exclusively. They use a single massive

#### COURT REPORTER'S CERTIFICATE

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STATE OF MISSISSIPPI

COUNTY OF HINDS

0.1 I, Colleen O. White, Official Court Reporter for the Fifth Chancery Court District of the State of Mississippi, do hereby certify that to the best of my skill and ability I have reported the proceedings had and done in the trial of THE RODERICK & SOLANGE MACARTHUR JUSTICE CENTER VS. MISSISSIPPI DEPARTMENT OF CORRECTIONS, being No. G2014-1885 on the Docket of the Chancery Court of the First Judicial District of Hinds County, Mississippi, and that the above and foregoing sixty-eight (68) pages contain a full, true, and correct transcript of my stenographic notes and tape taken in said proceedings.

 This is to further certify that I have this date filed the original and one copy of said transcript, along with one CD-ROM electronic disk of said transcript in PDF language, for inclusion in the record on appeal, with the Clerk of the Chancery Court of the First Judicial District of Hinds County, Mississippi, and have notified the attorneys of record, the Chancery Clerk and the Supreme Court Clerk of my actions herein.

I do further certify that my certificate annexed hereto applies only to the original and certified transcript and electronic disk. The undersigned assumes no responsibility for the accuracy of any reproduced copies not made under my control or direction.

This, the 22nd day of May, 2015.

COLLEEN O. WHITE, RMR, CSR

Cucum O. White

CSR NUMBER 1310

\$165.60 PAID

TRANSCRIPT FEE:

## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI NORTHERN DIVISION

RICHARD JORDAN AND RICKY CHASE

**PLAINTIFFS** 

THOMAS EDWIN LODEN, JR.

**PUTATIVE INTERVENOR** 

VS.

CIVIL ACTION NO. 3:15cv295-HTW-LRA

COMMISSIONER MARSHALL L. FISHER,
Commissioner, Mississippi Department
of Corrections, in his Official Capacity;
SUPERINTENDENT EARNEST LEE,
Superintendent, Mississippi State Penitentiary,
in his Official Capacity; THE MISSISSIPPI
STATE EXECUTIONER, in his Official Capacity;
AND UNKNOWNEXECUTIONERS, in their
Official Capacities

**DEFENDANTS** 

#### ORDER

#### I. Background

This lawsuit involves a challenge to Mississippi's current iteration of its three-drug lethal injection protocol. On April 16, 2015, plaintiffs Richard Jordan and Ricky Chase filed this action for declaratory and injunctive relief under 42 U.S.C. § 1983<sup>1</sup> in this federal forum for alleged violations and threatened violations of plaintiffs' rights to due process and to be free from cruel and unusual punishment under the First<sup>2</sup>, Eighth<sup>3</sup>,



<sup>&</sup>lt;sup>1</sup> Title 42 U.S.C. § 1983, in pertinent part, states:

<sup>&</sup>quot;Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress...."

<sup>&</sup>lt;sup>2</sup> U.S. Const. amend, I states:

and Fourteenth<sup>4</sup> Amendments to the United States Constitution and Article 3, Sections 14<sup>5</sup>, 24<sup>6</sup>, and 28<sup>7</sup> of the Mississippi Constitution. Plaintiffs' forty-two page complaint objects to the use of compounded drugs, including but not limited to compounded pentobarbital<sup>8</sup>, in lethal injections conducted by MDOC.

Named as defendants are: Marshall Fisher, Commissioner of the Mississippi

Department of Corrections ("MDOC"); Earnest Lee, Superintendent of the Mississippi

State Penitentiary; the Mississippi State Executioner; and other Unknown Executioners.

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Count V of plaintiffs' complaint alleges that the defendants have violated plaintiffs' First Amendment right to have a reasonable opportunity to present legal claims implicating constitutional rights to the courts.

<sup>4</sup> U.S. Const. amend. XIV, § 1 states:

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

<sup>&</sup>lt;sup>3</sup> U.S. Const. amend. VIII states: "Excessive ball shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted."

<sup>&</sup>lt;sup>5</sup> Miss. Const., Art.3, § 14 states: "No person shall be deprived of life, liberty, or property except by due process of law."

<sup>&</sup>lt;sup>6</sup> Miss. Const., Art. 3, § 24 states:" All courts shall be open; and every person for an injury done him in his lands, goods, person, or reputation, shall have remedy by due course of law, and right and justice shall be administered without sale, denial, or delay."

<sup>&</sup>lt;sup>7</sup> Miss. Const., Art. 3, § 28 states: "Cruel or unusual punishment shall not be inflicted, nor excessive fines be imposed."

<sup>&</sup>lt;sup>8</sup> It is agreed here that Mississippi has never before used compounded pentobarbital to execute a death row inmate.

Each of these defendants is being sued in his official capacity. In this order, the court shall refer to them as "defendants" or as the "State", since they propose to conduct executions on behalf of the State of Mississippi.

The State of Mississippi has asked the Mississippi Supreme Court to set an execution date of August 27, 2015, for plaintiff Richard Jordan. As of today, August 25, 2015, the Mississippi Supreme Court has not acted on the State's request to execute Jordan on August 27, 2015. Convicted of capital murder committed in the course of a kidnapping, Jordan is to die by lethal injection, a procedure approved by Miss. Code. Ann. § 99-19-51<sup>9</sup>. Mississippi currently employs a three-drug approach in performing this procedure. The condemnee first is provided an anesthetic drug, and then a second drug, vecuronium bromide which is a chemical paralytic agent. The third drug administered is potassium chloride, a chemical that disrupts the electrical signals in the heart, paralyzes the cardiac muscle, and kills the condemnee by cardiac arrest.

Pursuant to Federal Rule of Civil Procedure 65(b)<sup>10</sup>, plaintiffs have moved for a preliminary injunction to enjoin the State defendants from performing the following acts during the execution of plaintiffs: (1) administering any anesthetic that is not in the statutorily-mandated class of "ultra short-acting barbiturates"; (2) administering any drug

<sup>&</sup>lt;sup>9</sup> Miss, Code, Ann. § 99-19-51 states:

The manner of inflicting the punishment of death shall be by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice.

<sup>&</sup>lt;sup>10</sup> Rule 65(b) of the Federal Rules of Civil Procedure states: "The court may issue a temporary restraining order without written or oral notice to the adverse party or its attorney only if: . . . the movant's attorney certifies in writing any efforts made to give notice and the reasons why it should not be required."

that is not manufactured under the regulation of the Food and Drug Administration ("FDA"); (3) administering any drug that is produced by means of "non-traditional pharmacy compounding" as that term is used by the FDA; (4) administering any drug which has passed its expiration date; and (5) administering any chemical paralytic agent and any drug for stopping the heart, including but not limited to potassium chloride.

Plaintiffs urge this court to halt the execution of Jordan, and all future-planned executions that would be plagued by the same concerns here raised. Plaintiffs sub judice are not raising questions about their guilt, or even the trial rulings and procedures which led to their convictions. Plaintiffs instead focus their energies on the method of execution, whether this method is an unlawful deviation from § 99-19-51 of the Mississippi Code, and whether this method will occasion pain and suffering the law forbids.

Subsequent to the filling of the complaint, the defendants filed a motion to dismiss the complaint, arguing that this court does not have subject matter jurisdiction over this matter. On June 8, 2015, say the defendants, MDOC destroyed its entire supply of pentobarbital, which had expired on May 20, 2015. Defendants claim that MDOC has not been successful in its efforts to obtain a new supply of this drug. The defense argues that the unavailability of pentobarbital, the drug directly assailed here by plaintiffs, renders this case moot and unripe for adjudication. Because no live case or controversy exists here, as required by Article III of the United States Constitution 11, say the defendants, this court must dismiss this action.

<sup>&</sup>lt;sup>11</sup> United States Constitution Article III, § 2, Clause 1, states:

In support of their motion, defendants submitted to the court Commissioner Marshall Fisher's affidavit, wherein he avers, "MDOC has made numerous attempts to secure a new supply of pentobarbital from multiple sources. Defendants insist that all of MDOC's efforts to obtain a new supply of pentobarbital have been wholly unsuccessful." Doc. 25-1, Declaration of Commissioner Marshall Fisher at ¶ 8. Commissioner Fisher further states: "MDOC has been unable to obtain a new supply of pentobarbital, in any form whatsoever, for use in executions, and MDOC does not anticipate being able to obtain a new supply of pentobarbital, in any form whatsoever." *Id.* at ¶ 9.

On July 28, 2015, the day before the motion hearing held on these matters, defendants filed a notice informing the court that MDOC, on that same day, had amended its lethal injection protocol to include an anesthetic drug other than sodium thiopental or pentobarbital. This new protocol allows for the administration of 500 milligrams of midazolam as the first drug administered in the protocol.

Upon approving this new protocol, the State filed a motion with the Mississippi Supreme Court to re-set the execution of plaintiff Richard Jordan. The State hopes to execute Jordan with midazolam on August 27, 2015.

The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;—to all Cases affecting Ambassadors, other public Ministers and Consuls;—to all Cases of admiralty and maritime Jurisdiction;—to Controversies to which the United States shall be a Party;—to Controversies between two or more States;—between a State and Citizens of another State;—between Citizens of different States;—between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

### II. Discussion

Before addressing the arguments embedded in plaintiffs' motion for preliminary injunction, the court, first, must evaluate its basis for exercising subject matter jurisdiction over this action. The defense contends that jurisdiction does not exist here due to the allegedly moot and unripe nature of the claims alleged herein.

The court, however, is satisfied that it has subject matter jurisdiction over this litigation under Title 28 U.S.C. § 1331<sup>12</sup>, which provides federal district courts with subject matter jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." The court finds that a live controversy exists here because pentobarbital, which is still used by other states to execute inmates, continues to be an option for use by the State of Mississippi. Furthermore, plaintiffs challenge the use of midazolam in the three-drug protocol on similar bases as well. Defendants' Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction is, therefore, denied.

The court now addresses plaintiff's motion for temporary injunctive relief.

When considering a motion for injunctive relief, courts must study the pleadings and apply the standard enunciated in *Canal Auth. v. Callaway*, 489 F.2d 567 (5th Cir. 1974), and its progeny. As directed by these legion of cases, the court contemplates the following: whether the movants, plaintiffs Jordan and Chase, have shown a substantial likelihood of prevailing on the merits; whether the movants will suffer substantial and irreparable harm if their requested relief is not granted; whether a preliminary injunction would injure the defendant, here the State defendants; and whether an injunction would further the public interest.

<sup>&</sup>lt;sup>12</sup> Title 28 U.S.C. § 1331 states: "The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."

After reviewing the pleadings and the arguments presented to the court by the parties after the State's amendment to the protocol, the court finds that plaintiffs have satisfied their burden of persuasion here. First, the court finds that plaintiffs have shown a substantial likelihood in prevailing, at least, on their claim that Mississippi's failure to use a drug which qualifies as an "ultra short-acting barbiturate or other similar drug" as required by Miss. Code Ann. §99-19-51 violates Mississippi statutory law and the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution.

Moreover, the court finds that plaintiffs are threatened with substantial and irreparable harm here, especially considering that the State seeks to execute plaintiff Jordan on August 27, 2015. Third, the court agrees with plaintiffs that the threatened harm to the plaintiffs outweighs the same to the defendants. Lastly, the court is not persuaded that granting the preliminary injunction will disserve the interest of the public of Mississippi.

Therefore, plaintiffs' motion for temporary injunctive relief is granted. In granting plaintiffs' motion for temporary injunctive relief, this court is not forecasting any ultimate ruling on the merits. At this juncture, the court merely is persuaded to preserve the status quo until a final ruling is reached in this case. This order, in its abbreviated form, enjoins the State from using pentobarbital, specifically in its compounded form, or midazolam, from executing any death row inmate at this time. The court's full reasoning on this matter is forthcoming.

The court is unaware of any other method of execution that the State now contemplates, but should the State contemplate any other method of execution, the

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State first must submit said procedure to this court before executing with any other drug, or combination of drugs, any inmate.

SO ORDERED this 25th day of August, 2015.

/s/ Henry T. Wingate
UNITED STATES DISTRICT COURT JUDGE

## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI NORTHERN DIVISION

RICHARD JORDAN and RICKY CHASE,	) )
Plaintiffs,	
THOMAS EDWIN LODEN, Jr.,	) )
Intervenor,	) )
	)
ν,	) Civil Action No.
MARSHALL L. FISHER, Commissioner, Mississippi Department of Corrections, in his Official Capacity; EARNEST LEE, Superintendent, Mississippi State Penitentiary, in his Official Capacity; THE MISSISSIPPI STATE EXECUTIONER, in his Official Capacity; and UNKNOWN EXECUTIONERS, in their Official Capacities,	
Defendants.	) )

# FIRST AMENDED COMPLAINT

## NATURE OF ACTION

1. Plaintiffs<sup>1</sup> bring this action pursuant to 42 U.S.C. § 1983 for violations and threatened violations of their rights to due process and to be free from cruel and unusual punishment under the First, Eighth, and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14, 24, and 28 of the Mississippi Constitution.

<sup>&</sup>lt;sup>1</sup> In this First Amended Complaint, the term "Plaintiffs" will be used to refer collectively to named Plaintiffs Richard Jordan and Ricky Chase, as well as Intervenor Thomas Edwin Loden, Jr.



- 2. On July 28, 2015, Defendants gave notice to this Court of a change to the Mississippi Department of Corrections' lethal injection protocol. The July 2015 protocol now provides that in the event of the unavailability of a sufficient quantity of sodium thiopental or pentobarbital—the Department will substitute 500 milligrams of midazolam as the first drug in its three-drug series. No other changes were made to the protocol. The amended protocol continues to call for pentobarbital to be used as the first drug in the series when available.
- 3. Under the direction of the Defendants named herein, the Mississippi Department of Corrections ("MDOC") intends to execute Plaintiffs with compounded drugs that may be counterfeit, expired, contaminated, and/or sub-potent, creating a substantial risk of serious harm to the Plaintiffs. The decision of the Defendants to use compounded drugs, specifically a compounded anesthetic that has not been tested or approved by the United States Food and Drug Administration ("FDA") and the production of which was not under the supervision or regulation of the FDA, substantially risks that Plaintiffs may be conscious throughout their executions and will experience a torturous death by suffocation and cardiac arrest.
- 4. In the event compounded pentobarbital is unavailable to be used in Mississippi's lethal injection series, MDOC intends to execute Plaintiffs using midazolam as the first drug. Midazolam is a benzodiazepine, an entirely different class of drugs than barbiturates such as sodium thiopental or pentobarbital. Benzodiazepines are not pharmacologically equivalent to barbiturates. There is a substantial risk that midazolam will not render Plaintiffs sufficiently anesthetized and insensate to pain prior to the administration of the second and third drugs in the series, subjecting them to a torturous death by suffocation and cardiac arrest.
- 5. Further the Defendants intend to execute Plaintiffs using drugs which do not comply with the directive of the Mississippi legislature that death sentences be carried out by the

continuous intravenous administration of "an ultra short-acting barbiturate or other similar drug."

Neither compounded pentobarbital nor midazolam are ultra short-acting barbiturates or other similar drugs. Plaintiffs have a life and liberty interest in being punished only to the extent of the statutory authority conferred upon MDOC by the Mississippi legislature. The decision of the Defendants to execute Plaintiffs using a drug that is neither an ultra short-acting barbiturate nor other similar drug impermissibly violates the prescribed form and manner of punishment provided for by the Mississippi legislature, and thereby violates Plaintiffs' due process guarantees.

- 6. The entirety of the lethal injection protocol promulgated by MDOC is not at issue in this lawsuit. Rather, this civil action challenges the use of compounded drugs (including but not limited to compounded pentobarbital) and midazolam in lethal injection executions conducted by MDOC. Further this civil action specifically challenges the use of a three-drug lethal injection procedure. Lastly this civil action challenges MDOC's intent to have the raw ingredients for pentobarbital compounded into an injectable solution on the grounds of the Mississippi State Penitentiary at Parchman, where there is no pharmacy suitable for compounding sterile drugs.
- 7. The June 22, 2015 declaration of Defendant Commissioner Marshall Fisher asserts that the Department has destroyed all pentobarbital sodium in its possession, and that the Department has been unable to obtain a new supply of pentobarbital in any form. However, the Department's current protocol still provides for the use of pentobarbital in the event of the unavailability of sodium thiopental. Midazolam is only to be substituted as the first drug in the event of the unavailability of pentobarbital.
- 8. Other state departments of corrections have obtained and used compounded pentobarbital in 18 executions this year to date. In just the last week of September 2015, the Texas

Department of Criminal Justice provided three (3) vials of compounded pentobarbital to its counterpart in Virginia to be used in a scheduled execution.

- 9. Furthermore, while Commissioner Fisher declares that all pentobarbital in the custody of the Department has been destroyed, counsel for Plaintiffs have sought records as to the disposition of five (5) vials (of the 14 total vials) of pentobarbital sodium purchased by the Department in 2012. Defendants have failed to account for the whereabouts of these vials.
- 10. For the reasons set forth in ¶¶ 7 through 9, the allegations and causes of action pled herein with reference to compounded pentobarbital are not moot.
- 11. MDOC first ordered compounded drugs for purposes of lethal injection executions on May 20, 2012. That purchase instituted a policy, practice, or custom of using compounded drugs in MDOC executions.
- 12. MDOC first provided for the use of midazolam in lethal injections (in the event of the unavailability of pentobarbital) when it filed notice with this Court of an amendment to its protocol on July 28, 2015. That notice of amended protocol instituted a policy, practice, or custom of using midazolam in MDOC executions.
- 13. Plaintiffs seek permanent injunctive relief to prevent the Defendants from inflicting cruel and unusual punishment upon them during their executions, and from otherwise violating Plaintiffs' federal and state constitutional rights.
- 14. Plaintiffs also seek a preliminary injunction against the use of midazolam and compounded pentobarbital in their executions. This Court issued preliminary injunctive relief on August 26, 2015, preserving the status quo pending final adjudication of this civil action. Defendants have sought expedited appeal of this Court's ruling.

#### JURISDICTION AND VENUE

- 15. Plaintiffs' claims arise under the Constitution and laws of the United States, as well as under the Constitution of the State of Mississippi. This Court has original federal question jurisdiction over those claims arising under the Constitution and laws of the United States pursuant to 28 U.S.C. §§ 1331, 1343.
- 16. This Court has the authority to grant declaratory and injunctive relief under 28 U.S.C. § 2201-2202 and FED.R.CIV.P. 57 and 65. The federal rights asserted by Plaintiffs are enforceable under 42 U.S.C. § 1983.
- 17. Venue is proper in the Southern District of Mississippi under 28 U.S.C. §§ 1391(b)(1) and 1391(c)(2). With respect to Section 1391(b)(1), Defendant Marshall Fisher, Commissioner, Mississippi Department of Corrections, in His Official Capacity, is located in Jackson, Hinds County, Mississippi. With respect to Section 1391(c)(2), all Defendants in this action shall be served with process by service on the Attorney General of Mississippi in Jackson, Hinds County, Mississippi, pursuant to Miss.R.Civ.P. 4(D)(5), incorporated through Fed.R.Civ.P. 4(e)(1).

#### **PARTIES**

- 18. Plaintiff Richard Jordan is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Richard Jordan filed for relief under the MDOC Administrative Remedy Program on October 15, 2014. The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on October 23, 2014.
- 19. Plaintiff Ricky Chase is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Ricky Chase filed for

relief under the MDOC Administrative Remedy Program on October 26, 2014 (received October 29, 2014). The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on October 30, 2014.

- 20. Intervenor Thomas Edwin Loden, Jr. is a United States citizen, currently incarcerated under a sentence of death at the Mississippi State Penitentiary in Parchman, MS. Thomas Loden filed for relief under the MDOC Administrative Remedy Program on December 15, 2014. The request for relief gave MDOC notice and an opportunity to resolve the issues set forth in this Complaint. MDOC rejected the request for relief on January 1, 2015.
- 21. Defendant Marshall L. Fisher is the Commissioner of the Mississippi Department of Corrections.
- 22. The MDOC is the state agency charged with the incarceration, care, custody, and treatment of all state prisoners, including prisoners sentenced to death. Miss. Code Ann. §§ 47-5-10(a); 47-5-23.
- 23. Commissioner Fisher is the chief executive, administrative, and fiscal officer of MDOC, establishes the general policy of MDOC, and oversees the administration of all affairs within MDOC. Miss. Code Ann. §§ 47-5-20(a); 47-5-23; 47-5-24(1).
- 24. As the Commissioner of the MDOC, Mr. Fisher must perform "[a]Il duties and necessary acts pertaining to the execution of a convict . . . except where such duties and actions are vested in the state executioner." Miss. Code Ann. § 99-19-13. See also Miss. Code Ann. § 99-19-55.
- 25. Commissioner Fisher is responsible for ensuring that all prisoners committed to the custody of MDOC are treated in accordance with the United States and Mississippi Constitutions.

- 26. At all relevant times, Commissioner Fisher has been acting under the color of law and as the agent and official representative of MDOC, pursuant to MDOC's official policies and procedures. Commissioner Fisher is sued in his official capacity only.
- 27. Defendant Earnest Lee is the Superintendent of the Mississippi State Penitentiary in Parchman, MS, the prison that houses all male death row inmates, and the prison where all executions take place in the State of Mississippi, Miss. Code Ann. § 99-19-55(1).
- 28. Superintendent Lee is responsible for implementing MDOC's policies and procedures governing executions, managing the preparations for an execution, and for turning over the execution site to the State Executioner to perform the execution.
- 29. Superintendent Lee is also responsible for protecting the constitutional rights of all persons incarcerated at the Mississippi State Penitentiary in Parchman, and/or transported to Parchman for an execution.
- 30. At all relevant times, Superintendent Lee has been acting under color of law and as the agent and official representative of the Mississippi State Penitentiary and MDOC. He is sued in his official capacity only.
- 31. The State Executioner of the State of Mississippi is appointed by the Governor and shall supervise and inflict the punishment of death pursuant to Miss. Code Ann. § 99-19-53. The name of the State Executioner is withheld from the public by the State of Mississippi.
- 32. The names of Defendants Unknown Executioners are unknown to Plaintiffs, but they include the State Executioner, his or her designee, and members of the State Execution Team. On information and belief, the Unknown Executioners will participate in the process of the execution by virtue of their roles in designing, implementing, carrying out, and/or

supervising the lethal injection process, including the procurement and storage of lethal injection drugs and materials. Miss. Code Ann. § 99-19-53, 99-19-55(2).

33. At all relevant times, Defendants State Executioner and Unknown Executioners have been acting under the color of law. There are sued in their official capacities only.

#### RELEVANT PROCEDURAL BACKGROUND

- 34. Plaintiffs filed their original complaint on April 16, 2015 (Doc. 1). Defendants filed their answer on May 28, 2015 (Doc. 19).
- 35. Plaintiffs moved for preliminary injunction on June 3, 2015 (Doc. 21). Defendants moved to dismiss on June 22, 2015 (Doc. 22), arguing that Plaintiffs claims were simultaneously most and unripe as the Department had recently destroyed its supply of pentobarbital sodium active pharmaceutical ingredients ("API"), and the Department had been unsuccessful at obtaining any new supply of pentobarbital.
  - 36. Argument on these motions was scheduled for July 29, 2015 at 9:30 a.m.
- 37. On July 28, 2015, at 6:38 p.m., Defendants filed notice of an amended execution protocol (Doc. 38). The amended protocol (Doc. 38-2) provides for the use of midazolam as the first drug in the three-drug series in "the event of the unavailability of a sufficient quantity of Pentobarbital."
- 38. Following continued argument on July 31, 2015, this Court denied Defendants' motion to dismiss, and granted Plaintiffs' motion for preliminary injunction (Doc. 42).

#### **FACTUAL ALLEGATIONS**

## A. MISSISSIPPI'S THREE-DRUG LETHAL INJECTION PROTOCOL

39. In Mississippi, the manner of execution for individuals sentenced to death is "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or

other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

- 40. MDOC's lethal injection protocol calls for the serial administration of three drugs to put a prisoner to death.
- 41. The first drug, pentobarbital,<sup>2</sup> a short-acting or intermediate-acting barbiturate, is intended to sufficiently anesthetize the prisoner so that he is both unconscious and insensate when the executioner injects the second and third drugs, vecuronium bromide<sup>3</sup> and potassium chloride, respectively.<sup>4</sup>
- 42. In the event of the unavailability of pentobarbital, the July 2015 protocol now calls for the use of midazolam, a drug in the benzodiazepine class such as Valium, Xanax, or Klonopin, as the first drug.
- 43. Pentobarbital is not "an ultra short-acting barbiturate or other similar drug" as required by Mississippi law.
- 44. Midazolam is not "an ultra short-acting barbiturate or other similar drug" as required by Mississippi law.

<sup>&</sup>lt;sup>2</sup> MDOC's current protocol, promulgated July 28, 2015, calls for the use of Sodium Pentothal as the first drug in the series, but provides for the use of pentobarbital "[i]n the event of an unavailability of a sufficient quantity of sodium pentothal from available sources." As discussed *infra*, Sodium Pentothal is no longer available to MDOC. Sodium Pentothal is the trademarked name for sodium thiopental. The MDOC's execution protocols have never expressly authorized or referenced the use of compounded drugs in executions. "In the event of the unavailability of a sufficient quantity of Pentobarbital from available sources," the recently amended protocol now provides for the use of midazolam as the first drug in the series.

<sup>&</sup>lt;sup>3</sup> The July 2015 protocol calls for the use of pavulon as the second drug in the series, but provides for the use of vecuronium bromide "[i]n the event of unavailability of a sufficient quantity of pavulon from available sources."

<sup>&</sup>lt;sup>4</sup> MDOC purchased its current supply of vecuronium bromide in July 2014. The supply of vecuronium bromide will expire on October 1, 2015. MDOC purchased a supply of potassium chloride in October 2014. That supply of potassium chloride expired on September 1, 2015. MDOC has not indicated whether this expired supply has been destroyed and whether it has purchased any new supplies of vecuronium bromide or potassium chloride.

- 45. The second drug, vecuronium bromide, is a neuromuscular blocking agent that paralyzes all of the prisoner's voluntary muscles, including the muscles used for respiration, but does not suppress sensation, consciousness, cognition, or the ability to feel pain and suffocation. It is used by MDOC to be the "chemical paralytic agent."
- 46. There is no legitimate penological justification for the use of a neuromuscular blocking agent or other chemical paralytic agent in an execution by lethal injection.
- 47. Neuromuscular blocking agents are not necessary to produce death, and do not diminish the prisoner's awareness or ability to feel pain.
- 48. One hundred (100) executions have been accomplished in other jurisdictions in the United States without the use of a neuromuscular blocking agent or other chemical paralytic agent. In each of these executions, the prisoner died.
- 49. The only purpose of the neuromuscular blocking agent in Mississippi's lethal injection protocol is to mask the gasping and physical convulsions produced by injection of the final drug, potassium chloride.
- 50. The neuromuscular blocking agent is thus used to make the execution appear serene and peaceful where the State may have in fact failed to sufficiently anesthetize the prisoner against pain and suffering.
- 51. The third and final drug in Mississippi's lethal injection protocol is potassium chloride a chemical that disrupts the electrical signals in the heart, paralyzes the cardiac muscle, and kills the prisoner by cardiac arrest.
- 52. Provided that a lethal dose of a barbiturate is administered, there is no legitimate penological justification for the use of potassium chloride in an execution by lethal injection.

- 53. One hundred (100) executions have been accomplished in other jurisdictions in the United States without the use of potassium chloride. In each of these executions, the prisoner died.
- 54. Midazolam is not in the barbiturate class of drugs, and has never been used by any jurisdiction in a single-drug execution protocol, unlike sodium thiopental and pentobarbital.<sup>5</sup> Benzodiazepines are not pharmacologically equivalent to barbiturates.
- Where there is a substantial risk that the first drug injected in a three-drug series will not be administered correctly, will not be sufficiently potent, pure, and rapid in onset, and is not chemically capable of rendering the prisoner unconscious and insensate so he does not feel the painful effects of the second and third drugs, the execution will cause severe, torturous pain for the prisoner, in violation of the Eighth and Fourteenth Amendments.

## B. KNOWN RISKS OF THE DRUGS USED IN MISSISSIPPI'S LETHAL INJECTION PROTOCOL

- 56. The drugs used in Mississippi's lethal injection protocol have known and documented risks about which the Defendants are, or should be, aware.
- 57. The first risk is associated with the administration of vecuronium broinide, the drug currently stockpiled by MDOC to serve as the paralytic agent required by the Mississippi statute and protocol.
- 58. Vecuronium bromide causes the paralysis of all voluntary muscles, including the lungs and diaphragm.

<sup>&</sup>lt;sup>5</sup> Only two states have experimented with the use of midazolam as the first drug in a two-drug lethal injection series (to be followed by hydromorphone, an opioid). These experiments produced grisly results. On January 2014, Dennis McGuire's execution in Ohio (using a two-drug injection of midazolam and hydromorphone) took twenty-six (26) minutes. Mr. McGuire appeared to gasp for air and gag throughout the execution. The same protocol (midazolam and hydromorphone) was later used in Arizona's execution of Joseph Wood in July 2014, with even more troubling results. Mr. Wood gasped and gulped in the death chamber as prison officials injected 15 doses of lethal injection chemicals into his body for nearly two (2) hours before he was pronounced dead. While Oklahoma and Ohio previously provided for the use of midazolam in a two-drug series, those states have since amended their protocols to eliminate this option.

- 59. If vecuronium bromide is administered to a prisoner who is still conscious and able to feel pain, he will suffocate to death while experiencing the agonizing and conscious urge to breath.
- 60. Thus, if a prisoner is injected with the paralytic agent vecuronium bromide before he is fully anesthetized and before he is rendered insensate, he will experience conscious paralysis and suffocation.
- 61. However, because the prisoner is completely paralyzed and unable to talk, move, or make facial expressions as a result of being paralyzed, his agony will be completely masked and concealed to observers.
- 62. The second known risk associated with the drugs used in the Mississippi lethal injection protocol is associated with the third and final drug in the series, potassium chloride.
- 63. There is no medical dispute that the injection of potassium chloride into an individual who has not been adequately anesthetized will cause excruciating pain.
- 64. Potassium chloride induces an intense burning sensation throughout the blood vessel walls running through a prisoner's body. If a prisoner is not fully anesthetized prior to the injection of potassium chloride, then he will consciously experience the agony of cardiac arrest.
- 65. The two risks set forth in ¶¶ 57 to 64 above create a substantial risk of severe pain and serious harm, particularly where MDOC will not be administering an FDA-approved, 6 ultra short-acting barbiturate in sufficient dosage and potency to ensure that the prisoner is completely anesthetized prior to the injection of the paralytic agent and of potassium chloride.

<sup>&</sup>lt;sup>6</sup> As used in this Complaint, the term "FDA-approved" includes both the drug itself (i.e. that the drug's formula is approved for distribution to consumers) and the process for manufacturing the drug. An "FDA-approved" drug thus refers to the specific batch or supply of a medication after manufacture.

- 66. There is no penological justification for the use of a paralytic agent and potassium chloride in an execution by lethal injection. Executions may be carried out through the use of a single-drug anesthetic-only injection, a protocol now used in most executions nationwide and which has proven effective in executing over one hundred (100) prisoners to date.
- 67. An execution conducted by MDOC which continues to use a three-drug protocol, thereby refusing to adopt the feasible and readily implemented alternative of a single-drug protocol (which significantly reduces the substantial risks of severe pain and serious harm posed by the use of a chemical paralytic agent and potassium chloride), violates the Eighth Amendment.
  - C. RECENT HISTORY OF LETHAL INJECTION EXECUTIONS IN OTHER STATES DEMONSTRATES THE SEVERITY OF THE RISK OF EXTREME PAIN AND TORTURE WHERE THE POTENCY AND DOSAGE OF THE ANESTHETIC ARE INSUFFICIENT
- 68. Reflecting their revulsion against the use of their medications to execute prisoners in the United States, many pharmaceutical manufacturers have ceased production of drugs commonly used in American executions, have refused to sell them to corrections departments that may use them in executions, or have conditioned the sale of such drugs on "end-user agreements" which forbid the resale or use of the drugs for purposes of lethal injection executions.
- 69. In March 2015, the American Pharmacists Association, the largest association of pharmacists in the United States, voted to adopt a policy which discourages "pharmacist participation in executions on the basis that such activities are fundamentally contrary to the role of pharmacists as providers of health care." Just a week prior to this announcement, the top trade group representing compounding pharmacists in the United States, the International Academy of Compounding Pharmacists, similarly "discourag[ed] its members from participating in the preparation, dispensing, or distribution of compounded medications for use in legally authorized executions."

#### Sodium Thiopental

- 70. Hospira, Inc., the American manufacturer of the anesthetic sodium thiopental, stopped making sodium thiopental in 2011, after the drug's use in executions interfered with Hospira's ability to enter into manufacturing contracts in Europe. Hospira elected to stop making the drug entirely because it could not prevent the drug from getting into the hands of departments of corrections. Although sodium thiopental is manufactured in other countries, the FDA has not approved its importation into the United States.
- 71. Some states including Georgia resorted to violating federal law in order to procure sodium thiopental. Georgia illegally imported the drug from an English pharmaceutical distributor that operated out of the back of a driving school in London.
- 72. In May of 2011, the United States Drug Enforcement Agency ("DEA") seized the illegal sodium thiopental from the Georgia Department of Corrections; however Georgia had already executed two individuals with the illegal substance.
- 73. The compromised drug used in these Georgia executions failed to perform its necessary function of rendering the prisoners unconscious and insensate, causing the two prisoners to experience significant and unnecessary pain and suffering.
- 74. Thus, when Brandon Rhode was executed in September 2010 with the illegally-imported sodium thiopental, his eyes remained open for the entirety of his execution, indicating consciousness during the process.

<sup>&</sup>lt;sup>7</sup> In May 2015, the governor of Nebraska announced the state's purchase of sodium thiopental from a broker in India, despite statements from the FDA that it is unlawful for Nebraska to import the drug and that the FDA would refuse the drug's admission into the United States.

- 75. Similarly, when Emmanuel Hammond was executed in January 2011 with the illegally-imported sodium thiopental, his eyes also remained open, and he grimaced and appeared to be trying to communicate throughout his execution.
- 76. Mississippi's lethal injection protocol calls for the use of Sodium Pentethal (a trademarked name for sodium thiopental) as the first drug in its series (except in the event of the unavailability of a sufficient quantity of the drug).
- 77. The last execution in Mississippi using Sodium Pentothal as the anesthetic drug given first in the three-drug series was on July 21, 2010. Since that time Mississippi has been unable to legally obtain Sodium Pentothal for use in executions.

## Nembutal: Pentobarbital Sodium Manufactured by Lundbeck

- 78. Where Sodium Pentothal is unavailable for use as the first drug in the series, the Mississippi execution protocol allows the administration of pentobarbital in its place.
- 79. There is only one manufacturer of FDA-approved injectable pentobarbital sodium, sold under the name-brand Nembutal.
- 80. In July 2011, Lundbeck, the manufacturer of Nembutal, announced that it would no longer sell the drug to departments of corrections, and required purchasers of its drug to enter into end-user agreements by which they agreed not to sell or transfer the drugs to prisons in states that still use capital punishment.
- 81. In December 2011, Lundbeck sold the rights to Nembutal to Akom, Inc. and, as part of the agreement, Akorn agreed to maintain the restricted distribution program.
- 82. Any Nembutal sold prior to the July 2011 agreement would have expired no later than November 2013.
  - 83. The last time MDOC purchased Nembutal was on March 23, 2011.
  - 84. Any unused drugs from MDOC's purchase of Nembutal have expired.

- 85. By the March 23, 2011 transaction, MDOC purchased 12 units of Nembutal (50 mg/mL). It is unclear from the receiving report disclosed by MDOC what total volume of Nembutal was purchased.
- 86. The supply of Nembutal obtained by MDOC in March 2011 was utilized by MDOC in executions conducted in May 2011, and in executions conducted between February and June 2012.8
  - 87. The State of Mississippi has not executed any prisoner since June 20, 2012.
- 88. Mississippi no longer has any legally-obtained, FDA-approved, and unexpired pentobarbital to use in executions.

## Experimentation with Anesthetics Previously Not Used in Executions

- 89. Due to this nation-wide shortage of FDA-approved sodium thiopental and pentobarbital for use in executions, some states (including Florida, Ohio, Arizona, and Oklahoma) have executed prisoners with drugs never previously used for lethal injection.
- 90. In Florida, Ohio, and Arizona executions using these experimental drugs caused the prisoners to remain conscious for an unacceptable length of time.
- 91. Since October 2013, Florida has executed prisoners using a three-drug protocol featuring midazolam hydrochloride, a paralytic agent, and potassium chloride. William Happ's execution in Florida the first using this new series took twice the amount of time as prior executions, and he continued to make body movements after he was injected with an untested drug, midazolam hydrochloride.

<sup>&</sup>lt;sup>8</sup> As discussed *infra*, MDOC did not purchase any additional legally-obtained, FDA-approved, and unexpired pentobarbital after March 2011. Rather in May 2012, MDOC purchased the active pharmaceutical ingredients to compound pentobarbital. This supply was not received by MDOC until June 13, 2012, according to receiving reports disclosed by MDOC. The State of Mississippi has only conducted one execution – that of Gary Simmons on June 20, 2012 – since this date of receipt. MDOC utilized Nembutal still in its possession from the March 2011 purchase in the execution of Mr. Simmons, MDOC has never used pentobarbital sodium API in any execution in the state.

- 92. In January 2014, Dennis McGuire's execution in Ohio (using a two-drug injection of midazolam and hydromorphone) took twenty-six (26) minutes, and he gasped for air and gagged throughout the execution.
- 93. The same protocol (midazolam and hydromorphone) was later used in Arizona's execution of Joseph Wood in July 2014, with even more troubling results. Mr. Wood gasped and gulped in the death chamber as prison officials injected 15 doses of lethal injection chemicals into his body for nearly two (2) hours before he was pronounced dead.
- 94. A three-drug protocol featuring midazolam hydrochloride was subsequently tried by Oklahoma in April 2014 with torturous results in the botched execution of Clayton Lockett. Mr. Lockett was observed writhing on the execution table and attempting to speak, even after having been declared unconscious.
- 95. An investigation following Mr. Lockett's execution discovered numerous failures, from the placement of the IV to the lack of procedural safeguards which would have detected or deterred serious problems in the administration of the drugs. The Oklahoma Department of Corrections has since revised its protocol extensively, seeking to address the problems highlighted by Mr. Lockett's execution. It is this revised protocol which is the subject of litigation in the federal courts in the *Glossip* challenge to Oklahoma's method of execution.

## Experimentation with Compounded Drugs

- 96. Some states have responded to the unavailability of Nembutal by turning to the "gray market" of unregulated compounded drugs and unregulated active pharmaceutical ingredients to obtain compounded pentobarbital for use in executions.
- 97. This type of pharmacy compounding is a deviation from the traditional practice of pharmacy compounding, which involved the mixing of small batches of drugs in response to a

physician's prescription to meet the unique needs of an individual patient when an FDA-approved drug is not suitable for the patient.

- 98. Compounded drugs are not FDA-approved and have not been evaluated for effectiveness and safety. Until recently, the FDA did not regulate compounded drugs and compounding pharmacies at all, and even now, the FDA does not have regulatory authority over all compounding pharmacies.
- 99. Compounded drugs are created without producing the data on safety and efficacy that the FDA requires for new drugs, and without the requirement that they follow good manufacturing practice regulations which insure their identity, strength, quality and purity. Thus the FDA has noted "quality problems with various compounded drugs, including sub-potency, super-potency, and contamination."
- 100. State regulation of compounding pharmacies varies substantially, but no state regulates compounding pharmacies in a manner that would replicate the FDA's regulation of pharmaceutical manufacturers. Without unified standards and regulations there is no way to guarantee that drugs from a compounding pharmacy are what they purport to be and are safe and effective.
- 101. In recent years, a substandard compounding drug industry has emerged wherein compounding pharmacies create and market copies of FDA-approved drugs for general distribution. These drugs are developed and sold without the testing required by the FDA to ensure that the drugs are potent, pure, safe, and effective.
- 102. Additionally, there is a significant risk that compounded drugs are manufactured with counterfeit or substandard ingredients purchased from a range of manufacturers that operate outside of FDA supervision and regulation.

- 103. For these reasons, among others, the FDA has called the proliferation of compounded drugs a "troubling trend" because it has resulted in individuals taking harmful, contaminated, counterfeit, sub-potent, and/or super-potent drugs.
- 104. This is not a speculative risk. The 2012 outbreak of fungal meningitis caused by contaminated steroid injections from a compounding pharmacy in New England drew national attention to the regulatory vacuum within which compounding pharmacies operate, and the substandard and harmful products that these pharmacies can market to the public. Two senior executives of the New England pharmacy have since been indicted on charges of racketeering and murder. The compounded drugs responsible for the meningitis outbreak had been "tested" and found potent by a laboratory purporting to be "independent."
- 105. Further, Oklahoma executed Michael Lee Wilson with compounded pentobarbital on January 9, 2014. After Mr. Wilson spoke his final words, and after the executioner administered the first drug, Mr. Wilson spoke again and stated: "I feel my whole body burning."
- 106. The burning sensation relayed by Mr. Wilson during his execution is consistent with an excruciatingly painful reaction to the injection of contaminated pentobarbital.

# D. MISSISSIPPI'S DECISION TO USE COMPOUNDED DRUGS IN LETHAL INJECTION EXECUTIONS

- 107. Because MDOC can no longer obtain the FDA-approved form of pentobarbital, the Defendants, jointly and/or severally, obtained pentobarbital sodium API for use in lethal injections from a compounding pharmacy in Grenada, Mississippi that otherwise markets its expertise in herbal supplements.
- 108. On or around May 20, 2012, MDOC purchased \$3,150 worth of pentobarbital sodium from H&W Compounding Pharmacy d/b/a Brister Brothers ("Brister Brothers"), a compounding pharmacy in Grenada, MS. According to a receiving report disclosed by MDOC,

this supply was received by the Department on June 13, 2012. Brister Brothers purchased the pentobarbital sodium API from Professional Compounding Centers of America, Inc. ("PCCA"), in Houston, Texas.

- 109. Defendants did not purchase Nembutal or another sterile, injectable pentobarbital from Brister Brothers on or around May 20, 2012 or at any time thereafter.
- 110. Specifically Defendants purchased 70 grams of raw materials or active pharmaceutical ingredients from Brister Brothers. These 70 grams were packaged as 14 vials containing 5 grams each.
- 111. Of the 14 vials purchased in May 2012, MDOC has provided documentation that nine (9) vials were destroyed in June 2015, once the pentobarbital sodium API had passed its expiration date.
- 112. MDOC has not accounted for the disposition of the other five (5) vials of pentobarbital sodium API (containing 25 grams total) purchased in May 2012. Therefore, according to the documentation provided to Plaintiffs' counsel by MDOC, these drugs remain in the Department's possession.
- 113. If MDOC does not, in fact, possess the unaccounted for vials of pentobarbital sodium API, then, on information and belief, these vials have been transferred and/or sold by MDOC to departments of corrections in other jurisdictions.
  - 114. Defendants have not purchased any pentobarbital sodium API since May 20, 2012.

<sup>&</sup>lt;sup>9</sup> MDOC also purchased vecuronium bromide and potassium chloride from the Brister Brothers pharmacy but this supply expired in 2014 and has since been destroyed. MDOC has subsequently purchased new supplies of vecuronium bromide and potassium chloride (reported to expire in fall 2015). MDOC refuses to disclose the provider of its current supply of vecuronium bromide and potassium chloride. This failure to disclose the identity of lethal injection drug suppliers is the subject of ongoing litigation between the MacArthur Justice Center and MDOC under the Mississippi Public Records Act. A chancery court has ordered the disclosure of the identity of the drug supplier but MDOC has appealed this ruling to the Mississippi Supreme Court.

- 115. The pentobarbital sodium API which Defendants purchased from Brister Brothers were not compounded prior to the shipment from Brister Brothers to the grounds of the Mississippi State Penitentiary at Parchman. Any pentobarbital sodium API purchased by Defendants will have to be compounded before its use in any execution in Mississippi.
- 116. According to the records of the Mississippi State Board of Pharmacy, there is no registered or licensed pharmacy at the Medical/Dental Facility at Parchman (Mississippi State Department of Health License No. 11-317). Drugs administered to prisoners are kept in the Drug Room at the Medical/Dental Facility at Parchman.
- 117. Until May 2015, drugs used for lethal injection were not kept in the Drug Room, but at Unit 17, the building where death-sentenced prisoners were once incarcerated, and which is now used exclusively to house a condemned prisoner the days before his scheduled execution and to house the death chamber where he will be executed.
  - 118. MDOC has never used pentobarbital sodium API in an execution.
- 119. Defendants have never compounded raw pentobarbital into a sterile injection. There is no public record of MDOC sending pentobarbital sodium API to a compounding pharmacy to prepare an injectable form of pentobarbital for use in an execution. Additionally, an affidavit executed by Special Assistant Attorney General Jim Norris on March 10, 2014 describes the pentobarbital sodium purchased in May 2012 as being in a "powder" form.
- 120. Upon information and belief, Defendants intend to compound pentobarbital on the grounds of the Mississippi State Penitentiary at Parchman; or in the alternative, Defendants intend to send pentobarbital sodium API to a yet undisclosed location to prepare the drug for an execution.
- 121. If Mississippi proceeds with their executions, Plaintiffs will be among the first prisoners in Mississippi to be executed with compound pentobarbital.

# E. CONSTITUTIONAL, PHARMACEUTICAL, AND MEDICAL RISKS PRESENTED BY DEFENDANTS' USE OF COMPOUNDED PENTOBARBITAL

- 122. Where Mississippi intends to use a three-drug series in its executions, there is a substantial risk that the first drug administered (whether it be compounded pentobarbital or midazolam) will fail to render the prisoner unconscious and insensate prior to the administration of the second and third drugs, resulting in a painful and torturous death.
- 123. When compounded pentobarbital is used as the first drug in a three-drug series, risks are introduced to the execution procedure which serve no valid penological purpose. Compounded drugs are not FDA-approved, so they carry no guarantees of the identity, purity, or potency of the drug.
- 124. Compounding pharmacies such as Brister Brothers generally do not have the facilities to test chemicals for identity, potency, purity, and contamination.
- 125. It is not possible for the testing of API to eliminate the risks posed by impurities, contaminants, particulate matter, and/or an improper pH balance. Testing only provides a very provisional indication of an API's suitability for compounding given the unknowns about the chemical's integrity, storage, and custody in the timeframe from testing to pharmacy compounding and use.
- 126. Testing of non-sterile API by laboratories contracting with a distributor has proven unreliable. Poorly regulated, if regulated at all, contract-testing laboratories are supposed to test compounded drugs for safety and effectiveness. Too often, however, these laboratories are themselves substandard, and many are established to serve the financial interests of the pharmacies for which they are doing the testing. Five laboratories that test compounded drugs have had enforcement actions taken against them by the FDA.

- 127. Where the compounded pentobarbital is in any way sub-optimal, it poses a substantial risk of serious harm to the condemned prisoner either by inflicting pain and suffering itself or by failing to adequately anesthetize the prisoner, who then would experience conscious paralysis and the pain of potassium chloride, followed by cardiac arrest.
- 128. Moreover, each injection of compounded pentobarbital used in executions in Mississippi will be a new product, so the effectiveness of one dose does not demonstrate the effectiveness of the next.

## The Department's Lack of Safeguards to Insure the Integrity of Active Pharmaceutical Materials Held for Use in Executions

- 129. MDOC's lethal injection protocol does not include any means for verifying the integrity of the MDOC's supply of active pharmaceutical ingredients. There is a substantial risk that such raw ingredients are counterfeit, contaminated, or substandard.
- 130. The Defendants have not revealed the source of the active pharmaceutical ingredients that were purchased in 2012 for compounding pentobarbital.
- 131. PCCA's source for the pentobarbital sodium API purchased by MDOC in 2012 is not a matter of public record and is unknown to Plaintiffs.
- 132. Defendants themselves do not know the source of the pentobarbital sodium API sold by PCCA to Brister Brothers, and from Brister Brothers to MDOC.
- 133. PCCA expressly disclaimed any warranties in its sale of pentobarbital sodium API to Brister Brothers in 2012.

## The Questionable Process for the Compounding of Mississippi's Execution Drugs

134. The Defendants refusal to disclose critical facts surrounding the compounding process separately creates a substantial risk of serious harm to Plaintiffs.

- 135. In order to properly and safely compound the raw ingredients for pentobarbital into a sterile injectable, the compounding must be done in a sterile compounding laboratory with very specific and sophisticated physical requirements.
- 136. Under State law, a pharmacy or medical facility must be registered with the Mississippi State Board of Pharmacy in order to manufacture pentobarbital or another controlled substance. The pharmacy or facility cannot manufacture any controlled substance not authorized by its registration. Miss. Code Ann. §41-29-125, 41-29-141(2). Manufacture, in this context, includes compounding. Miss. Code Ann. §41-29-105(q).
- 137. As stated above, the State Board of Pharmacy does not list the Medical/Dental Facility at Parchman as a facility with a licensed pharmacy. The State Board of Pharmacy does not list the Medical/Dental Facility at Parchman as a facility registered to compound controlled substances.
- 138. There are a limited number of compounding laboratories in Mississippi, and MDOC has not revealed to Plaintiffs where or how they intend to compound pentobarbital sodium API into a sterile injectable solution.
- 139. The compounding of pentobarbital or any other drug on the grounds of the Mississippi State Penitentiary creates substantial risks that a drug so manufactured may be contaminated during compounding, and/or the compounding process may be flawed, resulting in the production of a sub-potent and ineffective drug.

#### The Risk That the Pentobarbital Is Degraded or Expired

140. The expiration dates for FDA-approved drugs are based on rigorous testing in a controlled and regulated environment. The same testing is not performed on compounded drugs,

resulting in an unacceptable risk that the drug may be degraded and sub-potent by the time it is used, and unable to perform its designated anesthetic function.

- 141. According to the March 10, 2014 affidavit of MDOC attorney Jim Norris and records from PCCA, the batch of pentobarbital sodium API purchased by MDOC in May 2012 has an expiration date of May 20, 2015. Defendants have provided documentation as to the destruction of nine (9) vials of the API in June 2015. However Defendants have failed to account for the disposition of the other five (5) vials purchased in May 2012. These vials of pentobarbital sodium API have now passed their expiration date.
- 142. Even a small level of contamination or small deviation in the preparation process will, over time, lead to increasing deterioration of the quality of the batch. A small problem with the initial preparation may well have progressed, over time, into a severe problem that will cause an anomaly or botch. Any contamination, sub-potency, or super-potency in the original preparation may be enhanced as the batch ages closer to and past its expiration date.
- 143. Other records provided by MDOC indicate that the vecuronium bromide possessed by the Defendants will expire on October 1, 2015, and the potassium chloride possessed by the Defendants expired on September 1, 2015.

#### The Risk of Counterfeit API

- 144. One of the purposes of FDA regulation is to ensure that the drugs and narcotics used by Americans are true and genuine. The risk of counterfeit or "watered-down" drugs is a substantial part of the FDA's justification for prohibiting Americans from purchasing narcotics and drugs from foreign pharmacies or sources.
- 145. Because Defendants have not procured drugs for lethal injections from an FDA-approved source, there is a risk that the materials which Defendants claim to be pentobarbital,

vecuronium bromide, and potassium chloride are, in fact, nothing of the sort. The materials in Defendants' possession may be "watered-down" or wholly counterfeit.

#### Compounded Pentobarbital Is Not an Ultra Short-Acting Barbiturate or Other Similar Drug

- 146. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.
- 147. Unable to obtain Sodium Pentothal or Nembutal, MDOC purchased pentobarbital sodium API to be compounded into an injectable solution to be used as the first drug in the three-drug series.
- 148. Compounded pentobarbital is not an ultra short-acting barbiturate like Sodium Pentothal. Rather pentobarbital is classified as a short- or intermediate-acting barbiturate.
- 149. This classification system refers to the rate of onset and length of duration for a given class of barbiturates. Those barbiturates classified as ultra short-acting have the fastest rate of onset, producing their anesthetic effect more quickly than all other classes of barbiturates. By contrast, short- or intermediate-acting barbiturates have a slower rate of onset than those barbiturates classified as ultra short-acting, taking longer to produce any anesthetic effect upon injection.
- 150. As there is substantial risk that compounded pentobarbital may be sub-potent, the onset rate of compounded pentobarbital would be even slower than that of FDA-approved pentobarbital.

- barbiturate is planned for use as the first drug in three-drug protocol for execution by lethal injection. Where the first drug does not act swiftly and effectively to anesthetize the prisoner such that he is both unconscious and insensate *before* the executioner injects the second and third drugs, there is a substantial risk of severe pain and suffering.
- 152. It was with this understanding in mind that the Mississippi legislature specifically directed the use of an ultra short-acting barbiturate for use in lethal injections. Furthermore any chemical which does not mirror the ultra short-acting property of the drug class explicitly prescribed for use by the statute cannot be considered an "other similar drug."
- 153. The current MDOC execution protocol does not account for the difference between an ultra short-acting barbiturate and other classes of barbiturates. The protocol simply substitutes pentobarbital for Sodium Pentothal with no other changes to the procedure.
- 154. According to execution logs produced by MDOC, the intervals between the administration of the anesthetic and paralytic drugs have not been lengthened as a result of substituting pentobarbital for the ultra short-acting barbiturate required by the Mississippi statute.

#### Summary of Risks Presented by Defendants' Conduct

- 155. For the reasons set forth above, there is a high risk that either: (a) the Defendants intend to use a degraded form of compounded pentobarbital for the execution of the Plaintiffs; (b) the Defendants have obtained only the raw ingredients for pentobarbital and intend to compound the pentobarbital at the Mississippi State Penitentiary; or (c) the Defendants have devised some other unknown and heretofore untested method of making pentobarbital.
- 156. The administration of pure and potent pentobarbital is a crucial step in the execution process to ensure that a condemned prisoner does not consciously experience the agonizing pain of live suffocation and cardiac arrest.

- 157. Defendants' decision to use a non-FDA-approved form of pentobarbital made with unknown and potentially contaminated or counterfeit ingredients is nothing short of human experimentation and presents an unacceptable risk that Plaintiffs will experience unnecessary pain and suffering if and when they are executed.
- 158. Defendants' decision to use a new and experimental lethal injection protocol without adequate assurances that the pentobarbital is manufactured according to accepted pharmaceutical practices and with pure and potent ingredients presents an unacceptable risk that MDOC will attempt to execute Plaintiff with an expired, contaminated, degraded, or sub-potent form of pentobarbital, resulting in the infliction of cruel and unusual punishment.

### Defendant's Policy of Secrecy

- 159. Over the past two years, counsel for Plaintiffs have submitted public records requests to MDOC pursuant to Miss. Code Ann. § 25-65-1 et seq., wherein counsel requested documents and correspondence pertaining to MDOC's lethal injection protocol, and where and how MDOC procured its lethal injection drugs.<sup>10</sup>
- 160. In response to a November 20, 2014 request, MDOC provided 10-pages of heavily-redacted documents, stating that MDOC would not disclose any information that could identify the supplier or manufacturer of their lethal injection drugs out of fear that such disclosure of public information would negatively affect MDOC's supply of such drugs.

<sup>&</sup>lt;sup>10</sup> Counsel for Plaintiffs first submitted a request to MDOC on February 7, 2014, requesting public documents pertaining to MDOC's lethal injection protocol and lethal injection drugs. After receiving records redacted for the identity of the supplier of MDOC's lethal injection drugs, the MacArthur Justice Center filed suit against MDOC for violations of the Mississippi Public Records Act (filed March 3, 2014). This lawsuit was ultimately mooted when the MacArthur Justice Center was able to determine the identity of MDOC's lethal injection drug supplier – the Brister Brothers – through information make publically-available by the MDOC on the state's Transparency website (as operated by the Department of Finance and Administration pursuant to the Mississippi Accountability and Transparency Act of 2008).

- 161. MDOC's failure to comply with the Mississippi Public Records Act and disclose public records related to their supply of lethal injection drugs is currently the subject of litigation between the MacArthur Justice Center and MDOC. The trial court has ruled in favor of the MacArthur Justice Center, ordering MDOC to provide un-redacted records as to their purchase of lethal injection drugs, awarding attorneys' fees, costs, and expenses, and denying a stay of this ruling pending appeal. MDOC has filed for appeal with the Mississippi Supreme Court.
- 162. In response to a February 20, 2015 request, MDOC again provided redacted records, claiming the ongoing litigation between the MacArthur Justice Center and MDOC as the basis for the denial.
- 163. Importantly, in the records provided on April 14, 2015, in response to the February 20 request, MDOC redacted *even more* information from records which have previously been made available to the MacArthur Justice Center. Specifically, MDOC redacted the month from records as to the date of purchase of the pentobarbital sodium API, and provided records of the six (6) executions carried out by Mississippi in 2012 in response to an inquiry about the disposition of five (5) vials of the pentobarbital sodium API that may have left the possession of the MDOC since June 2012.
- 164. By these calculated redactions of documents produced in response to a specific request for information about the use, disposal, or transfer of MDOC's pentobarbital sodium API, MDOC seeks to mislead the public to believe that several vials of the pentobarbital sodium API in MDOC's possession were used in the executions the state conducted in 2012. This is impossible given the fact known through records MDOC previously disclosed that the API was not in

MDOC's possession until after five (5) of the six (6) executions carried out in 2012 had already occurred.<sup>11</sup>

- 165. In response to requests for records submitted from May through July 2015, MDOC claimed attorney client privilege and work product doctrine protect the disclosure of records responsive to the requests.
- 166. Counsel for Plaintiffs were previously able to identify the supplier of MDOC's lethal injection drugs through their own investigation, see footnote 10 supra, but MDOC has since purchased new vecuronium bromide and potassium chloride (the second and third drugs in the execution series), and the identity of the supplier of these drugs is unknown.
- 167. Further, in response to an August 5, 2015 request for public records, MDOC provided 16 pages of redacted records indicating that the Department purchased 290 bottles of midazolam (containing 50mg/10mL each) from a supplier sometime in 2015. The name and all other identifying information regarding the supplier(s) is redacted. The date of purchase and/or receipt of the midazolam is redacted from all records except for the year. 12
- 168. MDOC maintains a policy of secrecy with regard to where and from whom they purchase lethal injection drugs, and how and where those drugs are prepared for use in executions.

<sup>&</sup>lt;sup>11</sup> The April 13, 2015 MDOC Public Records Act response was also inconsistent with the statement of counsel for the MDOC in a March 2, 2015 hearing in the chancery court case brought by the MacArthur Justice Center against MDOC. Counsel asserted then that the unaccounted-for pentobarbital sodium API had been destroyed because it had passed its expiration date. All documents produced by MDOC, however, demonstrate that all of the sodium pentobarbital API purchased from Brister Brothers had the same expiration date — May 20, 2015.

<sup>&</sup>lt;sup>12</sup> A redacted "supply inventory form" provided by MDOC appears to indicate "29 boxes" as the "amount received" of midazolam on July 27, 2015, but the purchase and receipt date is redacted from the receiving form and invoice provided by MDOC.

- 169. States continue to have difficulty purchasing lethal injection drugs. Consequently, Defendants may change their protocol or purchase different drugs or active pharmaceutical ingredients from different manufacturers before the next scheduled execution.
- 170. No execution is currently scheduled in the State of Mississippi. MDOC has repeatedly asserted in pleadings in the Chancery Court for the First Judicial District of Hinds County, Mississippi and in the Mississippi Supreme Court that Plaintiffs' counsel in this case has no immediate need for unreducted records related to its supply of lethal injection drugs because there are no current execution dates and the pentobarbital sodium API was set to expire on May 20, 2015.
- 171. On July 28, 2015, minutes after Defendants noticed this Court of an amended lethal injection protocol, the State moved the Mississippi Supreme Court to set an execution date for Plaintiff Richard Jordan within 30 days. The Mississippi Supreme Court has taken no action on the motion.
- 172. Defendants have never compounded pentobarbital sodium API into a sterile injectable form, and Defendants have never used compounded drugs in an execution. Plaintiffs' executions may be the first in which Defendants use compounded pentobarbital.
- 173. Defendants have failed to disclose any information as to their ability to or history of successfully compounding pentobarbital sodium API into a sterile injectable form for use in executions.
- 174. Defendants have also failed to disclose what information, if any, they have researched, gathered, or relied upon to evaluate the efficacy or effect of compounded pentobarbital or midazolam when used for an execution.

- 175. A request for public records submitted by counsel for Plaintiffs to MDOC on August 5, 2015 sought (among other items) any records as to whether midazolam is "ultra short-acting barbiturate or other similar drug" in Miss. Code Ann. § 99-19-51 and any records as to all drugs MDOC has contemplated for use as the first drug in its lethal injection protocol. The Department did not disclose any records responsive to these paragraphs of the request.
- 176. Defendants' failure to disclose the manufacturer of active pharmaceutical ingredients deprives Plaintiffs of any means to assess the purity of the API from which the injectable form of pentobarbital has or will be made; whether the API has been diluted with any substances which could impact the potency of the final product; whether the API is contaminated with either particulate foreign matter or a microbial biohazard that could lead to a severe allergic or neurotoxic reaction upon injection and several other similar issues.
- 177. Defendants will not disclose to Plaintiffs where and when they plan to compound lethal injection drugs, or the training and qualifications of the individuals who will participate in and supervise the compounding process. Plaintiffs have no way to assess the qualifications of the compounding pharmacy, whether the facility is actually equipped to make sterile injectable drugs such as pentobarbital, or whether the facilities are equipped to conduct any testing on the identity and/or purity of the API.
- 178. Defendants' policy of secrecy, their refusal to disclose to Plaintiffs the manufacturer and/or supplier of active pharmaceutical ingredients and other lethal injection drugs purchased for use in executions, and their failure to disclose where, how, and when they intend to try to compound API into a sterile injectable form violates Plaintiffs' rights to be free from cruel and unusual punishment, to due process, and to access to the courts.

#### F. MISSISSIPPI'S DECISION TO USE MIDAZOLAM IN LETHAL INJECTION EXECUTIONS

- 179. On July 28, 2015, Defendants filed notice with this Court of a change to their lethal injection protocol. The amended protocol is identical to the March 2012 protocol save for the provision that, in the event of the unavailability of pentobarbital, 500 milligrams of midazolam will be substituted as the first drug in the three-drug series.
- During ongoing litigation regarding violations of the state public records act by MDOC (see ¶ 161), the presiding Chancery Judge questioned MDOC's attorney regarding the steps MDOC would have to take in the event the Department could no longer obtain pentobarbital. MDOC counsel answered: "Well, our statute says ultra short-acting barbiturate or other similar drug. We are already limited." In the same colloquy, MDOC counsel stated, "counsel for the state is not interested in using [midazolam] right now and that's not an option for this counsel at this point, which means that you've got to find something else and there's a whole process that would be involved in trying to find an alternative anesthetic."
- August 5, 2015 sought (among other items) any records as to whether midazolam is "ultra short-acting barbiturate or other similar drug" in Miss. Code Ann. § 99-19-51 and any records as to all drugs MDOC has contemplated for use as the first drug in its lethal injection protocol. The Department did not disclose any records responsive to these paragraphs of the request, and have provided no records as to any research, assessment, consultation, or other actions taken by the Department prior to amending its protocol to provide for the use of midazolam.
- 182. MDOC has made no amendments to its lethal injection protocol to account for the important differences in pharmacology and physical effect between sodium thiopental, the manufactured ultra short-acting barbiturate originally used in lethal injections in the state, and

compounded pentobarbital (a non-FDA-approved, short- or intermediate-acting barbiturate) or midazolam (a drug in a wholly different class, benzodiazepines).

- 183. The Mississippi protocol does not provide for any procedural safeguards which have been added to the revised lethal injection protocols of other jurisdictions in an effort to reduce the substantial risk of serious harm that results from failures in the administration of lethal injection drugs. Importantly the MDOC protocol does not provide any instruction, timeline, procedure, or training for assessing the level of anesthetic depth of the prisoner prior to the administration of the second and third drug in the three-drug series.
- 184. Aside from providing for the use of midazolam as the first drug in a three-drug series, the Mississippi protocol in no way resembles the Chart D protocol that Oklahoma's Department of Corrections has adopted (following the botched execution of Mr. Lockett), which is the subject of litigation in federal court in Oklahoma and was the subject of the United States Supreme Court opinion in *Glossip v. Gross*.
- 185. Furthermore, the July 2015 protocol only provides for the use of midazolam in executions conducted by MDOC where a sufficient quantity of pentobarbital is unavailable.
  - 186. Defendants have stated that MDOC is unable to obtain pentobarbital in any form.
- 187. However, other state departments of corrections continue to obtain and utilize compounded pentobarbital in lethal injection executions. The States of Texas and Missouri, not to mention Georgia, <sup>13</sup> have had no difficulty obtaining pentobarbital or using it to carry out executions by lethal injection.

<sup>&</sup>lt;sup>13</sup> Since 2014, Georgia has conducted four (4) executions using pentobarbital in a single-drug lethal injection protocol, most recently in January 2015.

- 188. Texas and Missouri each carried out more executions than any other state in 2014 (10 executions each), and combined, these two states account for 80 percent of the executions in 2015 to date (16 of the 20 executions). All executions conducted by Texas and Missouri in 2014 and 2015 have involved the use of pentobarbital in a single-drug lethal injection protocol.
- 189. Furthermore, Texas is known to have twice obtained new supplies of pentobarbital just this year, first in March 2015, and as recently as May 2015.
- 190. In just the last week of September 2015, the Texas Department of Criminal Justice provided three vials of compounded pentobarbital to its counterpart in Virginia to be used in a scheduled execution. On information and belief, it is not unusual for departments of corrections in the executing states to transfer, exchange, or sell execution drugs to each other.

## Pharmacology of Midazolam

- 191. Unlike sodium thiopental and pentobarbital, both classified as barbiturates, midazolam is classified as a benzodiazepine, a class of drugs including Valium, Xanax, and Klonopin that are commonly used in the treatment of anxiety and panic disorders. Midazolam is incapable of inducing a "deep, comalike unconsciousness." Midazolam acts to depress the activity of the central nervous system ("CNS"), but the depth of that depression is limited, and even a large dose of midazolam will not result in unconsciousness or general anesthesia.
- 192. There is no pharmacological equivalency between benzodiazepines and barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms of action, magnitude of pharmacological effect produced (considering partial versus full effects, as well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence properties.

- 193. This lack of pharmacological equivalency between benzodiazepines and barbiturates is also reflected by the different scheduling of these drugs by the DEA.
- 194. Both benzodiazepines and barbiturates act upon the same type of receptor complex in the brain, the GABA receptor-chloride ion channel complex ("GABA receptor"). When the GABA receptor is acted upon, chloride ion channels open. The influx of chloride ions from the outside of the neuron to the inside causes a decrease in electrical activity of the neuron, neuronal inhibition, and ultimately CNS depression.
- 195. However benzodiazepines and barbiturates exhibit different mechanisms of action upon the receptor complex. These different mechanisms significantly impact the form and extent of the effect of these two drug classes on the GABA receptor.
- 196. Benzodiazepines (such as midazolam) require the presence of GABA, an inhibitory neurotransmitter in the brain, to exhibit any effect on the GABA receptor. GABA is a limited resource as it is made and released by inhibitory neurons, which are finite in number. GABA must be released and must act upon the GABA receptor at the same time as the benzodiazepine for drugs like midazolam to produce an inhibitory neuronal effect. Further, the presence of a benzodiazepine only increases the frequency at which the GABA receptor complex opens, not the duration of that opening. As a result of their mechanism of action, benzodiazepines can only produce a partial pharmacological effect.
- 197. In contrast, barbiturates do not require the presence of GABA to act upon the GABA receptor. Barbiturates can cause neuronal inhibition even when GABA is not present. Further, unlike benzodiazepines, barbiturates increase the duration of opening at the GABA receptor such that activity of the neuron is completely shut down, resulting in electrical silence.

- 198. Midazolam has a ceiling effect that is not present in barbiturates. A ceiling effect refers to a limit on the magnitude of the produced effect of a drug as the dose is increased. Midazolam's ceiling effect is a direct result of the mechanism of action described above, and explains why benzodiazepines are incapable of rendering a person unconscious and insensate to pain.
- 199. Injection of an IV bolus of 500 milligrams of midazolam, as called for by the July 2015 MDOC protocol, would produce a brain concentration many times higher than the concentration at which the ceiling effect is observed.
- 200. However, increasing the dose of midazolam above the amount necessary to reach the ceiling effect will have no additional effect on the neurons.
- 201. Thus even at concentrations of midazolam at or above the concentration at which the ceiling effect is observed, the drug cannot be relied upon to render a person anesthetized and insensate to pain.

## Midazolam Is Not an Ultra Short-Acting Barbiturate or Other Similar Drug

- 202. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.
- 203. Unable to obtain Sodium Pentothal or Nembutal, and having declared its inability to obtain pentobarbital sodium API, MDOC has now purchased midazolam to be used as the first drug in the three-drug series.

- 204. Midazolam is not an ultra short-acting barbiturate like Sodium Pentothal. Midazolam is not a short- or intermediate-acting barbiturate like pentobarbital. Midazolam is not a barbiturate at all. Rather midazolam belongs to the benzodiazepine class of drugs.
- 205. An understanding of the pharmacological differences between barbiturates and benzodiazepines is of the utmost importance when a benzodiazepine like midazolam is planned for use as the first drug in a three-drug protocol for execution by lethal injection. Where the first drug does not act swiftly and effectively to anesthetize the prisoner such that he is both unconscious and insensate before the executioner injects the second and third drugs, there is a substantial risk of severe pain and suffering.
- 206. It was with this understanding in mind that the Mississippi legislature specifically directed the use of an ultra short-acting barbiturate or other similar drug for use in lethal injections.
- 207. There is no pharmacological equivalency between midazolam and ultra shortacting barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms
  of action, magnitude of pharmacological effect produced (considering partial versus full effects,
  as well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence
  properties (as reflected by the different scheduling of these drugs by the DEA).
- 208. Any chemical that is not pharmacologically equivalent to an ultra short-acting barbiturate cannot serve as a valid pharmacological substitute.
- 209. The current MDOC execution protocol does not account for the difference between an ultra short-acting barbiturate and midazolam, a benzodiazepine. The protocol simply substitutes midazolam for pentobarbital, which is in term substituted for Sodium Pentothal, with no other changes to the procedure.

210. The Mississippi protocol does not provide for any procedural safeguards which have been added to the revised lethal injection protocols of other jurisdictions in an effort to reduce the substantial risk of serious harm that can result from failures in the administration of lethal injection drugs. Importantly the MDOC protocol does not provide any instruction, timeline, procedure, or training for assessing the level of anesthetic depth of the prisoner prior to the administration of the second and third drug in the three-drug series.

#### CLAIMS FOR RELIEF

Count I.A.: Use of Compounded Pentobarbital in a Three-Drug Lethal Injection Protocol Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

- 211. Plaintiffs reallege and incorporate by reference the allegations contained in ¶ 39 to 210.
- 212. Defendants claim they can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is among the ultra short-acting barbiturates authorized by the Mississippi lethal injection statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 213. Defendants also claim they no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of the Mississippi statute.
- 214. MDOC's decision to act contrary to the Mississippi statute for method of execution violates Plaintiffs' rights to be free from cruel and unusual punishment and to due process, as guaranteed by the United States and Mississippi Constitutions, and as discussed in claim II *infra*.

- 215. Defendants plan to use a compounded form of pentobarbital made from active pharmaceutical ingredients of unknown origin that may be counterfeit, contaminated, or ineffective.
- 216. In the alternative, Defendants intend to compound the drug by some other means pursuant to an unknown process and protocol, and by individuals with unknown qualifications.
- 217. The Eighth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, and the corresponding provisions of the Mississippi Constitution, prohibit the infliction of unnecessary pain in the execution of a death sentence.
- 218. Because it is nearly impossible to determine with certainty whether a prisoner will suffer serious and needless pain and suffering during an execution, the question of whether a particular execution procedure will inflict such pain and suffering involves an inquiry as to whether the prisoner is subject to a substantial or intolerable risk of serious harm.
- 219. Such a substantial or intolerable risk of serious harm may occur when a state lacks a clear protocol for lethal injection, when experience with the procedure demonstrates that there are foreseeable problems, or when it is known that the drugs intended for use in lethal injections will very likely result in the prisoner suffering intense pain that an alternative procedure would not cause.
- 220. The Defendants' decision to use a previously untried form of pentobarbital created with unknown and unregulated ingredients through an unknown and unregulated compounding process creates a substantial and intolerable risk that the pentobarbital will be counterfeit, contaminated, degraded, expired, or sub-potent, resulting in the infliction of cruel and unusual punishment.

- 221. The Defendants' untried and untested drugs create a substantial risk that Plaintiffs will suffer unnecessary and excruciating pain either by the injection of the compounded pentobarbital causing a painful reaction itself, or by the compounded pentobarbital failing to work, resulting in a torturous death by life suffocation and cardiac arrest.
- 222. Thus, Mississippi's planned use of compounded pentobarbital as the first drug in a three-drug series, which is completed with the intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to Plaintiffs.
- 223. There is a feasible alternative which could substantially reduce the risk of severe pain and serious harm presented by the continuous intravenous administration of compounded pentobarbital in combination with a chemical paralytic agent and potassium chloride.
- 224. The use of an FDA-approved, ultra short-acting barbiturate in a single-drug protocol is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure. Other jurisdictions have already moved towards the use of a single-drug anesthetic-only protocol.
- 225. If no FDA-approved ultra short-acting barbiturate can be legally sold to a department of corrections for use in executions, and only in that event, the use of an FDA-approved short- or intermediate-acting barbiturate in a single-drug protocol is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure.
- 226. If the alternatives pled in ¶¶ 224 to 225 are not legally available, and only in that event, the use of an ultra short-acting barbiturate, compounded by a duly licensed compounding pharmacy, tested for integrity, purity, and potency by a laboratory unaffiliated with the

compounding pharmacy industry or a department of corrections, and used in a single-drug anesthetic-only protocol (without a paralytic agent or potassium chloride), is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure.

- 227. If the alternatives pled in ¶¶ 224 to 226 are not legally available, and only in that event, the use of a short- or intermediate-acting barbiturate, compounded by a duly licensed compounding pharmacy, tested for integrity, purity, and potency by a laboratory unaffiliated with the compounding pharmacy industry or a department of corrections, and used in a single-drug anesthetic-only protocol (without a paralytic agent or potassium chloride), is a feasible and available alternative which would significantly reduce the substantial risk of severe pain presented by Mississippi's current procedure.
- 228. Defendants' refusal to adopt these alternatives for the executions of Plaintiffs, in the face of these documented advantages, without a legitimate penological justification for adhering to its current method of execution, constitutes cruel and unusual punishment prohibited by the Eighth Amendment.
- 229. To the extent that Defendants' refusal to adopt the single-drug anesthetic-only barbiturate technique is based on the requirements of Miss. Code Ann. §99-19-51, that part of the statute which requires the use of a "chemical paralytic agent" in executions should be held unconstitutional as contrary to the Eighth Amendment.
- 230. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.

- 231. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count I.A.
  - Count I.B.: Use of Midazolam in a Three-Drug Lethal Injection Protocol Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution
- 232. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 231.
- 233. Defendants claim they can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is among the ultra short-acting barbiturates authorized by the Mississippi lethal injection statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
- 234. Defendants also claim they no longer possess an FDA-approved form of pentobarbital, whose classification as a short- or intermediate-acting barbiturate renders its use in executions (even in its FDA-approved form) a direct violation of the Mississippi statute.
- 235. Defendants further claim they have been unsuccessful at obtaining pentobarbital is any form despite the fact that several other jurisdictions have obtained and utilized compounded pentobarbital in lethal injection executions this year.
- 236. On July 28, 2015, MDOC amended its lethal injection protocol. The current protocol now provides for the use of midazolam as the first drug in the series in the event of the unavailability of pentobarbital. No other changes were made to the protocol.

- 237. The Eighth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, and the corresponding provisions of the Mississippi Constitution, prohibit the infliction of unnecessary pain in the execution of a death sentence.
- 238. Because it is nearly impossible to determine with certainty whether a prisoner will suffer serious and needless pain and suffering during an execution, the question of whether a particular execution procedure will inflict such pain and suffering involves an inquiry as to whether the prisoner is subject to a substantial or intolerable risk of serious harm.
- 239. Such a substantial or intolerable risk of serious harm may occur when a state lacks a clear protocol for lethal injection, when experience with the procedure demonstrates that there are foreseeable problems, or when it is known that the drugs intended for use in lethal injections will very likely result in the prisoner suffering intense pain that an alternative procedure would not cause.
- 240. The Defendants' decision to use midazolam as the first drug in its lethal injection series in the event of the unavailability of pentobarbital creates a substantial and intolerable risk that the Plaintiff will not be anesthetized and insensate prior to the administration of the second and third drugs, resulting in the infliction of cruel and unusual punishment, a torturous death by life suffocation and cardiac arrest.
- 241. Midazolam is not a barbiturate. Rather, midazolam is classified as a benzodiazepine, the same class of drugs as Valium, Xanax, and Klonopin.
- 242. There is no pharmacological equivalency between benzodiazepines and barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms of action, magnitude of pharmacological effect produced (considering partial versus full effects, as

well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence properties (as reflected by the different scheduling of these drugs by the DEA).

- 243. Unlike barbiturates, benzodiazepines have a ceiling effect. This ceiling effect restricts the magnitude of pharmacological effects that can be produced by midazolam, and is a direct result of benzodiazepines' mechanism of action. Barbiturates have a different mechanism of action and therefore do not exhibit a ceiling effect.
- 244. Injection of an IV bolus of 500 milligrams of midazolam, as called for by the July 2015 MDOC protocol, would produce a brain concentration many times higher than the concentration at which the ceiling effect is observed.
- 245. However, increasing the dose of midazolam above the amount necessary to reach the ceiling effect will have no additional effect on the neurons.
- 246. Thus even at concentrations of midazolam at or above the concentration at which the ceiling effect is observed, the drug cannot be relied upon to render a person anesthetized and insensate to pain.
- 247. Mississippi's planned use of midazolam as the first drug in a three-drug series, which is completed with the intravenous administration of a chemical paralytic agent and potassium chloride, creates a substantial risk of serious harm and severe pain to Plaintiffs.
- 248. There is a feasible alternative which could substantially reduce the risk of severe pain and serious harm presented by the continuous intravenous administration of midazolam in combination with a chemical paralytic agent and potassium chloride.
- 249. The use of a single-drug anesthetic-only protocol as set forth in ¶¶ 224 to 227 above is a feasible and available alternative which would significantly reduce the substantial risk of

severe pain presented by the use of midazolam as the first drug in a three-drug series. Other jurisdictions have already moved towards the use of a single-drug anesthetic-only protocol.

- 250. Defendants' refusal to adopt these alternatives for the executions of Plaintiffs, in the face of their documented advantages, without a legitimate penological justification for adhering to its current method of execution, constitutes cruel and unusual punishment prohibited by the Eighth Amendment.
- 251. To the extent that Defendants' refusal to adopt the single-drug anesthetic-only barbiturate technique is based on the requirements of Miss. Code Ann. §99-19-51, that part of the statute which requires the use of a "chemical paralytic agent" in executions should be held unconstitutional as contrary to the Eighth Amendment.
- 252. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.
- 253. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count I.B.
  - Count II: Failure to Use an Ultra Short-Acting Barbiturate or Other Similar Drug as Directed by Mississippi Statute Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment and Right to Due Process under the Eighth and Fourteenth Amendments to the United States Constitution
- 254. Plaintiffs reallege and incorporate by reference the allegations contained in ¶ 39 to 253.
- 255. The Mississippi legislature has directed that the manner of execution for individuals sentenced to death be "by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until

death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice." Miss. Code Ann. § 99-19-51.

- 256. Plaintiffs have a life and liberty interest created by the requirement of an "ultra short-acting barbiturate or other similar drug" in Section 99-19-51. This interest is protected by the Due Process Clause of the Fourteenth Amendment.
- 257. Prior to 2011, Defendants used Sodium Pentothal (also known as sodium thiopental) as the first drug in a three-drug lethal injection protocol. Sodium Pentothal is classified as an ultra short-acting barbiturate. This classification is based on the drug's speed of onset and duration of effect.
- 258. By the enactment of Miss. Code Ann. § 99-19-51, the Mississippi legislature has directed that use of an ultra short-acting barbiturate is necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs. In addition to creating a life and liberty interest protected by the Fourteenth Amendment, the statute's legislative determination of the method of minimizing the risks of torturous harm in Mississippi executions is relevant for Eighth Amendment purposes.
- 259. Defendants claim they can no longer purchase Sodium Pentothal, as detailed *supra*. As a result, MDOC amended its protocol to allow for the use of pentobarbital as the first drug in the three-drug series where Sodium Pentothal is unavailable.
- 260. Pentobarbital even in its FDA-approved form is not classified as an ultra short-acting barbiturate. Rather it is classified as a short- or intermediate-acting barbiturate. This classification recognizes the slower speed of onset of pentobarbital when compared to an ultra short-acting barbiturate.

- 261. While the Mississippi statute provides for use of an "ultra short-acting barbiturate or other similar drug," pentobarbital is not sufficiently similar to an ultra short-acting barbiturate as to be considered an "other similar drug" within the meaning of a statute. This is true even for FDA-approved pentobarbital, let alone for compounded pentobarbital made from unknown active pharmaceutical ingredients, as MDOC intends to now use.
- 262. Defendants have further amended the MDOC protocol to provide for the use of midazolam as the first drug in a three-drug series in the event of the unavailability of pentobarbital.
- 263. Midazolam is not a barbiturate. Rather, midazolam is classified as a benzodiazepine, the same class of drugs as Valium, Xanax, and Klonopin.
- 264. There is no pharmacological equivalency between benzodiazepines and barbiturates when evaluated using the criteria of chemical (atomic) structures, mechanisms of action, magnitude of pharmacological effect produced (considering partial versus full effects, as well as ceiling effects), approved and known therapeutic uses, or drug abuse and dependence properties (as reflected by the different scheduling of these drugs by the DEA).
- 265. MDOC's decision to use compounded pentobarbital or midazolam as the first drug in its upcoming executions is in clear violation of Miss. Code Ann. § 99-19-51. As such this decision violates Plaintiffs' rights guaranteed by the Eighth Amendment to the United States Constitution.
- 266. MDOC's decision to use compounded pentobarbital or midazolam as the first drug in its upcoming executions further violates Plaintiffs' right, guaranteed by the Fourteenth Amendment to the United States Constitution, to not be executed except in accordance with Section 99-19-51. Mississippi law provides no adequate post-deprivation remedy for the harm that

will be caused by Defendants' denial of Plaintiffs' right to be executed only with the use of an ultra short-acting barbiturate or other similar drug.

- 267. For the reasons set forth above, MDOC's failure to use an ultra short-acting barbiturate as required by Miss. Code Ann. §99-19-51 creates an unacceptable risk of severe pain and serious harm in violation of the Eighth Amendment, and violates Plaintiffs' due process guarantees under the Fourteenth Amendment.
- 268. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count II.

Count III: Mississippi's Continued Use of a Three-Drug Protocol in the Face of Evolving Standards of Decency Which Require Abandonment of the Use of a Chemical Paralytic Agent and Potassium Chloride, Violates Plaintiffs' Right to be Free from Cruel and Unusual Punishment under the Eighth and Fourteenth Amendments to the United States Constitution and Article 3, Sections 14 and 28 of the Mississippi Constitution

- 269. Plaintiffs re-allege and incorporate by reference the allegations contained in ¶¶ 39 to 268.
- 270. "The basic concept underlying the Eighth Amendment is nothing less than the dignity of man . . . . The Amendment must draw its meaning from the evolving standards of decency that mark the progress of a maturing society." Atkins v. Virginia, 536 U.S. 304, 311-312 (2002) (quoting Trop v. Dulles, 356 U.S. 86 (1958)). The United States Supreme Court has repeatedly looked to legislation enacted by the states as the "clearest and most reliable objective evidence of contemporary values," id. at 312 (quoting Penry v. Lynaugh, 492 U.S. 302, 331 (1989)), relying on such legislative evidence of evolving trends to narrow the classes of those individuals we seek to punish through the death penalty and to determine the suitability of those methods and protocols by which we carry out such sentences.

- 271. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Defendants have not used Sodium Pentothal in an execution since 2010.
- 272. Defendants have amended their lethal injection protocol to provide for the use of pentobarbital in the event that Sodium Pentothal is unavailable. In executions conducted in 2011 and in 2012, MDOC used pentobarbital as the first drug in its three-drug lethal injection protocol, in place of Sodium Pentothal.
- 273. These eight (8) executions used the FDA-approved form of pentobarbital, marketed as Nembutal and purchased by MDOC in March 2011.
- 274. Defendants no longer possess an FDA-approved form of pentobarbital. Instead Defendants have purchased pentobarbital sodium API to be compounded into injectable pentobarbital for use in upcoming lethal injections.
- 275. Defendants have also amended the MDOC lethal injection protocol to provide for the use of midazolam as the first drug in its three-drug series in the event a sufficient quantity of pentobarbital is unavailable. As detailed *supra*, defendants have purchased midazolam from an unknown source on an unknown date.
- 276. Mississippi's decision to continue use of a three-drug lethal injection protocol runs contrary to the trend towards single-drug anesthetic-only protocols employed successfully by other states in recent years.
- 277. No state has used pentobarbital in a three-drug protocol this year (with 20 executions having been conducted by five states to date). Only Oklahoma used pentobarbital in a three-drug protocol in 2014, accounting for just two (2) of the 35 executions conducted by seven (7) states last year.

278. The chart below summarizes this evolving trend away from the use of three-drug lethal injection protocols, particularly those involving pentobarbital. The execution methods, protocols, and drugs (as contained in the chart) track the lethal injection statutes propagated by state legislatures, as well as the lethal injection protocols propagated and implemented by state departments of corrections.

-	3-drug sodium thiopental	1-drug sodium thiopental	3-drug pentobarbital	1-drug pentobarbital	3-drug midazolam	2-drug midazolam	Other	Total
2010	TX, LA, OK, FL, MS, VA, AL, GA, AZ	9 OH, WA	1 OK	0	0	0	2 VA, UT	46
2011	7 AL, GA, MO, TX, AZ	OH	OK, TX, SC, MS, AL, AZ, GA, DE, VA, FL, ID	4 OH	0	0	0	43
2012	Ö	0	OK, TX, MS, FL, DE	AZ, OH, ID, TX, SD	0	0	0	43
2013	0	0	OK, FL, AL	TX, GA, OH, AZ, MO	2 FL	0	1 VA	39
2014	0	0	2 OK	22 TX, MO, GA	9 FL, OK	2 OH, AZ		35
2015	0	0	0	18	2	0	0	(to date)

279. The trend towards abandonment of the three-drug protocol is evidence of the evolving standards of decency which inform the Eighth Amendment. From 2010 to 2012, of the 132 executions conducted nationwide, over 70 percent (94 executions) were conducted using a three-drug protocol. Yet since 2013, just three states have conducted executions using a three-drug protocol, a total of 27 executions (29 percent) of the 94 conducted nationwide. Only 14 of these 94 executions used pentobarbital in a three-drug series (15 percent of executions nationwide). Only 13 of these 94 executions used midazolam in a three-drug series (14 percent of executions nationwide).

- 280. Put another way, forty-seven of the fifty states punish murder without undertaking the risk of conscious, torturous pain and suffocation which is raised by the use of a chemical paralytic agent and potassium chloride in the three-drug protocol.
- 281. It follows that use of the three-drug protocol by Mississippi constitutes cruel and unusual punishment in violation of the Eighth Amendment.
- 282. Defendants continued use of a three-drug lethal injection protocol, when other states have abandoned this method in favor of a single-drug, anesthetic-only protocol, violates Plaintiffs' right to be free from cruel and unusual punishment as guaranteed by the United States and Mississippi Constitutions.
- 283. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count III.

# Count IV: Violation of Plaintiffs' Right to Notice of the Defendants' Method of Execution under the Fourteenth Amendment to the United States Constitution and Article 3, Section 14 of the Mississippi Constitution

- 284. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 283.
- 285. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
  - 286. Defendants also no longer possess an FDA-approved form of pentobarbital.
- 287. Defendants have obtained active pharmaceutical ingredients from a compounding pharmacy to try to manufacture a sterile injectable form of pentobarbital.

- 288. Defendants have not disclosed to Plaintiffs where they have compounded, or where they intend to compound the raw ingredients to try to make a sterile injectable form of pentobarbital.
- 289. Defendants have not disclosed to Plaintiffs the training or qualifications of the individuals responsible for trying to compound the raw ingredients to make a sterile injectable form of pentobarbital.
- 290. Furthermore, Defendants have obtained midazolam from an unknown source on an unknown date. Defendants have amended the MDOC lethal injection protocol to provide for the use of midazolam as the first drug in the three-drug series in the event of the unavailability of pentobarbital.
- 291. On information and belief, Defendants intend to execute Plaintiffs with drugs or ingredients that have never been used before in an execution in Mississippi.
- 292. Under the due process clauses of the United States and Mississippi Constitutions, Plaintiffs are entitled to notice of the Defendants' intended method of execution, including information about the drugs Defendants have obtained and the steps by which any API will be compounded into a sterile injection to be used in executions.
- 293. Defendants' failure to disclose the manufacturer of the active pharmaceutical ingredients it purchased to make pentobarbital, Defendants' failure to disclose the supplier of its recent purchase of midazolam, and Defendants' failure to disclose how, where, and when they intend to try to compound any raw ingredients into sterile injectable solutions for use in executions violates Plaintiffs' right to due process under the United States and Mississippi Constitutions.
- 294. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.

295. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count IV.

## Count V: Violation of Plaintiffs' Right of Access to the Courts under the First and Fourteenth Amendment to the United States Constitution and Article 3, Section 14 and 24 of the Mississippi Constitution

- 296. Plaintiffs reallege and incorporate by reference the allegations contained in ¶¶ 39 to 295.
- 297. Defendants can no longer purchase Sodium Pentothal, as detailed *supra*. Sodium Pentothal, also known as sodium thiopental, is an ultra short-acting barbiturate, required by Mississippi statute and necessary to ensure that a prisoner is properly anesthetized prior to the administration of the second and third drugs in the state's lethal injection protocol.
  - 298. Defendants also no longer possess an FDA-approved form of pentobarbital.
- 299. Due to the unavailability of FDA-approved pentobarbital, Defendants have changed their lethal injection protocol by substituting a compounded form of pentobarbital for the FDA-approved drug Nembutal.
- 300. Defendants have further amended their protocol to provide for the use of midazolam in the event of the unavailability of pentobarbital.
- 301. Defendants have purchased the active pharmaceutical ingredients for pentobarbital, and already have, or will in the future, devise a way to try to compound the active pharmaceutical ingredients to create a sterile injectable form of pentobarbital.
- 302. Defendants have purchased midazolam in an unknown form, from an unknown supplier, on an unknown date.

- 303. Defendants have asserted that the identity of the manufacturer and supplier of lethal injection drugs is confidential for fear the disclosure of such information would forestall MDOC's ability to obtain lethal injection drugs in the future. MDOC will not tell Plaintiffs who manufactured the active pharmaceutical ingredients, who manufactured or supplied the midazolam, where lethal injection drugs have been or will be compounded, and the training and qualifications of the individuals who have or will compound the drugs. This information is necessary in order for Plaintiffs to more fully determine the risks associated with Defendants' lethal injection drugs.
- 304. Plaintiffs possess a right to file a legal challenge to enjoin their executions if Defendants' execution procedure presents a substantial risk of serious harm, in violation of the Eighth and Fourteenth Amendments to the United States Constitution.
- 305. Plaintiffs also possess a right under the First and Fourteenth Amendments to the United States Constitution and Article 3, Section 24 of the Mississippi Constitution to have a reasonable opportunity to present legal claims implicating fundamental constitutional rights to the courts.
- 306. Defendants' policy of secrecy prevents Plaintiffs from accessing all of the relevant information they need to mount an Eighth Amendment challenge to Defendants' lethal injection protocol, and thus violates their right of access to the courts.
- 307. For the reasons set forth above, Defendants are deliberately indifferent to Plaintiffs' constitutional rights.
- 308. This Court has the jurisdiction and authority to enter a declaratory judgment, and a preliminary and permanent injunction to prevent the violations of the Eighth and Fourteenth Amendments alleged in Count V.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court:

- Grant a declaratory judgment that neither pentobarbital nor midazolam are ultrashort acting barbiturates or other similar drugs and are therefore not permitted for lethal injection executions in Mississippi;
- Grant preliminary and permanent injunctive relief to enjoin the Defendants, their
  officers, agents, employees, and all persons acting in concert with them from
  executing Plaintiffs with any drug which is not an ultra short-acting barbiturate;
- 3. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs with either compounded pentobarbital or midazolam, which are neither ultra-short acting barbiturates nor similar to ultra short-acting barbiturates;
- 4. Grant a declaratory judgment that the words "in combination with a chemical paralytic agent" in Miss. Code Ann. §99-19-51 violate the Eighth and Fourteenth Amendment to the United States Constitution;
- Grant preliminary and permanent injunctive relief to enjoin the Defendants, their
  officers, agents, employees, and all persons acting in concert with them from
  executing Plaintiffs with compounded drugs;
- 6. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs with a three-drug series which includes a chemical paralytic agent and potassium chloride;

- 7. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs until such time as Defendants can demonstrate the integrity, purity, potency, and legality of any and all controlled substances they intend to use for Plaintiffs' executions;
- 8. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs without providing full and complete information about the drugs that Defendants intend to use in their execution, within sufficient time for Plaintiffs to raise any statutory or constitutional challenges to the use of said drugs.
- 9. Grant preliminary and permanent injunctive relief to enjoin the Defendants, their officers, agents, employees, and all persons acting in concert with them from executing Plaintiffs until such time as Defendants can demonstrate that measures are in place to allow for Plaintiffs' execution in a manner that complies with the Eighth and Fourteenth Amendments to the United States Constitution;
- 10. Award costs and attorney's fees pursuant to 42 U.S.C. §1988; and
- 11. Grant any such other relief that this Court determines to be just and proper in these premises.

Respectfully submitted,

/s/ James W. Craig

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Counsel for Plaintiffs Jordan and Chase

Respectfully submitted,

/s/ Stacy Ferraro

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lifestoryms@gmail.com

Counsel for Intervenor Loden

Dated: September 28, 2015

#### CERTIFICATE OF SERVICE

I hereby certify that I have filed this pleading with the Electronic Case Filing System of the United States District Court for the Southern District of Mississippi, and have thereby served counsel of record for the Defendants and the Intervenor in this case.

This, the 28th of September, 2015.

/s/James W. Craig

IN THE CIRCUIT COURT OF ITAWAMBA COUNTY, MISSISSIPPI

STATE OF MISSISSIPPI

VS.

CR00-068

THOMAS EDWIN LODEN, JR.

#### SENTENCING ORDER

This cause is before the Court for proceedings on entry of pleas of guilty by the Defendant, Thomas Edwin Loden, Jr., who is charged in an indictment with Capital Murder committed while engaged in the underlying felony of kidnapping the alleged victim, rape and four counts of sexual battery.

The Defendant, his attorneys and the State of Mississippi have waived trial by jury in both the guilt and sentencing phases on the Capital Murder charge, in writing pursuant to Section 99-19-101(1), Mississippi Code of 1972, Annotated.

The Court conducted an extensive, on the record, examination of the Defendant for the purpose of determining whether or not the pleas of guilty offered by him were to be entered by him knowingly, freely, understandingly and voluntarily. The Court further made specific inquiry concerning the Defendant's understanding of his rights under the Constitution of the United States and the State of Mississippi and his right to have a jury hear the evidence offered by the State of Mississippi and himself on the issue of guilt or innocence on each of the charges against him and to decide those issues. The Court further examined Defendant concerning his understanding of his right to have a jury fix the punishment to be imposed (i.e. death, life without parole or life imprisonment) in the event he was found guilty of Capital Murder by a jury.

In the course of the examination of Defendant during the proceedings on entry of pleas of



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guilty to all charges against the Defendant, the State of Mississippi read into the record an offer of proof, signed by the Defendant and in response to a specific question directed to him by the Court, acknowledged that the offer of proof contained a true and correct statement of the facts and circumstances concerning the charges in this case and his actions in the kidnapping, rape, sexual battery and murder of the victim, Leesa Marie Gray.

The Court, on the record during the proceedings on entry of the pleas of guilty by the Defendant, found and does hereby find that each of the pleas of guilty entered by Defendant were knowingly, freely, understandingly and voluntarily made and that such pleas were not the result of any promises, threats or coercion of any kind and that the Defendant was fully advised by his attorneys and the Court of his Constitutional and statutory rights with regards to each charge and more specifically with reference to the sentence to be imposed; that is that the Defendant had a statutory right to have the punishment to be imposed for the crime of Capital Murder determined by a jury and not the Court acting without a jury.

At the conclusion of the proceedings on entry of the pleas of guilty by Defendant to all charges in this cause, the Court accepted each such plea and adjudged the Defendant guilty as to each charge, including Capital Murder.

The Court then proceeded to consider the matter of the sentences to be imposed on each of the crimes to which Defendant had pled guilty.

For purposes of determining a proper sentence to be imposed in Count I of the indictment, that being the charge of Capital Murder, the Court conducted a hearing without a jury in accord with the waiver previously mentioned in this order. During this phase of the proceedings the Court considered all of the evidence previously introduced in the proceedings on entry of Defendants pleas of guilty, and the additional proof offered including photographs introduced by

the State, a video tape recovered from the vehicle of the Defendant introduced by the State, the psychiatric reports of Dr. Reb McMichael and members of the Staff at Mississippi State Hospital, and Dr. C. Gerald O'Brien, a clinical psychologist and forensic consultant who examined Defendant at the request of the Defendant's attorneys.

The Court having found the Defendant guilty of the crime of Capital Murder, must now decide whether the Defendant will be sentenced to death, life imprisonment without eligibility for parole, or life imprisonment as provided in Section 99-19-101. In reaching its decision the Court must objectively consider the detailed circumstances of the offense for which the Defendant has been convicted, and the character and record of the Defendant himself. The Court may not be swayed by mere sentiment, conjecture, sympathy, passion, prejudice, public opinion or public feeling.

As a threshold finding, the Court, when making a determination of the sentence without a jury, must find from the evidence beyond a reasonable doubt in writing that one or more of those factors set out in Section 99-19-101(7)(a.-d.) exists in order to impose a death sentence. In this case the Court finds beyond a reasonable doubt that (a) the Defendant, Thomas Edwin Loden, Jr., actually killed Leesa Marie Gray, a human being; (b) the Defendant, Thomas Edwin Loden, Jr., attempted to kill Leesa Marie Gray; (c) the Defendant, Thomas Edwin Loden, Jr., intended the killing of Leesa Marie Gray take place, and (d) the Defendant, Thomas Edwin Loden, Jr., contemplated that lethal force would be employed.

Having found each of the four factors provided in Subsection (7) of Section 99-19-101, Mississippi Code of 1972, Annotated, to exist, the Court must then determine whether sufficient aggravating circumstances exist as enumerated in Subsection (5) of that code section. The Court is limited to those circumstances enumerated and may not consider any other factors.

3 000050 In considering those circumstances the Court must find beyond a reasonable doubt that they exist. The Court, having considered the aggravating circumstances, is of the opinion and finds beyond a reasonable doubt that the following aggravating circumstances provided in that subsection exist as follows:

- The capital offense (Capital Murder) was committed while the Defendant, Thomas
   Edwin Loden, Jr., was engaged in the commission of the felony crimes of
   kidnapping, rape and sexual battery of Leesa Marie Gray, a human being;
- 2. The capital offense (Capital Murder) was committed by the Defendant, Thomas

  Edwin Loden, Jr., for the purpose of avoiding or preventing his lawful arrest; and
- 3. The capital offense (Capital Murder) was especially heinous, atrocious or cruel.

The Court, having found that one or more of the aggravating circumstances exist beyond a reasonable doubt as set out above, must now consider whether there are mitigating circumstances which outweigh the aggravating circumstances found to exist. In doing so, the Court must consider the following elements in determining whether the death penalty should be imposed:

- 1: The Defendant's age at the time of the Capital Murder;
- Any other matter, any other aspect of the Defendant's character or record, and any other circumstance of the offense brought before you during the trial of this case which the Court, deems to be mitigating on behalf of the Defendant;
- Whether or not the Defendant has significant history of prior criminal activity;
- 4. Whether or not the offense was committed while the Defendant was under the influence of extreme mental or emotional disturbance;
- Whether or not the capacity of the Defendant to appreciate the criminality of his conduct or to conform his conduct to the requirements of law was substantially

impaired;

Any other matter, any other aspect of the Defendant's character or record, and any other circumstance of the offense brought to the Court during the presentation of evidence in this cause which the Court deems to be mitigating on behalf of the Defendant.

The Court having considered and weighed the aggravating and mitigating circumstances finds that the aggravating circumstances outweigh the mitigating circumstances and that the mitigating circumstances do not outweigh the aggravating circumstances and that the death penalty should be imposed.

It is therefore the verdict of this Court, acting without a jury pursuant to the waiver by the State and the Defendant, as follows as to Count I in the indictment:

"The Court finds that the Defendant, Thomas Edwin Loden, Jr., should suffer death."

It is therefore the judgment and order of this Court that the Defendant, Thomas Edwin Loden, Jr., having been adjudged guilty of Capital Murder in the death of Leesa Marie Gray on his plea of guilty to said charge, be and he is hereby sentenced to suffer death by administration of a substance or substances in the manner required by law at a time to be fixed in accord with Section 99-19-106, Mississippi Code 1972, Annotated.

As to Count II of the indictment, it is the order of this Court that the Defendant serve a term of 30 years in the custody of the Mississippi Department of Corrections. This sentence shall run consecutive to all other sentences imposed in this cause.

As to Count III of the indictment, the sentence of this Court is that the Defendant serve a term of 30 years in the custody of the Mississippi Department of Corrections. This sentence is to run consecutive with all other sentences imposed in this cause.

As to Count IV of the indictment, it is the order of this Court that the Defendant serve a term of 30 years in the custody of the Mississippi Department of Corrections. This sentence shall run consecutive to all other sentences imposed in this cause.

As to Count V of the indictment, the sentence of this Court is that the Defendant serve a term of 30 years in the custody of the Mississippi Department of Corrections. This sentence is to run consecutive with all other sentences imposed in this cause.

As to Count VI of the indictment, it is the order of this Court that the Defendant serve a term of 30 years in the custody of the Mississippi Department of Corrections. This sentence shall run consecutive to all other sentences imposed in this cause.

It is the further order of the Court that the Defendant, Thomas Edwin Loden, Jr., be placed in the custody of the Sheriff of Itawamba County, Mississippi, or other lawful officer of this State and that he be immediately transported because of security reasons to the custody of the Mississippi Department of Corrections at a facility designated by the Department to be held by the said Department until execution of this sentence.

ORDERED, this the 21<sup>st</sup> day of September, 2001.

CIRCUIT JUDGE

FILED

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Carol Gates, Circuit Clerk

D.C.

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#### IN THE CIRCUIT COURT OF HARRISON COUNTY, MISSISSIPPI FIRST JUDICIAL DISTRICT

STATE OF MISSISSIPPI

VS

NO. 18,807

RICHARD GERALD JORDAN

#### FINAL JUDGMENT

On this day, April 24, 1998, the fifth (5th) day of this trial, Court convened in the First Judicial District of Harrison County, Mississippi. The jury composed of David Mackay and eleven (11) others together with two (2) alternates all good and lawful citizens of the First Judicial of Harrison County, Mississippi, were placed in the jury box and the sentencing phase of Richard Gerald Jordan continued. After both parties rested, the jury received the instructions of the court, heard arguments of counsel and retired to the jury room to consider their verdict, with the exception of the alternates who were excused by the court. After their deliberations, the jury returned into open court with the following verdicts, to-wit:

"We, the jury, unanimously find from the evidence beyond a reasonable doubt that the following facts existed at the time of the commission of the Capital Murder.

1.) That the defendant actually killed Edwina Marter.

Next, we the jury, unanimously find that the aggravating circumstances of:

- 1.) Richard Jordan committed the Capital Murder while engaged in the crime of Kidnapping Edwina Marter.
- 2.) Richard Jordan committed the Capital Murder for pecuniary gain.
- 3.) Richard Jordan committed a Capital offense which was especially heinous, atrocious & cruel & whether the murder was conscienceless & pitiless. In support of this circumstance the State claims that Edwina Marter was murdered in execution style & that she was subjected to extreme mental torture caused by her abduction from the home wherein she was forced to abandon her unattended three year

Page 2 Richard Gerald Jordan 18,807

old child & removed to a wooded area at which time she was shot in the back of the head by Jordan.

exist beyond a reasonable doubt & are sufficient to us to impose the death penalty and that there are insufficient mitigating circumstances to out weigh the aggravating circumstances and we further find unanimously that the defendant should suffer death."

### s/David M. Mackay FOREMAN OF THE JURY

A polling of the jury confirmed their verdict. ..

Thereupon the defendant was placed at the bar of the court and was asked if he had anything to say as to why the sentence of the law should not be pronounced against him herein. No sufficient reasons were given.

ORDERED that in accordance with the verdict of the jury and the law, the Defendant, Richard Gerald Jordan, for his offense of Capital Murder, is hereby sentenced to suffer death as provided by law. The date of execution of this death sentence is set for May 26, 1998.

ORDERED that the Defendant, Richard Gerald Jordan, is hereby remanded to the lawful custody of the Sheriff of Harrison County, Mississippi, for immediate transportation to the Maximum Security Unit at the Mississippi State Penitentiary, Parchman, Mississippi, where at some time on the 26th day of May, 1998, he shall suffer the penalty of DEATH to be administered as provided by law.

ORDERED this the 24th day of April, 1998.

KOSTA NIVLAHOS, ARDER 1998

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IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE RODERICK & SOLANGE MAY 22 2015

PLAINTIFF

MACARTHUR JUSTICE CENTER CHANCERY CLERK

NO. G2014-1885

MISSISSIPPI DEPARTMENT OF CORRECTIONS

DEFENDANT

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TRANSCRIPT OF PROCEEDINGS HAD IN THIS CAUSE BEFORE THE HONORABLE DENISE OWENS, CHANCELLOR

IN THE FIFTH CHANCERY COURT DISTRICT OF MISSISSIPPI ON THE 2ND DAY OF MARCH 2015

#### APPEARANCES:

REPRESENTING THE PLAINTIFF:

JIM CRAIG, ESQUIRE CO-DIRECTOR RODERICK & SOLANGE MACARTHUR JUSTICE CENTER 4400 S. CARROLLTON AVENUE NEW ORLEANS, LA 70119

#### REPRESENTING THE DEFENDANT:

PAUL ELDRIDGE BARNES, ESQUIRE ALISON ELIZABETH O'NEAL, ESQUIRE JASON LEWIS DAVIS, ESQUIRE OFFICE OF THE ATTORNEY GENERAL POST OFFICE BOX 220 JACKSON, MISSISSIPPI 39205-0220

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aware, there are no other responsive documents, whether -- whatever plaintiff might make of that, notwithstanding, it's our understanding that the 10 pages of documents which MDOC produced are the documents in its possession, custody or control responsive to their most recent request. One moment, Your Honor.

(PAUSE IN THE PROCEEDINGS)

MR. BARNES: Your Honor, I'd just like to conclude, at least this portion of the argument. I certainly would be willing to answer any other — any questions the court might have and provide the court with any other argument after Mr. Craig discusses the confidential financial information exemption further; but again, this is an issue of utmost importance to the state. The public has an interest in the enforcement of the laws and if the court gets to the balancing test — go head, Your Honor.

THE COURT: Well, I do understand that, you know, you said it's really effectively impossible to get the pentobarbital. So, it's impossible to execute someone here now --

MR. BARNES: At this time, the protocol that Mississippi -- that has been approved uses the three-drug protocol. If we change the protocol, it will, of course, be challenged by the plaintiffs, and so --

THE COURT: But has that happened in other

states that seem to have the same problem?

MR. BARNES: I'll let Mr. Davis speak to that.

MR. DAVIS: Let me make sure I understand your question, Your Honor.

THE COURT: I mean, I understand that -- I mean, you're saying it's really virtually impossible to get the pentobarbital to execute the person, but does that mean you're not going to execute or would you change the protocol like they have in other states?

mr. DAVIS: Well, you would -- obviously if
you couldn't get the one, you'd have to come up
with another --

THE COURT: I mean, so, the state --

MR. DAVIS: -- but the other states have been doing that, and that's what we've been seeing in the press lately is the change to the drug -- and Your Honor may be familiar with it -- midazolam, and that's the one that Ohio utilized and that Oklahoma, I believe.

THE COURT: I guess my question goes: You could still carry on your duty even if you're unable to get the pentobarbital?

MR. DAVIS: Well, our statute says ultra short-acting barbiturate or other similar drug. We are already limited. We've already -- if we lose pentobarbital, that's two down from that.

THE COURT: So, you'd have to change the

protocol for executions.

MR. BARNES: Absolutely, Your Honor.

THE COURT: But you would change the protocol? Is that --

MR. DAVIS: Provided we could find a suitable drug, Your Honor. Counsel would state for the court that based on my years of doing this and what I'm seeing with the use of midazolam and counsel for the state is not interested in using that right now and that's not an option for this counsel at this point which means that you've got to find something else and there's a whole process that would be involved in trying to find an alternative anesthetic. And I don't know -- I'm not a doctor, so I don't know what the classes what the -- how many are left, but there aren't very many that are in that ultra short-acting category that we can utilize.

THE COURT: Okay.

MR. BARNES: And, Your Honor, just one moment. I was going to say that — and it's also — you know, I've had to educate myself somewhat about this and Mr. Davis, you know, has educated me a great deal, but obviously he hasn't taught me everything. It's my understanding that when veterinarians put animals to sleep, they use pentobarbital and almost exclusively. They use a single massive

#### COURT REPORTER'S CERTIFICATE

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STATE OF MISSISSIPPI

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COUNTY OF HINDS

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I, Colleen O. White, Official Court Reporter for the Fifth Chancery Court District of the State of Mississippi, do hereby certify that to the best of my skill and ability I have reported the proceedings had and done in the trial of THE RODERICK & SOLANGE MACARTHUR JUSTICE CENTER VS. MISSISSIPPI DEPARTMENT OF CORRECTIONS, being No. G2014-1885 on the Docket of the Chancery Court of the First Judicial District of Hinds County Mississippi and that the above and foregoing County, Mississippi, and that the above and foregoing sixty-eight (68) pages contain a full, true, and correct transcript of my stenographic notes and tape taken in said proceedings.

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This is to further certify that I have this date filed the original and one copy of said transcript, along with one CD-ROM electronic disk of said transcript in PDF language, for inclusion in the record on appeal, with the Clerk of the Chancery Court of the First judicial District of Hinds County, Mississippi, and have notified the attorneys of record, the Chancery Clerk and the Supreme Court Clerk of my actions herein.

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I do further certify that my certificate annexed hereto applies only to the original and certified transcript and electronic disk. The undersigned assumes no responsibility for the accuracy of any reproduced copies not made under my control or direction.

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This, the 22nd day of May, 2015.

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TRANSCRIPT FEE:

Course O. White

COLLEEN O. WHITE, RMR, CSR

CSR NUMBER 1310

#### STATE OF OKLAHOMA

#### COUNTY OF TULSA

#### AFFIDAVIT OF CRAIG W. STEVENS, Ph.D.

PERSONALLY APPEARED BEFORE ME, the undersigned authority in and for the jurisdiction aforesaid, the within-named Craig W. Stevens, Ph.D., who being by me first duly sworn, deposed and said:

- 1. My name is Craig W. Stevens, Ph.D. I am over eighteen years of age and am competent to give sworn testimony in a court of law. I have personal knowledge of the matters and facts set forth in this affidavit.
- 2. I am a Professor of Pharmacology, a full-time faculty member in the department of Pharmacology and Physiology at the College of Osteopathic Medicine, a unit of the Oklahoma State University, Center for Health Sciences campus in Tulsa, Oklahoma. I have held this position since 2000.
- 3. After receiving my Ph.D. in Pharmacology from the Mayo Clinic, in Rochester, Minnesota, I completed a 2-year postdoctoral fellowship at the University of Minnesota Medical School in Minnesota. I secured a position as an Assistant Professor of Pharmacology with my present employer in 1990, and rose to Associate Professor of Pharmacology in 1993.
- 4. Besides my regular duties of teaching medical students, pursuing research and scholarly activities, and serving on college committees, I work part-time as a litigation consultant and/or expert witness on cases involving pharmacological issues.
- 5. On March 6, 2016, I provided an amended litigation report on issues related to lethal injection executions in Mississippi in the case of Richard Jordan, et al., v. Marshall Fisher,



et al., no. 3:15-cv-00295, in the United States District Court for the Southern District of Mississippi.

- 6. A true and correct copy of that report is attached hereto.
- 7. The matters contained in the March 2016 report are true and correct to the best of my knowledge.

FURTHER AFFIANT SAYETH NAUGHT.

This the day of March, 2016.

OFFICIAL SEAL ROBERT A PERRY NOTARY PUBLIC STATE OF OXILAHOMA ERAIGW. STEVENS, Ph.D.

Sworn to and subscribed before me, this the Stage of

NOTARY PUBLIC

My commission expires:

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### THE PHARMACOLOGY OF MIDAZOLAM AND THIOPENTAL WITH REGARD TO THE LETHAL INJECTION PROTOCOL IN THE STATE OF MISSISSIPPI

AMENDED REPORT: March 6, 2016

Re: Mississippi Lethal Injection Case

Researched and written by:
Craig W. Stevens, Ph.D.
Professor of Pharmacology
Oklahoma State University-Center for Health Sciences
1111, W. 17<sup>th</sup> Street
Tulsa, OK 74107

Prepared for and submitted to:
Emily Washington
Attorney
Roderick & Solange MacArthur Justice Center
4400 S. Carrollton Ave.
New Orleans, LA 70119



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#### 1. Background and Qualifications of the Author

Craig W. Stevens, Ph.D., is the author of this report. He performed the medical and pharmacological literature research, the pharmacological calculations used to determine the blood levels of thiopental and midazolam, and completed the writing of the entirety of this report. Dr. Stevens is a Professor of Pharmacology, a full-time faculty member in the department of Pharmacology and Physiology at the College of Osteopathic Medicine, a unit of the Oklahoma State University, Center for Health Sciences campus in Tulsa, Oklahoma.

After receiving his Ph.D. in Pharmacology from the Mayo Clinic, in Rochester, Minnesota, Dr. Stevens completed a 2 year postdoctoral fellowship at the University of Minnesota Medical School in Minneapolis, Minnesota, and secured a position as an Assistant Professor of Pharmacology with his present employer in 1990. He advanced through the academic ranks to Associate Professor of Pharmacology in 1993, and Professor of Pharmacology in 2000.

Besides his regular duties of teaching medical students, pursuing research and scholarly activities, and serving on college committees, Dr. Stevens works part-time as a litigation consultant/expert witness on cases involving pharmacological issues. He has consulted in both civil and criminal cases, working with both the prosecution or plaintiff and the defendant. With regard to the pharmacological issues of lethal injection, he has consulted with the State as well as with Federal Public Defenders representing condemned inmates.

Dr. Stevens was asked to investigate the pharmacological nature of midazolam regarding its use as a lethal injection drug and specifically (a) whether midazolam can be characterized as an "other similar drug" to an ultra short-acting barbiturate, such as thiopental (the original first drug used in the MS three drug lethal injection protocol), and (b) whether the use of midazolam as the first drug in Mississippi's three-drug lethal injection protocol creates a substantial risk of serious harm and severe pain to the condemned prisoner.

Dr. Stevens' curriculum vitae (CV) is attached as Appendix A to this report.

#### 2. Midazolam and Thiopental are not Pharmacologically Equivalent

#### A. Pharmacological Equivalency and Pharmacological Substitution

Each drug has a unique chemical (atomic) structure and exerts a unique profile of pharmacological effects. Drugs are classified both by their chemical structures and by their therapeutic uses. Drugs that have very similar chemical structures are grouped together based on that structure. Drugs that have similar therapeutic uses are also grouped together by their therapeutic or pharmacological effects.

Pharmacological equivalency is present when two or more drugs exhibit the same or closely similar pharmacological properties. It is a working principle used by physicians who often substitute drugs due to drug allergies or for reasons of cost. Pharmacological equivalency is also the guiding principle for the FDA to accept a generic version of the same branded drug (e.g.

Walgreen's ibuprofen, the generic form, is *pharmacologically equivalent* to Advil®, the branded formulation of ibuprofen. See *Meredith 2003, Borgheini 2003*).

Pharmacological substitution is the act of using one drug in the place of another. It is axiomatic that in order to maintain the same pharmacological and therapeutic effect of two drugs, the drug that is substituted must have pharmacological equivalency to the new drug.

There is no question that midazolam and thiopental are different drugs. The key question in substituting drugs for lethal injection is one of a pharmacological nature: Does midazolam have pharmacological equivalency to thiopental such that a valid pharmacological substitution can be made? Pharmacological equivalency between midazolam, a benzodiazepine, and thiopental, a barbiturate, is examined herein with respect to pharmacological classification by chemical (atomic) structure, mechanisms of action, partial and full effects of these agents and the 'ceiling effect', therapeutic uses, and DEA scheduling of these agents.

#### B. Pharmacological Classification of Midazolam and Thiopental

Midazolam belongs to the class of drugs called benzodiazepines and thiopental is a member of the barbiturate class of drugs (*Brenner and Stevens, 2013*). The chemical structure of midazolam and thiopental are shown in the first row of Table 1 below (next page) to provide an accessible first exposure to the differences between the two drugs. The untrained eye clearly recognizes that midazolam and thiopental do not have similar structures and are not close analogs. The second row in Table 1 (previous page) shows examples of other drugs from the same class of drugs as midazolam and thiopental. Most notably, at the center of the benzodiazepines there is 7-sided ring with two nitrogen atoms (N) attached to a 6-sided ring with one chloride atom (Cl). Quite differently, the two barbiturates do not contain such a core structure and instead consist of a single 6-sided ring containing two nitrogen atoms. The non-expert can see that the chemical structure of the benzodiazepine, midazolam is similar to diazepam (Valium®), and the chemical structure of the barbiturate, thiopental, is similar to pentobarbital (Nembutal®). There is an irrefutable difference between midazolam and thiopental at the atomic level.

In summary, Table 1 (next page) shows that pharmacological equivalency by consideration of chemical structures is NOT met when employing midazolam as a substitute for thiopental.

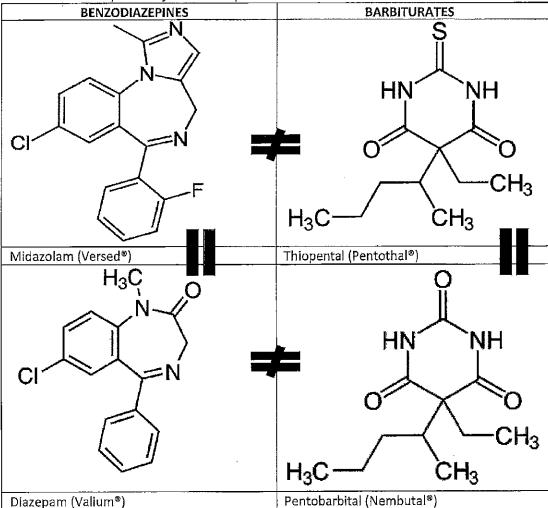


Table 1. Visual comparison of benzodiazepine and barbiturate chemical structures.

#### C. Mechanism of Action of Midazolam and Thiopental

The description of the pharmacology of drugs range from effects on the whole organism, to effects on specific tissues or organs, down to the actual mechanism of action at the molecular level. For many drugs, the action at the molecular level can be traced upward to the effect on the whole organism, yielding a nearly complete description of drug action.

Starting at the molecular level, both midazolam and thiopental act on the GABA<sub>A</sub> receptor-chloride ion channel complex (henceforth GABA<sub>A</sub> receptor). GABA is the acronym for gamma-aminobutyric acid, an inhibitory neurotransmitter in the brain that is the natural activator of GABA<sub>A</sub> receptors (*Sigel and Steinmann 2012, Sieghart 2015*). When inhibitory neurons of the brain release GABA onto other brain neurons, the recipient neurons are inhibited and become more quiescent. This is an ongoing neurotransmitter action, occurring without the presence of any drugs or exogenous substances in the brain. The GABA<sub>A</sub> receptor is shaped like a funnel

with a lid on it. When GABA binds to the receptor, the lid opens and chloride ions rush from the outside of the neuron to the inside. The chloride ions rushing inside the neuron causes the neuron to decrease its electrical activity.

Benzodiazepines act at the GABA<sub>A</sub> receptor on brain neurons where GABA itself acts (*Chang et al. 1981, Sigel and Barnard 1984*). Midazolam and all benzodiazepines do not increase the synthesis of the inhibitory neurotransmitter GABA but enhance the effect of GABA at the GABA<sub>A</sub> receptor (*Greenblatt et al. 1983*). Benzodiazepines bind to the GABA<sub>A</sub> receptor at a different site than GABA binds (*Cromer et al. 2002, Ernst et al. 2003*). GABA must be released by inhibitory neurons and be acting on the GABA<sub>A</sub> receptor at the same time as the benzodiazepine for drugs like midazolam to enhance GABA inhibition (*D'Hulst et al. 2009, Sieghart et al. 2012*). GABA acts on the receptor and opens the lid to the chloride ion channel (funnel) and midazolam increases the frequency that the lid opens (*Study and Barker 1981, Rogers et al. 1994*). In that way, midazolam helps GABA have a greater inhibitory effect, however without GABA present, midazolam does not activate the inhibitory GABA<sub>A</sub> receptor.

Barbiturates such as thiopental also act at the GABA<sub>A</sub> receptor on brain neurons where GABA itself acts (*Olsen and Snowman 1982, Greenfield LI 2013*). Barbiturates bind to a different spot on the GABA<sub>A</sub> receptors than benzodiazepines (*Cestari et al. 1996*). Unlike midazolam, thiopental and other barbiturates enhance GABA inhibition by increasing the time that the ion channel lid remains in the open position (*Study and Barker 1981*). Contrary to the mechanism of action of midazolam, thiopental, like all barbiturates, can cause neuronal inhibition even when GABA is not present (*Mathers and Barker 1980, Jackson et al. 1982*). Barbiturates therefore can open the lid on the ion channel by themselves and keep it open longer than benzodiazepines (*MacDonald et al. 1989, Sancar and Czajkowski 2011*). As a result, the flow of chloride ions into the neuron is not limited to enhancement only when GABA is present, but barbiturates can increase the rush of chloride ions into the neuron in the absence of GABA so that the activity of the neuron is completely shut down. Thus, barbiturates are more potent drugs at the GABA<sub>A</sub> receptor than benzodiazepines.

In summary, a large body of pharmacological research on the mechanisms of action of midazolam and thiopental clearly demonstrates that benzodiazepines, like midazolam, and barbiturates, such as thiopental, do NOT exhibit pharmacological equivalency with regard to their detailed mechanism of action. Compared to barbiturates, benzodiazepines bind to a different site on the GABAA receptor, need GABA to co-activate the GABAA receptor to work, and increase the frequency of the opening of the chloride ion channel not the time it remains open.

D. The Pharmacology of the Partial Agonist, Midazolam, and the Full Agonist, Thiopental

Most drugs that are used clinically do something to cells or neurons that they affect. They bind to (act on) a target receptor and the receptor does something, like open an ion channel. These types of drugs that do something are called agonists. Other types of clinically-used drugs, like the antihypertensive drugs called 'beta-blockers', bind to a receptor and prevent another substance from doing something. These drugs are called antagonists.

Agonists are further subdivided into partial agonists and full agonists. As their name suggests, full agonists produce a full pharmacological effect and partial agonists only produce a partial pharmacological effect. The difference between one drug being a partial agonist and another drug being a full agonist arises from the two drugs differing mechanism of action.

As noted above, midazolam, like all benzodiazepines, increases the frequency (not the duration) of ion channel opening only when GABA is present. As GABA is a neurotransmitter synthesized by inhibitory brain neurons, the amount of GABA released onto GABAA receptors is limited. Because midazolam depends on the co-activation of GABA to produce its effects, midazolam effects on the brain are therefore also limited. In this regard, midazolam is a partial agonist. Thiopental, to the contrary, does not need co-activation by GABA to produce its effects. In this regard, the neuronal inhibition produced by barbiturates is not limited. In this regard, thiopental is a full agonist.

By definition, partial agonists will exhibit a 'ceiling effect' in which greater doses will not produce a greater pharmacological effect. The ceiling effect of benzodiazepines, and the lack of ceiling effect for barbiturates, is so well-accepted that many medical pharmacology textbooks contain a Figure illustrating this fact. Fig. 1 below shows one such example.

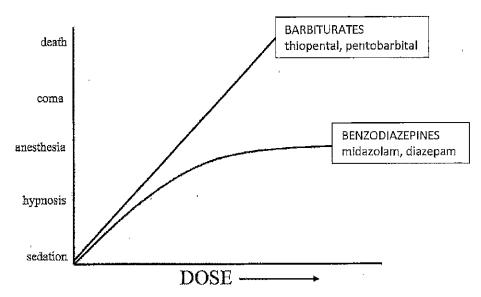


Fig. 1. Typical textbook example of a graph showing the differences between barbiturates (top line) and benzodiazepines (bottom line). The dose increases along the horizontal axis as you move to the right; the effects in humans increase as you move up the vertical axis. Note that the ceiling effect shown for benzodiazepines versus lack of ceiling effect for barbiturates. As the dose of benzodiazepine increases, a plateau ('ceiling') is reached before reliable general anesthesia is obtained. Increasing doses of barbiturates reliably produce anesthesia, coma, and death. Note: the term 'hypnosis' is medical terminology for 'sleep'. Adapted from Brenner and Stevens 2013.

In summary, the fact that midazolam is a partial agonist, and that thiopental is a full agonist, arises directly from their mechanisms of action as barbiturates can act in the absence of GABA and increase the inhibition of brain neurons whereas midazolam and other benzodiazepines are limited with their effect only when GABA is present and thus cannot inhibit neurons as much as barbiturates. This pharmacological fact demonstrates that pharmacological equivalency is NOT met by substitution of a barbiturate with a benzodiazepine. The ceiling effect of midazolam and other benzodiazepines, and the lack of ceiling effect with the use of thiopental and other barbiturates, is beyond controversy and taught to all medical and pharmacology students.

#### E. Therapeutic Uses of Benzodiazepines and Barbiturates

The therapeutic use of a drug is a direct result of the drug's pharmacological properties, including, most importantly, a drug's mechanism of action. As noted above, while both benzodiazepines and barbiturates act on the GABAA receptor, they do so in very different ways. Because of the difference in their mechanism of action, the clinical use of benzodiazepine and barbiturate drugs are for different therapeutic reasons.

Table 2 is a list of therapeutic uses for benzodiazepines and barbiturates. Entries marked with a 'YES' indicate that the class of drugs is FDA-approved for this indication and show which particular drug(s) is approved for this therapeutic use.

Table 2. Comparison of therapeutic uses for five benzodlazepines and five barbiturates.

Therapeutic Use	Benzodiazepines	Barbiturates		
Anxiety disorders	YES, alprazolam, diazepam, lorazepam	YES but only for 'sedation' with butabarbita!		
Panic Disorder	YES, alprazolam, clonazepam	NO		
Acute Alcohol Withdrawal	YES, diazepam	NO		
Skeletal Muscle Spasm	YES, diazepam	NO		
Seizure Disorders	YES, clonazepam, diazepam	YES, pentobarbital (IV), phenobarbital (IV), thiopental (IV)		
Preoperative Sedation	YES, midazolam (IM/IV)	YES, pentobarbital (IV), secobarbital		
Outpatient Sedation	YES, midazolam (IV)	NO		
Anesthesia Induction	YES, midazolam (IV)	YES, thiopental (IV)		
Sole Anesthesia (brief)	NO	YES, thiopental (IV)		
Sedation for Intubated Ptx	YES, midazolam (iV cont.)	NO		
Co-Anesthesia (Adjunct)	YES, midazolam (IV)	YES, thiopental (IV)		
Insomnia (short-term)	NO	YES, butabarbital, secobarbital, pentobarbital (IV)		
Induce Coma in Brain Trauma	NO	YES, thiopental (IV)		
Psychiatric Use (Narcoanalysis)	NO	YES, thiopental (IV)		

Notes: Benzodiazepine data of therapeutic uses are from the FDA-approved Prescribing Information labels of alprazolam (Xanax®), clonazepam (Klonopin®), diazepam (Valium®), lorazepam (Ativan®), and midazolam (Versed® injection). Barbiturate data are from the current FDA-approved labels for butabarbital (Butisol®), pentobarbital (Nembutal® injection), phenobarbital (Luminal®), secobarbital (Seconal®) except the discontinued label for thiopental (Pentothal®) which is no longer marketed. All drug formulations are oral tablets except where noted; IV=intravenous, IM=intramuscular.

As shown in Table 2 above, there are 14 therapeutic uses for the benzodiazepine and barbiturate drugs. Among these 14 therapeutic uses, only 5 (or 35.7%) are common to both benzodiazepines and barbiturates. These shared indications are Anxiety Disorders, Seizure Disorders, Preoperative Sedation, Anesthesia Induction, and Adjunct/Co-Anesthesia (used with a general anesthetic). It should be noted that benzodiazepines for the treatment of Anxiety Disorders have almost universally supplanted the older barbiturate drugs for this use (*Howie 1975*, *Pieters and Snelders 2007*). Five indications are for the use of benzodiazepines only; Panic Disorder, Acute Alcohol Withdrawal, Skeletal Muscle Spasms, Outpatient Sedation, and Sedation for Intubated Patients. Four indications are for the use of barbiturates only; Sole Anesthesia (for brief procedures), Insomnia (for short-term treatment of 2 weeks), Induce Coma in Brain Trauma, and the Psychiatric Use (Narcoanalysis), which is the limited and historical use of thiopental to get a therapy patient to talk, as in 'truth serum'.

With regards to specific drugs, out of five indications for midazolam, midazolam shares only two therapeutic uses with thiopental – anesthesia induction and co-anesthesia.

The demonstration that benzodiazepines and barbiturates, and more specifically midazolam and thiopental, have different therapeutic uses shows that pharmacological equivalency of barbiturates and benzodiazepines is NOT met considering the criteria of approved therapeutic uses. Most importantly, midazolam was not approved for use as a Sole Anesthetic. In contrast, thiopental, was approved as a Sole Anesthetic for brief procedures.

#### F. DEA Scheduling of Midazolam and Thiopental

Most prescription drugs are safe and without the potential for abuse and dependence. Thus the vast majority of drugs prescribed by physicians do not come under the purview of the Drug Enforcement Administration (DEA). Drugs that pose a special danger of abuse or drug dependence are tightly regulated by the DEA and are called controlled substances.

Midazolam and thiopental are controlled substances according to the DEA, as promulgated by the Controlled Substances Act of 1970. The DEA places dangerous drugs into five schedules, with Schedule I drugs being the most dangerous drugs with no approved medical use. Schedule II-V are drugs with medical uses but with decreasing danger of abuse and dependence. Midazolam, as with most of the other benzodiazepines like diazepam (Valium®) and lorazepam (Ativan®) are placed into Schedule IV. Thiopental is deemed a more dangerous drug than midazolam as thiopental is a Schedule III controlled substance. This is evidence that midazolam is deemed safer to use by the DEA, with less evidence of abuse and drug dependence than thiopental. Simply put, the DEA decision to schedule midazolam and thiopental differently reflects the DEA finding that midazolam and thiopental do NOT exhibit pharmacological equivalency in causing drug dependence and abuse.

#### G. Summary

Pharmacological equivalency between benzodiazepines and barbiturates, and more specifically between midazolam and thiopental, was investigated by examining key aspects of the pharmacology of the two drugs and their drug classes. The findings from this section are:

- i. There is no pharmacological equivalency between midazolam and thiopental using the criterion of chemical structures for benzodiazepines and barbiturates
- ii. There is no pharmacological equivalency when examining the different mechanisms of action of benzodiazepines (midazolam) and barbiturates (thiopental).
- iii. There is no pharmacological equivalency between the magnitude of pharmacological effects produced by benzodiazepines (partial agonists) and barbiturates (full agonists). In particular, it is well-known that midazolam has a ceiling effect that is not present in thiopental.
- iv. There is little pharmacological equivalency when examining the different therapeutic uses of benzodiazepines and barbiturates, or between midazolam and thiopental.
- v. There is no pharmacological equivalency in the drug abuse and dependence properties of midazolam and thiopental as confirmed by the different scheduling of these drugs by the DFA.

## 3. Dosage and Characteristics of Thiopental Used in Lethal Injection

A. Therapeutic, Toxic, and Lethal Blood Concentrations of Thiopental

Barbiturates are a class of sedative-hypnotic drugs, largely replaced in clinical therapeutics by the benzodiazepine class of sedative-hypnotics (*Brenner and Stevens 2013*). Examples of common barbiturate drugs are thiopental, pentobarbital, phenobarbital, and methohexital.

Clinical studies and forensic toxicology studies have determined the therapeutic, toxic, and lethal blood concentrations of thiopental, pentobarbital, midazolam, and diazepam (*Musshoff et al. 2004; Regenthal et al. 1999; Schulz 2012; Winek et al. 2001*). These values are given in blood concentration ranges from the most recent paper, as shown in Table 3 below.

Table 3. Therapeutic, toxic, and lethal ranges of thiopental, pentobarbital, midazolam, and diazepam blood concentrations. Concentrations given in mg/L (milligram per Liter). Half-life ( $t_{1/2}$ ) is the time in hours it takes for half the amount of drug to be eliminated. From Schulz et al. 2012.

Substance/Class	Blood-plasma concentration (mg/L)			Half-life, t <sub>1/2</sub> (hours)	
	Therapeutic	Toxic	Comatose-Fatal		
BARBITURATES					
Thiopental	1-5	7	10-15	3-8 h	
Pentobarbital	1-10	10-19	15-25	20-40 h	
BENZODIAZEPINES					
Midazolam	0.04-0.25	1-1.5		1.5-3.0 h	
Diazepam	0,1-0.25	3-5		24-48	

Table 3 above shows that there are known therapeutic and toxic blood concentrations for the barbiturates, thiopental and pentobarbital, and for the benzodiazepines, midazolam and

diazepam. However, there are only Comatose-Fatal concentrations given for thiopental and pentobarbital. The Comatose-Fatal concentration for midazolam (or diazepam) is not known.

Given the fatal blood concentrations for thiopental above, it is of considerable interest to calculate the blood concentration that results from the IV administration of 2 grams thiopental used in the 3-drug lethal injection protocol. Once a reasonable estimate is made of the thiopental blood concentration after a 2 gram IV thiopental dose, this blood concentration obtained can be compared to fatal thiopental concentration range as shown in Table 3, above.

# , B. Thiopental Blood Levels following a 2 gram dose of IV Thiopental in Humans

There are no clinical studies determining the lethal dose of IV thiopental in humans for obvious reasons. However, there is an early report from 1950 that used IV thiopental doses of 1, 2 and 3.8 grams administered over 5 minutes (two lower doses) or 50 minutes (3.8 g dose) to human volunteers (*Brodie et al. 1950*). While initial blood concentrations of thiopental were not determined in these volunteers, the authors note that following these large doses of IV thiopental, the volunteers were deeply asleep and had to be on an a respirator until spontaneous ventilation was deemed adequate. Such studies could not be performed today due to safety and ethical concerns, but it is clear that 1–3.8 grams of IV thiopental was a lethal dose in this study as it caused the volunteers to stop breathing on their own.

The study of drug movement after administration is called pharmacokinetics. The pharmacokinetics of thiopental are characterized by a rapid distribution of thiopental from the bloodstream to the tissues of the body and into the brain. With direct IV administration, there is no absorption phase of the drug like when a pill is swallowed. For this reason, the peak plasma concentration of IV thiopental is observed with the first time point of sampling after the IV bolus injection.

As mentioned above, there are no studies in the literature that give the initial blood concentrations of thiopental following a 2 gram IV dose as this is higher than approved clinical doses. However it is possible to examine the thiopental blood concentrations in humans from studies following the administration of lower doses of IV thiopental. The data from these clinical studies can then be used to model the blood concentrations of thiopental after a 2 gram IV dose.

An early clinical study examined the relationship between IV thiopental doses and blood concentrations of thiopental in surgical patients with renal failure compared to age-matched normal controls (Burch and Stanski 1982). These authors found that renal patients had a larger unbound fraction of thiopental in their blood. In another clinical study, an IV bolus dose of 300 mg thiopental gave a peak blood concentration of approximately 40 mg/L (Morgan et al. 1981). In a study comparing ages of patient groups, the administration of 285 mg of IV thiopental gave an initial thiopental blood concentration of approximately 35 mg/L (Avram et al. 1990). Although sufficient clinical data are lacking to assure a linear relationship between the administered doses of IV thiopental and resulting thiopental blood levels, the above studies and

the one highlighted next, show that the relationship between IV thiopental dose and thiopental blood concentrations is at least dose-dependent.

The graph below (Fig. 2, top of next page) shows the blood concentrations of thiopental from a study of surgical patients following a 400 mg IV thiopental dose given in 5 seconds (*Burch and Stanski 1983*). The maximum (peak) concentration of thiopental was approximately 60 mcg/ml (equal to 60 mg/L) at 30 seconds after administration. By 10 mins after administration, thiopental blood levels are within the therapeutic range at 5 mg/L (see Table 3 above).

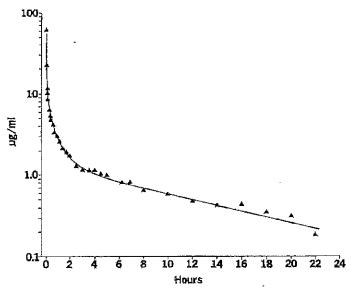


Fig. 2. Blood levels of thiopental after rapid IV injection of 400 mg thiopental. From (Burch and Stanski 1983). Note: µg/mL (mcg/mL) is equal to mg/L.

Given that a 400 mg IV dose of thiopental gave an initial thiopental blood concentration of 60 mg/L , to a first approximation, it follows that a 2,000 mg (=2 gram) IV dose of thiopental would give an initial thiopental blood concentration of 300 mg/L. This is calculated from the fact that a 2,000 mg IV dose is 5 times greater than the 400 mg IV dose and 5 times 60 mg/L equals 300 mg/L. By examining therapeutic, toxic, and fatal blood levels given in Table 3 above, this initial thiopental blood concentration of 300 mg/L after a 2 gram IV dose of thiopental is 20 to 30 times greater than the fatal blood concentration for thiopental listed as 10-15 mg/L.

The above calculation that shows that a dose of 2 grams of IV thiopental yields an initial blood concentration of 300 mg/L, which quickly decreases over the next hour, as shown in Fig. 2 above. It can be seen from Figure 2 above that the fall of thiopental blood concentrations occurs in two parts; the decrease in thiopental occurs more rapidly for the first hour, then the concentration of thiopental changes slowly from the thiopental levels seen at one hour. The first rapid phase of the decrease in thiopental concentrations is due to the rapid distribution of thiopental from the blood to the brain and other tissues. The second, slower phase in the decrease of thiopental is due to a slower distribution of thiopental to the tissues and the elimination of thiopental from the blood by metabolism and excretion. The time it takes for the

thiopental blood level to decrease by one-half is called the 'half-life' ( $t_{1/2}$ ). The first rapid phase of thiopental decrease has a smaller half-life than the half-life of the second slower phase of thiopental decrease.

In order to determine the fall of thiopental concentrations over time, it is necessary to use the half-life data for IV thiopental from the pharmacokinetic studies cited above. Pharmacokinetic studies of IV thiopental show a rapid distribution half-life of 4.6 min and an elimination half-life of 11.5 hours (*Morgan et al. 1981*). Using these half-life values, the pharmacokinetic modeling of a 2 gram (2,000 mg) IV thiopental dose was done using an Excel® spreadsheet, as noted previously in the scientific literature (*Chamberlain 2003*).

The resulting graph of the decrease in thiopental blood levels after IV injection of 2 grams (2,000 mg) is shown in Figure 3 below. This graph shows that with an initial plasma concentration of 300 mg/L thiopental, the blood levels of thiopental decrease to 13 mg/L after 120 minutes. Within the first 5 minutes, the blood levels decrease to 140 mg/L (inset graph, Figure 3, below). Comparing these blood levels of thiopental with the fatal concentrations summarized in Table 3 above, after the first 5 minutes, the 2 gram IV dose of thiopental yields blood levels of thiopental (140 mg/mL) that are 9.3 to 14 times higher than fatal thiopental blood concentrations (10-15 mg/L). After 120 minutes, the 2 gram thiopental dose gives blood levels (13 mg/mL) that remain in the range of fatal thiopental concentrations.

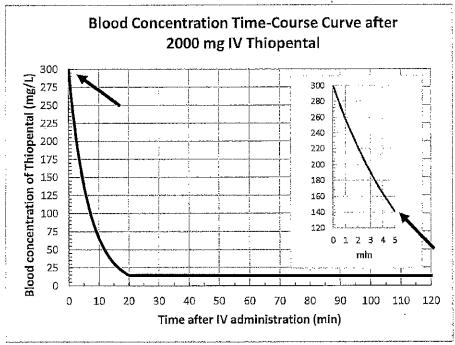


Fig. 3. Blood levels of thiopental following IV injection of 2 grams (2,000 mg) as modeled by available data. The initial plasma concentration was 300 mg/L (at left arrow). The rapid decrease used a half-life of 4.6 min that lasted for 20 min; the slower elimination phase used a half-life of 11.5 hours (Morgan et al. 1981). Inset graph in upper right corner shows an enlargement of the first 5 minutes after IV injection (right arrow).

## C. Summary

The findings from this section are:

- i. The normal therapeutic blood concentration of thiopental ranges from 1-10 mg/L. Toxic blood concentrations of thiopental occur at 7 mg/L and fatal concentrations of thiopental range from 10-15 mg/L and higher.
- ii. A 2 gram IV bolus dose of thiopental produces initial thiopental blood concentrations of about 300 mg/L, which is 20 to 30 times greater than the fatal blood concentration range of thiopental. After 5 minutes, the blood concentration of thiopental decreases to about 140 mg/mL which is 9.3 to 14 times greater than the fatal blood concentrations of thiopental. After 2 hours, the blood concentration of thiopental remains within the fatal blood concentration range for thiopental.

## 4. Calculation of the 'Ceiling Effect' Dosage of Midazolam Used in Lethal Injection

A. Introduction to the Issue of the 'Ceiling Effect' With an IV Bolus Dose of Midazolam

In the denial of the Petitioners' appeal in Oklahoma's Glossip et al. v. Gross et al case, the Supreme Court of the United States makes a point of the ceiling effect and the importance of knowing the dosage of midazolam wherein the ceiling effect occurs (Slip Opinion, Glossip et al. v. Gross et al. No. 14-7955, Argued April 29, 2015-Decided June 29, 2015):

"What matters for present purposes is the dosage at which the ceiling effect kicks in, not the biological process that produces the effect." (p. 25)

Therefore, the determination of the midazolam IV dosage that reaches the ceiling effect, and a comparison of the concentration of midazolam that produces a ceiling effect in research studies and the concentration of midazolam in the brain of the condemned inmate after receiving a dose of 500 mg IV midazolam, is detailed in this section.

A 500 mg IV dose of midazolam is examined because the current Lethal Injection Protocol embedded in the Mississippi Department of Corrections (MDOC) Policy "Capital Punishment Procedures" (Doc. 38-2, filed 7/28/2015) was amended to include the use of midazolam as an alternative first drug (if thiopental and pentobarbital are not available) in a 3-drug protocol with midazolam given at an IV dose of 500 mg.

In light of the revised MDOC's lethal injection protocol, the present determination is based on whether the ceiling effect of midazolam is reached at or below the brain concentration of midazolam produced immediately after the IV bolus administration of 500 mg midazolam dose and the brain concentration up to 5 minutes after IV midazolam administration. There is no reference in the MDOC Protocol to a time point when the effect of midazolam will be assessed after IV administration of 500 mg midazolam.

The 'ceiling effect' refers to the fact that greater amounts or doses of midazolam do not produce a greater pharmacological effect. The ceiling effect is well-known for midazolam and all similar drugs in the class called benzodiazepine sedative-hypnotics. By way of contrast, there is no ceiling effect seen with barbiturate sedative-hypnotics like thiopental and pentobarbital.

To determine the midazolam dose which produces a ceiling effect in humans is not easy, as it is ethically not possible to experiment on humans and administer doses greater than those used clinically. Therefore, the approach used in this report is to first examine the midazolam concentrations used in studies done in vitro (using cells in a laboratory dish) and determine at which concentration of midazolam that the ceiling effect occurs. Secondly, a calculation of the plasma (blood) concentration of midazolam following a 500 mg IV bolus dose (bolus means a single IV injection all at one time as opposed to continuous infusion at a lower rate) will be made based on blood concentrations of midazolam following clinically-used doses. Thirdly, based on the pharmacological data of midazolam crossing into the brain in preclinical studies, the extent of the 500 mg midazolam dose that enters the brain will be calculated. Fourthly, published studies will be researched to calculate the concentration of midazolam in the brain after a 500 mg IV dose. Finally, by comparing the concentration of midazolam that produces a ceiling effect in studies done in vitro and in the clinic, with the calculated concentration of midazolam in the human brain after a 500 mg dose, conclusions will be reached to determine if this 500 mg dose is above or below a midazolam concentration shown to produce a ceiling effect.

## B. Ceiling Effect of Midazolam and Other Benzodiazepines Observed In Vitro

As detailed in §2C above, the mechanism of action of midazolam and other benzodiazepines is enhancing the inhibitory effect of the neurotransmitter, GABA, on brain neurons. The decrease in neuronal activity produced by the inhibitory neurotransmitter, GABA, is not 'all or none'. GABA simply decreases the ongoing activity of neurons by a graded amount, depending on how much GABA is present. GABA is a limited resource in the brain as it is made and released by inhibitory brain neurons, which are finite in number. The concentration of GABA around brain neurons is reported to be 10-400 nM (*Houston et al. 2012*). This information on the concentration of GABA is important in calculating the celling effect of midazolam (see below), as midazolam has to have GABA present to exert its pharmacological effect.

A little more pharmacology of benzodiazepine's mechanism of action and an analogy is needed. Midazolam and other benzodiazepines potentiate the binding of GABA at the GABAA receptor, but at a site different than where GABA binds. This is called allosteric modulation. To use an analogy, the allosteric action of midazolam might be thought of as a Boy Scout helping an elderly woman (GABA) across the street. The woman can cross the street without the Boy Scout (midazolam) but his presence and assistance helps the elderly woman move faster. Midazolam and other benzodiazepines can only enhance GABA action and have no inhibitory action on brain neurons on their own. Benzodiazepines by this allosteric mechanism of action have an innate 'ceiling effect' and can only produce a limited plateau effect. Using our analogy, the Boy Scout can move the elderly woman across the street only so fast, the act of getting the woman

across the street is still limited by the ability of the woman to ambulate on her own two legs. There is a 'ceiling effect' in how fast the woman can cross the street, even if two or more Boy Scouts were to help her.

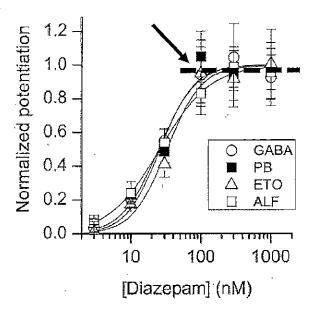
The celling effect of midazolam and other benzodiazepines is not controversial and is portrayed in many introductory pharmacology textbooks (see Fig. 1 above). The remainder of this section will highlight studies from the scientific literature that show the ceiling effect of midazolam and other benzodiazepines and provide specific threshold drug concentrations from these studies when the ceiling effect was reached. This ceiling effect with benzodiazepines, including diazepam (Valium®) and midazolam (Versed®) was observed early and consistently in the research studies that determined the mechanism of action for benzodiazepine drugs. Samples of figures from these original research papers are reproduced below (next two pages) so that it will be obvious that a ceiling effect is documented and pervasive in the scientific and pharmacological literature.

The studies shown on the next two pages and others are summarized in Table 4 below showing the threshold dose(s) that produced the observed ceiling effect. Most studies of diazepam show a ceiling effect threshold at 100 nM and all three studies of midazolam gave 100 nM as the concentration producing a ceiling effect.

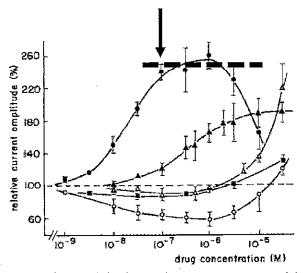
Table 4. Summary of selected studies showing ceiling effect of diazepam and midazolam

Benzodiazepine	Ceiling effect at:	Preparation	Reference  Skerritt and Macdonald  (1984)	
Diazepam	10 nM <sup>a</sup>	Cell culture (mouse spinal neurons)		
Diazepam	100 nM	Cell culture (oocytes)	Sigel and Baur (1988)	
Diazepam	50-100 nM	Cell culture (mouse spinal neurons)	Rogers et al. (1994)	
Diazepam	100 nM Cell culture (HEK cells)		Li et al. (2013)	
Diazepam	100 nM	100 nM Cell culture (oocytes) Rüsch		
Midazolam	100 nM Brain slices (rat) R		Rovira and Ben-Ari (1999)	
Midazolam	100-200 nM	Brain slices (rat)	Bai et ál. (2001)	
Midazolam	100 nM	Cell culture (oocytes)	Rüsch and Forman (2005)	

<sup>&</sup>lt;sup>a</sup> nM stands for 'nanomolar' which is a concentration term relating the number of drug molecules in a liter of solution.



**Fig. 4.** Various doses of the benzodiazepine, Diazepam, were added with GABA (open circles) and other drugs and the current measured on the vertical scale (Y-axis). Arrow shows ceiling effect threshold at 100 nM. Horizontal dash line shows the ceiling effect. From Fig. 4 in *Li et al. 2013.* 



**Fig. 5.** Various doses of the benzodiazepine, Diazepam (closed circle, top curve) were applied to cells in the presence of GABA and the current measured on the vertical scale (Y-axis). Arrow shows ceiling effect threshold at 10<sup>-7</sup> M which is equal to 100 nM. Horizontal dash line shows the ceiling effect. From Fig. 4 in *Sigel and Baur 1988*.

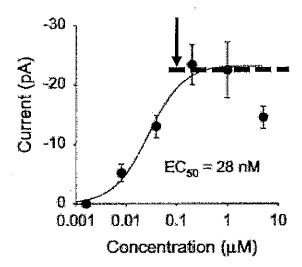
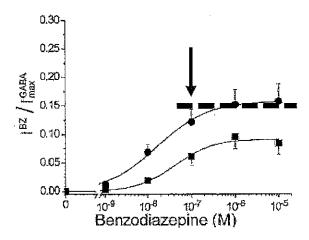


Fig. 6. Various doses of Midazolam (closed circle, top curve) along the horizontal scale (x-axis) were applied to cells in the presence of GABA and current measured on the vertical scale (Y-axis). Arrow shows ceiling effect threshold at 0.1  $\mu$ M which is equal to 100 nM. Horizontal dash line shows ceiling effect. From Fig. 5B in *Bai et al. 2001*.



**Fig. 7.** Various doses of Midazolam (closed circle, top curve) or Diazepam (closed squares, bottom curve) along the horizontal scale (x-axis) were applied to cells in the presence of GABA and current measured on the vertical scale (Y-axis). Arrow shows ceiling effect threshold at 10<sup>-7</sup> M which is equal to 100 nM. Horizontal dash line shows ceiling effect. From Fig 2A in *Rüsch and Forman 2005*.

## C. Blood Levels of 500 Mg Midazolam after IV Bolus Dose in Humans

As mentioned above, there are no studies in the literature that give the plasma concentrations of midazolam following a 500 mg IV dose in humans as this is higher than approved clinical doses. However, it is possible to review the plasma concentrations in humans from studies examining the plasma concentrations after clinical doses of IV midazolam. The data from these studies can then be used to model the plasma concentrations of midazolam after a 500 mg IV dose.

A clinical study measured the peak amount of midazolam in the plasma after IV bolus administration of 5 mg midazolam in eight healthy volunteers (*Schwagmeier et al. 1998*). This study gave peak plasma concentrations of nearly 120 ng/mL (nanogram per milliliter) after a 5 mg IV dose. It follows then that with a 500 mg IV dose, the initial amount after direct IV bolus infusion is 100 times of what occurred with the 5 mg dose, which gives an initial plasma concentration of 12,000 ng/mL of midazolam after a 500 mg IV dose.

A direct linear modeling of the 500 mg IV dose from the 5 mg dose is supported by other studies. In a more recent study using half of the above 5 mg IV dose, a 2.5 mg IV dose of midazolam, the peak plasma concentration of 51.2 ng/mL which is about half the peak plasma concentration seen in the above clinical study using a 5 mg IV dose of midazolam (*Veldhorst-Janssen et al. 2011*). Therefore it is not unreasonable to use this linear relationship to extrapolate from the 5 mg giving 120 ng/mL and one-hundred times that dose (500 mg) giving one-hundred times the initial blood concentration for a result of 12,000 ng/mL.

Given the estimate that the initial concentration of midazolam in the plasma after a 500 mg IV bolus dose is 12,000 ng/mL, the next determination is to model the fall of midazolam plasma concentration over time to determine the amount of midazolam that is available for transfer to the brain during the first 5 minutes.

In order to determine the midazolam plasma concentrations over time, it is necessary to have established pharmacokinetic data for IV midazolam. A key paper in this regard examined the pharmacokinetic data after dosing volunteers with 0.1 mg/kg midazolam IV infusions after 1 minute, 1 hour, and 3 hour lengths of infusion (*Greenblatt et al. 2004*). The dosing of midazolam with a 1 minute bolus infusion comes closest to the method to be used by the Mississippi Department of Corrections (MDOC, see above). The Greenblatt study found that midazolam IV dose given in 1 minute had a half-life of immediate distribution ( $t_{\text{M alpha}}$ ) of 21 min and a half-life of elimination ( $t_{\text{M beta}}$ ) of 171.6 minutes. Using these two parameters, it was possible to model the plasma concentration curve over time following the IV dose of 500 mg midazolam (see Fig. 6 next page). The modeling of the blood concentration curve following a 500 mg IV midazolam dose was done using an Excel spreadsheet, as noted in the scientific literature (*Chamberlain 2003*) and was done above in §3B.

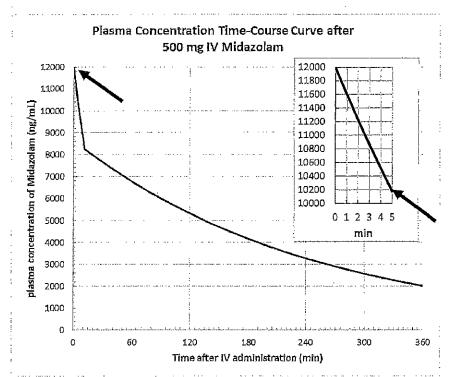


Fig. 8. Plasma concentration curve following a single IV bolus dose of 500 mg midazolam. Inset shows the region of the plot from 0-5 minutes. See text for further details. Arrows denote the initial blood concentration of midazolam and midazolam concentration after 5 minutes (inset).

The key parameters calculated above are that following the 500 mg IV dose of midazolam, the initial highest concentration of midazolam is 12,000 ng/mL and after 5 minutes, the concentration of midazolam is 10,200 ng/mL.

### D. Extent of Midazolam Entering the Human Brain after an IV Bolus Dose

Studies that show the amount or extent of midazolam that enters the human brain would be best done by administering an IV dose and then sampling brain tissue at various time points after administration in numerous people. These studies, of course, cannot be done. However, there have been a number of preclinical studies in non-human animals that provide the fraction of midazolam that crosses into the brain from the blood to give reliable data. These studies are reviewed next and will provide a value that can be used to determine the amount or extent of midazolam that enters the human brain after a 500 mg IV dose.

However, it should first be noted that drugs in the plasma or blood bind to plasma proteins such as albumin and gamma-globulins and the amount of protein binding varies with each drug. This is important as only the free (unbound) drug is available to cross from the blood into the brain to exert its effect. Midazolam is a drug with high plasma protein binding, on the order of

94-97% (*Fragen 1997*). Using 95% as an estimate, this gives only 5% of the amount of midazolam in the blood available for crossing the blood-brain barrier and entering the brain. Taking this into account for the two key parameters of interest noted above, a 500 mg IV bolus of midazolam gives an initial free drug blood plasma concentration of 600 ng/mL (12,000 X 0.05) and a free drug blood concentration at 5 minutes of 510 ng/mL (10,200 X 0.05).

Preclinical studies of the fraction of midazolam that enters the brain after an IV dose are done by sampling the cerebrospinal fluid (CSF) along with the plasma at various times after midazolam administration (*Arendt et al. 1983*, *Jones et al. 1988*). The CSF is a good surrogate for the fluid surrounding the brain cells as it is relatively protein-free so there is little to no binding of drugs to proteins like that which occurs in the blood. The CSF circulates around and through the brain and spinal cord, bathing the CNS (*Lin 2008*). Fig. 9 below (next page) shows the concentration of midazolam in the blood and in and brain CSF at the same time points from the paper by *Arendt 1983*.

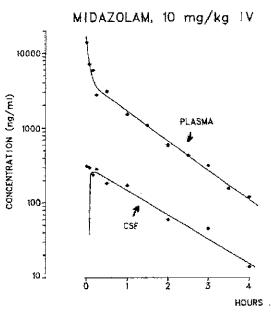


Fig. 9. Midazolam concentrations curve in plasma (top curve) and in brain CSF (bottom curve) after a single 10 mg/kg IV bolus dose. Note that the CSF concentration is much less than plasma at all time points but mirrors the plasma curve. From Fig 2 (left panel) in *Arendt et al.* (1983).

The calculations performed in the study shown in Fig. 9 yielded a brain CSF/plasma concentration ratio of 0.14 or 14% (*Arendt et al. 1983*). This ratio can be used in our determinations of brain concentration after 500 mg IV dose of midazolam to calculate that an initial plasma concentration of 600 ng/mL midazolam equals 84 ng/mL in the brain (600 X 0.14) and at 5 minutes after start of infusion, the plasma concentration of 510 ng/mL is equal to 71.4 ng/mL (510 X 0.14) in the brain.

## E. Dosage of IV Midazolam That Produces a Ceiling Effect in Humans

The above data gave the measurement of midazolam in blood in the units of ng/mL, or nanogram per milliliter (ng/mL is a weight per volume measure, like mixing a teaspoon of salt in a glass of water). However, the existing data on the concentration of midazolam that produces a ceiling effect from *in vitro* studies reviewed above gave a value of 100 nM (nanomolar) which is in different units. The brain concentration of midazolam (in ng/mL) calculated in the last section above needs to be converted to nanomolar terms (nM) to compare it with the existing *in vitro* data showing that midazolam's ceiling effect occurs at a midazolam concentration of 100 nM. This conversion is done by using the molecular weight of midazolam which gives the relationship between grams and moles<sup>1</sup>. For example, a concentration of midazolam of 32.6 ng/mL in the brain equals 100 nM in nanomolar terms.

The calculated values of the brain concentrations of midazolam following a 500 mg IV dose give an estimate of 84 ng/mL when the infusion begins and 71.4 ng/mL after 5 minutes elapsed since the start of the infusion. These two values expressed in nM are: 84 ng/mL = 257.9 nM and 71.4 ng/mL = 219.2 nM.

Given that midazolam shows ceiling effects at 100 nM concentration (see Table 1 above), the estimated brain concentrations for midazolam under the current MDOC Mississippi lethal injection protocol using a 500 mg IV dose of midazolam as the first drug are about 2.2 to 2.6 times higher than the concentration of midazolam that produces a ceiling effect. Furthermore, the concentration of the inhibitory neurotransmitter, GABA, in the vicinity of neurons in the brain is reported as ranging from 10-400 nM (Houston et al. 2012). Taking a mid-range value of the GABA concentration at 200 nM, when the midazolam brain concentration produced by a 500 mg IV dose of midazolam is at 257.9 nM, there is about 1.3 times more midazolam than GABA (calculated by 257.9/200). As midazolam cannot by itself work without GABA present, once midazolam has worked with all the GABA that is available, there is about a third more midazolam that cannot exert a pharmacological effect.

The midazolam dose that results in a 100 nM concentration of midazolam, the ceiling effect concentration, is obtained by using the values of brain concentration obtained with a 500 mg IV dose above. A 500 mg IV dose gives a brain concentration of 257.9 nM (call it 250 nM) which is 2.5 times the ceiling effect concentration of 100 nM. Therefore, a dose that is 2.5 times less than 500 mg is 200 mg. Thus, a 200 mg IV dose of midazolam would be expected to reach the threshold concentration of midazolam to produce a ceiling effect.

In the clinic, the range of midazolam IV doses for intravenous sedation is 5 to 15 mg IV, with a standard patient weighing 100 kg or about 220 pounds (*Reves et al. 1985*). Even when used at higher doses for induction of anesthesia, the range is 15 to 40 mg IV. The analysis presented here suggest that the highest clinically-used do not approach the ceiling effect dosage and that the usual clinical midazolam IV doses produce brain concentrations that are far below the

<sup>&</sup>lt;sup>1</sup> Calculations were assisted by the Molar solution concentration calculator found at www.physiologyweb.com.
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<u>ceiling or plateau effect</u>. This is consistent with clinical rationale whereby greater doses of drugs are not given if there is no greater pharmacological effect observed.

Most telling is the lack of a fatal blood level range for midazolam in the latest compendium of therapeutic, toxic, and fatal blood levels of over 1,000 drugs (*Schulz et al. 2012*). Table 5 below (which is a repeat of Table 3 above) highlights in bold lines the <u>blank space</u> for the fatal blood levels of midazolam (and for diazepam). This shows that there are few reported fatalities and no consensus whether fatal effects occur with midazolam and at what dosage range they may occur.

Table 5. Therapeutic, toxic, and lethal ranges of thiopental blood concentrations. Concentrations given in mg/L (milligram per Liter) which is equal to mcg/mL (microgram per milliLiter). Half-life ( $t_{1/2}$ ) is given in the last column and is the time in hours it takes for half the amount of drug to be cleared from the bloodstream. From Schulz et al. 2012.

Substance/Class	Blood-plasma concentration (mg/L)				
	Therapeutic	Toxic	Comatose-fatal	Half-life, t <sub>1/2</sub> (hours)	
BARBITURATES					
Thiopental	1-5	7	10-15	3-8 h	
Pentobarbital	1-10	10-19	15-25	20-40 h	
BENZODIAZEPINES					
Midazolam	0.04-0.25	1-1.5		1,5-3.0 h	
Diazepam	0.1-0.25	3-5		24-48	

### F. Summary

The findings from this section are:

- i. The ceiling effect of midazolam is a direct result of midazolam's mechanism of action. Thiopental and other barbiturates have a different mechanism of action and therefore do not exhibit a ceiling effect.
- ii. Research done in vitro show that the ceiling effect of midazolam occurs at a concentration of
- iii. An IV bolus dose of 500 mg midazolam produces a brain concentration of 257.9 nM after dosing and 219.2 nM after 5 minutes.
- *iv.* An IV bolus dose of 500 mg midazolam produces a brain concentration that is about 2.5 times higher than the concentration that midazolam produces a ceiling effect.
- v. An IV bolus dose of about 200 mg midazolam is sufficient to reach the threshold of midazolam's ceiling effect; greater doses should not lead to a greater pharmacological effect.

## 5. Comparison of the Effects of Midazolam and Thiopental on Consciousness

A. Translation of 'Unconsciousness' to a Drug-Induced State of General Anesthesia

Anesthesia is the loss of all feeling and is generally meant to be in a state of unconsciousness. General anesthesia is often used to contrast with the term local anesthesia, which is the loss of feeling in only part of the body (*Brenner and Stevens 2013*).

Science demands measurement. The pharmacological data that is the essence of drug characterization is based on numbers and measured parameters. Using a scientific approach to determine the relative potency of midazolam or thiopental to produce 'unconsciousness', first the linkage between unconsciousness and general anesthesia must be examined because 'unconsciousness' per se cannot be measured but one can measure to a certain degree the depth (magnitude) of general anesthesia.

Scientific models of consciousness rely on the measurement of activity in different areas of the brain and the known functions associated with them. When a general anesthetic is given, there is inhibition of the activity in the higher-order association areas of the brain more so than primary processing areas of the brain (*MacDonald et al. 2015*). Most telling, as patients come out of general anesthesia there is dramatic and sudden activation of the higher-order association areas of the brain regions that correlates with patient responding to verbal commands (*Långsjö et al. 2012*). To a first approximation, consciousness is correlated to activity in brain association areas and therefore unconsciousness is correlated to lack of activity in these brain association areas.

Clinical experience with non-responsive patients shows that a cautious approach to the risk evaluation of midazolam's ability to produce anesthesia should be taken. Patients that are nonresponsive are diagnosed of being in a vegetative state after repeated tests of consciousness show no evidence of sustained, reproducible, purposeful, or voluntary behavioral response to visual, auditory, tactile, or noxious stimuli (MacDonald et al. 2015). These tests in non-responsive patients are the same as tests used by anesthesiologist to detect the surgical plane of anesthesia. In the non-responsive patients, studies show that up to 43% of these patients that are diagnosed as vegetative are actually aware or conscious. This finding and the numerous studies documenting the lack of unconsciousness during surgery, called 'awareness during anesthesia' (Escallier et al. 2014) in some patients even when using strong general anesthetics like thiopental or inhalation agents, mandates a conservative approach to questions of the first drug used in a 3-drug lethal injection protocol. In other words, even under the best circumstances, clinicians assessing non-responsive patients and anesthesiologists inducing general anesthesia appear to get it wrong a significant percentage of the time and their patients are not unconscious (or anesthetized) as often as they think. In the case of lethal injection using a 3-drug protocol, it is even more crucial to insure general anesthesia by the action of the first drug due to the intolerable effects of the second drug (muscle paralytic) and third drug (potassium chloride) if the condemned inmate is not unconscious after the first drug.

B. The Potency of Thiopental to Induce General Anesthesia

In general, thiopental or other barbiturates are more potent than midazolam or other benzodiazepines in inducing anesthesia because thiopental produces a dose-dependent depression of the central nervous system while midazolam is limited by a ceiling effect (Rosenberg and Weaver 1991).

Researchers and clinicians developed a way to measure the depth of general anesthesia using EEG recordings of the frontal lobe brain and computer processing called bispectral analysis or BIS (Escallier et al. 2014). BIS gives a single number, on the scale from 100 (completely awake and alert) to 0 (coma and total EEG burst suppression). Clinical signs of anesthesia correlate moderately well with BIS scores (Weaver et al. 1970). BIS values of less than 60 are targeted during anesthesia procedures as that is the depth of anesthesia associated with lack of anesthesia awareness (Weaver et al. 1970). In this study, BIS values of 60 correlated with general anesthesia, 65 with deep sedation and 80 to moderate sedation. Using thiopental doses to induce (but not maintain general anesthesia) gave BIS values as low as 60 (Yoo et al. 2012).

## C. The Inability of Midazolam to Induce General Anesthesia

There are general characteristics that differentiate the use of midazolam from thiopental in use as an anesthetic induction agent. Midazolam has a significantly slower onset of action than thiopental (*White 1982*). Midazolam also does not produce the early activation of EEG that is seen with thiopental and other IV general anesthetics (*Kuizenga et al. 2001*).

There are few research reports from the medical and pharmacological literature looking at the level of anesthesia after midazolam by measuring the BIS. Generally, midazolam is used as a premedicant before general anesthesia or for regional anesthesia (*Khanderia and Pandit 1987*). Midazolam is a less reliable induction agent than thiopental and induction of anesthesia using midazolam alone is unpredictable. Clinically, benzodiazepines such as midazolam are not used as much for anesthesia or induction of anesthesia but for conscious sedation (*Giovannitti and Trapp 1991*). Conscious sedation is a drug-induced state of relaxation where the patient remains conscious with reflexes intact and little effect on cardiovascular or respiratory function. Midazolam is often used with an opioid analgesic in outpatient procedures such as colonoscopy and oral surgery.

In light of the lesser potency of midazolam compared to thiopental, most studies have investigated the relation of BIS values to levels of anesthesia. BIS values of in the range of 77-92 were reported after repeated IV doses of midazolam in a surgical outpatient study (Sandler 2000). In surgery patients, the lowest BIS score for IV midazolam was 65, whereas the inhalational agent, sevoflurane, and the intravenous anesthetic, propofol, produced low BIS scores ranging from 32-40 (Ibrahim et al. 2001). In a clinical study using adult healthy volunteers, IV midazolam was infused until patients become unresponsive to mild prodding or shaking (Lui et al. 1996). Midazolam at the greatest dose decreased the BIS to the lowest value of 69. All the above studies support the finding that midazolam does not induce general anesthesia which is stated to occur at BIS values less than 60.

## D. Summary

The findings from the section are:

- 1. Studies show a link between unconsciousness, anesthesia, and decreased activity in brain association areas.
- ii. Thiopental and other barbiturate anesthetics decrease activity in these brain association areas, and are potent in decreasing the BIS value which is associated with depth of anesthesia.
- iii. There are few studies of midazolam's depth of anesthesia because midazolam cannot produce the same anesthetic effects as thiopental on the brain, and midazolam is less potent in reducing BIS values.
- iv. Scientific studies show that a cautious and conservative approach is warranted in positing an 'anesthetic' action of midazolam, as a significant number of patients are found to be underanesthetized and conscious during surgery even when using the strongest general anesthetic agents are used.
- v. For these reasons, it is my opinion, to a reasonable degree of scientific certainty, that the use of midazolam in the Mississippi three-drug protocol creates a substantial risk of serious harm and severe pain to the condemned prisoner.

### 6. Overall Summary and Conclusions

TITLE 99 - CRIMINAL PROCEDURE of the Mississippi Code, Chapter 19 - Judgment, Sentence, and Execution, § 99-19-51 "Manner of execution of death sentence" states:

"The manner of inflicting the punishment of death shall be by continuous intravenous administration of a lethal quantity of an ultra short-acting barbiturate or other similar drug in combination with a chemical paralytic agent until death is pronounced by the county coroner where the execution takes place or by a licensed physician according to accepted standards of medical practice."

The Mississippi Department of Corrections (MDOC) "Capital Punishment Procedures" (version date 3/7/2012) listed as the first drug in a 3-drug protocol, the use of 2 grams of Sodium Pentothal® (thiopental) or, if not available, the use of 5 grams of Sodium Nembutal® (pentobarbital). For the second drug, the use of 50 mg Pavulon® (pancuronium) or, if not available, the use of 40 milligrams of Norcuron® (vecuronium). The third drug to be used in the lethal injection protocol is 50 milliequivalents of Potassium Chloride.

MDOC Amended "Capital Punishment Procedures" (Document 38-2, filed 7/28/2015) was revised solely to include 500 mg of Versed® (midazolam) as the first drug in the 3-drug protocol if both thiopental and pentobarbital are not available.

It is my opinion, to a reasonable degree of scientific certainty, that midazolam is not an "other similar drug" to an ultra short-acting barbiturate as required by Mississippi Code § 99-19-51, the manner of execution statute.

A lethal quantity of an ultra-short acting barbiturate or other similar drug means that another drug that is pharmacologically equivalent to thiopental (which is an ultra short-acting barbiturate) can be used instead of thiopental. Midazolam, a benzodiazepine, has a fast onset but is not an 'ultra short-acting' drug and is not a barbiturate. The fact that thiopental is not pharmacologically equivalent to midazolam is evidenced by midazolam and thiopental failing' the tests of equivalency detailed in §2A-F; the supporting fact that lethal levels of thiopental are obtained after a 2 gram IV bolus dose as calculated in §3B and that midazolam produces a ceiling effect and does not produce a fatal blood level after 500 mg bolus IV dose as shown in §4E; and the supporting fact that midazolam does not produce general anesthesia nor a depth of anesthesia equal to thiopental in clinical studies detailed in §5A-C. By using midazolam, which is neither ultra short-acting, nor a barbiturate, and therefore cannot be considered a similar drug, the current MDOC Lethal Injection Protocol is in violation of the Mississippi State Statute § 99-19-51 "Manner of execution of death sentence."

In conclusion, the decision by the Mississippi Department of Corrections to substitute midazolam for an ultra short-acting barbiturate as the first drug in the 3-drug lethal injection protocol was made without sound medical or scientific reasoning or expert pharmacological advice. Pharmacological substitution is a legitimate method to provide equal pharmacological effects when one drug is no longer be available. However, it is not permissible to pharmacologically substitute one drug, such as the barbiturate thiopental, with another drug, such as the benzodiazepine midazolam, where no such pharmacological equivalency exists.

It is therefore my opinion, to a reasonable degree of scientific certainty, that (a) midazolam is not an "other similar drug" to an ultra short-acting barbiturate, and that (b) the use of midazolam in the Mississippi three-drug protocol creates a substantial risk of serious harm and severe pain to the condemned prisoner.

I reserve the right to amend this report if further information becomes available that may alter the findings in this report.

I declare under penalty of perjury that I have examined this report and all statements contained herein, and to the best of my knowledge and belief, they are true, correct and complete. My opinions stated herein are based on reasonable degree of scientific and medical certainty.

Craig W. Stevens, Ph.D.

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- Yoo KY, Jeong CW, Jeong HJ, Lee SH, Na JH, Kim SJ, Jeong ST, Lee J (2012) Thiopental dose requirements for induction of anaesthesia and subsequent endotracheal intubation in patients with complete spinal cord injuries. Acta Anaesthesiol Scand. 56:770-776.

### **CURRICULUM VITAE**

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2000-present	Professor of Pharmacology, Dept. of Pharmacology/Physiology, OSU-CHS, Tulsa, OK
2012-present	Chair, Coalition Against Prescription and Substance Abuse of Tulsa (CAPSAT), Tulsa, OK
2007-2009	Chair, Dept. of Pharmacology/Physiology, OSU-CHS, Tulsa, OK
1993-2000	Associate Professor of Pharmacology, Dept. of Pharmacology/Physiology, OSU-CHS, Tulsa, OK
1990-1993	Assistant Professor of Pharmacology, Dept. of Pharmacology/Physiology, OSU-CHS, Tulsa, OK
1989-1990	Development Manager, Minnesota Academy of Science, St. Paul, MN
1984-1986	President (founding), Mayo Graduate Students Association, Mayo Grad, Schl Med, Rochester MN

EDUCATION AND T	RAINING
2005	Molecular Biology and PCR Course, Smith College/New England Biolabs, Northampton,
	Massachusetts
1988-1990	Postdoctoral Research Fellow, Dept. of Cell Biology and Neuroanatomy, Univ. of Minnesota,
	Minneapolis, MN. Supervisor: Dr. Virginia Seybold
1984-1988	Mayo Graduate School of Medicine, Rochester, MN, Ph.D. in Pharmacology. Thesis: Behavioral and
	Biochemical Characteristics of Opioid Tolerance in Rat Spinal Cord. Supervisor: Dr. Tony L. Yaksh
1981-1984	University of Illinois, Chicago, IL; M.S. in Biological Sciences. Thesis: Endogenous Opioid Systems in
	Amphibians. Supervisor: Dr. Paul D. Pezalla

1985-1986

1978-1981	American Peace Corps in Nepal; Science/Math Instructor, Katmandu, NEPAL
1974-1978	Augustana College, Rock Is., IL; B.A. in Biology, cum laude
EXTRAMURAL F	UNDING
2010-2014	"Novel Opioid Action at Toll-Like Receptors", Oklahoma Center for the Advancement of Science and
	Technology (OCAST) C.W. Stevens, (PI), \$126,090 (direct costs)
2007-2011	"Functional Evolution of Opioid Receptors", NIH NIDA AREA Grant, R15DA12448, C.W. Stevens
	(PI), \$150,000 (direct costs) (no-cost extension for 2011)
2004-2007	"Functional Evolution of Opioid Receptors", NIH NIDA AREA Grant, R15DA12448, C.W. Stevens
	(PI), \$100,000 (direct costs)
2002-2004	"Sequence and Pharmacology of Novel Opioid Receptors", Oklahoma Center for the Advancement of
	Science and Technology (OCAST) C.W. Stevens, (PI), \$68,264 (direct costs)
2001-2003	"Functional Evolution of Opioid Receptors", NIH NIDA AREA (Academic Research Enhancement
	Award) Grant, R15DA12448, C.W. Stevens (PI), \$100,000 (direct costs)
1999-2001	"Functional Evolution of Opioid Receptors", NIH NIDA AREA (Academic Research Enhancement
	Award) Grant, R15DA12448, C.W. Stevens (PI), \$69,605 (direct costs)
1998-1999	"Testing and Comparison of Analgesic Agents", American College of Laboratory Animal Medicine
	(ACLAM), C.W. Stevens (PI), \$11,555 (direct costs)
1995-1997	"Graduate Student Research", Gardner Spring, Co., Tulsa, OK (\$4,000)
1994-1996	NRSA postdoctoral grant for Dr. Stan Willenbring, C.W. Stevens (sponsor).
1992-1998	"Studies of Opioid Analgesia in Amphibians", NIH-NIDA First Award (DA07326), C.W. Stevens,
	Principal Investigator (PI), \$418,000. (direct costs) (no-cost extension for 1998)
1992-1995	"Spinal Sites of Endogenous Opioid Action in Amphibians", Research Grant, Whitehall Foundation,
	C VII Orange BT 070 705

C.W. Stevens, PI, \$70, 785. 1991-1992 "Nociceptive Processing in the Amphibian Spinal Cord", Grants-In-Aid, Whitehall Foundation, C. W.

Stevens, PI, \$10,375. 1988-1990

NIDA Neuroscience Training Grant, Postdoctoral position, Dept. of Cell Biology and Neuroanatomy, University of Minnesota Medical School, Minneapolis, MN

"Issues related to tolerance development and tissue toxicology of chronically administered 4-1987-1988 anilinopiperidines", T.L. Yaksh (PI) and C.W. Stevens (Co-I). Janssen Pharm., \$46,000.

"Effects of capsaicinoid agents on peptide levels and behavioral function", T.L. Yaksh (PI) and C.W. 1985-1986 Stevens (Co-I). Procter and Gamble Co., \$25,000.

"Effects of drugs on the shock titration threshold in the primate", T.L. Yaksh (PI) and C.W. Stevens (Co-

I). \$10,000, Sterling Winthrop Pharmaceuticals.

## TEACHING EXPERIENCE

1990-2014	Lecturer, Medical Pharmacology I-II, (Course-Coordinator 1997-2007) OSU-CHS, COM, Tulsa, OK
2009-2013	Instructor, Receptors II (graduate course, alternate years) OSU-CHS, COM, Tulsa, OK
1997-2009	Instructor, Neuropharmacology (graduate course, alternate years) OSU-CHS, COM, Tulsa, OK
1991-2009	Facilitator, Medical Information Systems Course, OSU-CHS, COM, Tulsa, OK
2000-2004	Visiting Professor, Neuroscience Lab Course, U of MN Medical School, Minneapolis, MN
1998-2001	Adjunct Professor of Pharmacology, University of Tulsa Nursing School, Tulsa, OK
1989-1990	Lecturer, Pharmacology for Nurse Anesthetists, University of Minnesota, Minneapolis, MN
1989-1990	Lecturer, Neuropharmacology Course, Dept. of Neurology, Univ. of MN, Minneapolis, MN
1984-1987	Community Education, Juggling Instructor, Rochester, MN
1984-1987	IBM-PC Instructor, Microcomputer Education Cntr., Mayo Clinic, Rochester, MN
1981-1983	Teaching Assistant; Dept. of Biological Sciences, University of IL at Chicago, IL

## ACADEMIC COMMITTEES

2011	Member, Honorary Degree Committee, OSU-Stillwater
2010-2012	Secretary, Group 6 of the Graduate College, OSU-Stillwater
2004	Member, Research and Creative Activities Task Force, OSU-System, appt. by OSU President Schmidly
2003	Member, Search Committee for VP Health Affairs OSU/Dean OSU-COM
2002-2003	President, Faculty Senate
2002-2003	Member, Board of Directors for Academic Health Center, joint affiliation of TRMC and OSU-CHS
2001-2002	Vice-President Faculty Senate
1994-2001	Founding Member & Chair (2000-2001), Biomedical Sciences Graduate Committee
1996-2001	Chair, Hazardous Materials and Equipment
1994-98, 2000-16	Member, Chair (2001-2004; 2006-2007; 2010-2013) OSU-CHS Promotion and Tenure Committee
1996-1998, 2009	Senator, Faculty Senate
1991-2000, 2006	Member, (Chair, 2006) Research Committee
1991-92, 2002-04	Member, (Chair, 2002-2004) Academic Appeals Board
1991-1992	Member, Learning Resources Committee
1990-1999	Chair (1990-1993), Member (1994-1999), Animal Use Committee (IACUC)

## PROFESSIONAL SOCIETY MEMBERSHIPS

International Narcotics Research Conference (INRC, member of Executive Committee)
American Society for Pharmacology and Experimental Therapeutics (ASPET)
Society for Neuroscience (SFN), American Association for the Advancement of Science (AAAS)
Committee on Problems of Drug Dependence (CPDD)

HONORS AND AN	WARDS			
2006	106 Regents Research Award, Inaugural awardee for OSU-Center for Health Sciences			
1992	Young Investigator Travel Award, American Pain Society, San Diego, CA			
1992	NIDA Travel Award, International Narcotics Res. Comm. (INRC), Keystone, CO			
1991	Young Investigator Travel Award, American Pain Society, New Orleans, LA			
1991	Young Scientist Travel Award, ASPET Annual Meeting, San Diego, CA			
1990	Fulbright Scholarship for Research & Teaching in India (declined to accept faculty position)			
1990	CPDD Travel Award, CPDD Annual Meeting, Keystone, CO			
NIDA Travel Award, CPDD Annual Meeting, Keystone, CO				
1987	1987 Upjohn Travel Award, ASPET Annual Meeting, Honolulu, HA			
1987	NIDA Training Grant, Gordon Research Conference, "Mode of Action of Opiates", CA			
1983				
1983	NIH Training Grant,"Neural Systems & Behavior", MBL Summer course, Woods Hole, MA			
1982	UIC Research Board Travel Grant, "Strategies for studying the role of peptides in neuronal function",			
	Society for Neuroscience Short Course, Minneapolis, MN			

## GRADUATE TRAINING ACTIVITIES

1997-2000	Chair/Major Advisor to Leslie C. Newman (Ph.D. student, completed 8/2000 with university-wide honors).
1998-2005	Member, Advisory Committee for John Paulson (Ph.D. student, completed 8/2005)
2001-2005	Chair, Advisory Committee for Eva Garringer (Ph.D. student, completed 5/2005)
2002-2004	Member, Advisory Committee for Randy Benton (M.S. student; completed 5/2004)
2002-2004	Member, Advisory Committee for Raju N. Kacham (M.S. student at OSU-CVHS, Stillwater; completed 5/2004)
2001-2007	Chair/Major Advisor to Kristin K. Martin (M.S. student; completed 5/2007)

GRADUATE TRAINING ACTIVITIES (CONT.)

2003-2008	Chair/Major Advisor to Christopher M. Brasel (Ph.D. student, completed 5/2008)
2004-2008	Chair/Major Advisor to Shekher Mohan (Ph.D. student, completed 12/2008)
2005-2008	Chair/Major Advisor to Julie Duffey (M.S. student, completed M.S. degree 5/2008)
2007-2009	Member, Advisory Committee for Danielle Armstrong (M.S. student, completed M.S. 7/2009)
2006-2011	Member, Advisory Committee for Neda Saffarian-Toussi (Ph.D. student, Ph.D. awarded May, 2011)
2007-2011	Member, Advisory Committee for Arunkumar Thangaraju (Ph.D. student, Ph.D. awarded Dec., 2011)
2008-2011	Chair/Major Advisor to Shruthi Aravind (M.S. student, M.S. awarded May 2011)
2010-2013	Chair/Major Advisor to Larry Johnston (D.O./M.S. student)
2009-2013	Chair/Major Advisor to John Knox (D.O./M.S. student)
2011-2015	Chair/Major Advisor to Summer Dodson (Ph.D. degree awarded Summer, 2015)
2011-	Member, Advisory Committee for Leandra Figueroa (Ph.D. student)

### LITIGATION CONSULTANT/EXPERT WITNESS CASES

- 1. Researched, wrote report on diphenhydramine (BENADRYL) adverse effects, Riggs, Abney, et al., P.C., Tulsa, OK (1998).
- 2. Researched, wrote report, and testified on opioids and federal drug sentencing guidelines, Stan Monroe, Tulsa, OK (1999).
- 3. Researched, wrote report, and was deposed on zolpidem (AMBIEN) effects in the elderly, Pinkerton & Finn, Tulsa, OK (1999).
- 4. Researched, consulted on the adverse effects of cisapride (PROPULSID) for Brewster & De Angelis, P.L.L.C., Tulsa, OK (2001).
- 5. Researched, wrote report, and testified in preliminary hearing and trial on tramadol (ULTRAM), LeFlore Co., Poteau, OK (2004).
- 6. Researched, wrote report on venlafaxine (EFFEXOR) and zolpidem (AMBIEN) effects, DA, LeFlore County, Poteau, OK (2005).
- 7. Researched, wrote report on OXYCONTIN, LORTAB, ULTRAM, and XANAX effects, Sneed & Lang, P.C., Tulsa, OK (2005).
- 8. Researched and consulted on marijunana intoxification and behavioral effects, Brewster & De Angelis, Tulsa, OK (2005).
- 9. Researched, wrote report, and testified in court on alcohol neurotoxicity, Faulkner Law Firm, Tulsa, OK (2006).
- 10. Researched, was deposed, and testified in court on effects of oxycontin (OXYCONTIN), Devlin Law Firm, Stillwater, OK (2007).
- 11. Researched, wrote report on alcohol/alprazolam (XANAX) and behavioral disinhibition, Glassco Law Firm, Tulsa, OK (2007).
- 12. Researched, wrote report on venlafaxine (EFFEXOR) effects on driving, DA office, Le Flore County, Poteau, OK (2007).
- 13. Researched, wrote report, and testified in court on propoxyphene (DARVON)/zolpidem (AMBIEN), LeFlore County, OK (2008).
- 14. Researched, wrote report on zolpidem (AMBIEN) disinhibition behavior, Scott Troy Law Firm, Tulsa, OK (2009).
- 15. Researched and consulted on zolpidem (AMBIEN) in vehicular manslaughter case, Monroe & Associates, Tulsa, OK (2009).
- 16. Researched and consulted on impact of morphine levels in wrongful death case, Corley & Associates, Tulsa, OK (2009).
- 17. Researched, wrote report, and testified in court on drugs and hospital confession, Rabon Martin Law Firm, Tulsa, OK (2010).
- 18. Researched and consulted on fentanyl (DURAGESIC) levels in wrongful death case, Brewster & De Angelis, Tulsa, OK (2010).
- 19. Researched and consulted on blood alcohol levels in vehicular manslaughter case, Sneed, Lang & Herrold, Tulsa, OK (2010).
- 20. Researched, wrote report on benzylpiperazine (BZP), Taylor, Ryan, Schmidt, & Van Dalsem, P.C., Tulsa, OK (2010).
- 21. Researched and consulted on blood alcohol levels in dram shop case, Sneed, Lang & Herrold, Tulsa, OK (2010).
- 22. Researched, wrote report on marijuana testing results in child custody case, Arras Law Firm, Tulsa, OK (2010).
- 23. Researched, wrote report on zolpidem (Ambien)/propoxyphene (DARVOCET)/alcohol, Hoch & Associates, OKC, OK (2011).
- 24. Researched, wrote report on phenobarbital and disinhibition behavior, Martin Hart, Federal Public Defender, Tulsa, OK (2012).
- 25. Researched, wrote report, and testified on UA and methamphetamine manufacturing, Monroe & Associates, Tulsa, OK (2012).
- 26. Researched, wrote report, and testified on alcohol and disinhibition, Oklahoma Indigent Defense System, Norman, OK (2012).
- 27. Researched, wrote report on post-mortem hydrocodone levels, E. Terrill Corley & Associates, Tulsa, OK (2012)
- 28. Researched, wrote report, deposed, and testified on cognitive effects of chemo drugs, Hall Estill Firm, Tulsa, OK (2012).
- 29. Researched, wrote report on motor effects of anxiolytic drugs, Allen M. Smallwood Law Firm, Tulsa, OK (2012).
- 30. Researched, wrote report on wrongful death due to opioid overdose, Jay Dunham Law Firm, Tulsa, OK (2012).
- 31. Researched, wrote report, and testified on antipsychotic use and rape, Larry Roberson, OIDS, Sapulpa, OK (2013).
- 32. Researched, wrote report on wrongful death due to opioid overdose, Van Meter Law Firm, OkCity, OK (2013).
- 33. Researched, wrote report on use of zolpidem (AMBIEN) and suicidality, Keach & Murdock, Las Vegas, NV (2013).
- 34. Researched, wrote report, and deposed on hydrocodone overdose and wrongful death, Blue Law Firm, OkCity, OK (2013).
- 35. Researched, wrote report on prescription/non-prescription drugs in accidental death, Jay Dunham Law Firm, Tulsa, OK (2014).
- 36. Researched, wrote report, and deposed on prescription drugs in workmens comp case, Jay Self Law Firm, OKCity, OK (2014).
- 37. Researched, wrote report, deposed on cocaine metabolites in workmens comp case, Roy S. Dickinson, Norman OK (2014).
- 38. Researched, wrote report on alcohol use and accuracy of Breathylzer test, Goldstein and Price, L.C., St. Louis, MO (2014).
- 39. Researched, wrote report, and testified in court on psychotropics and witness, Randy Lynn, Public Defender, Tulsa, OK (2014).
- 40. Researched, wrote report, deposed, testified twice opioid/benzodiazepine and MVA, Jennings & Teague, OkCity, OK (2014).
- 41. Researched, wrote report on use of zolpidem and suicidality, Mark Cooper Law Firm, Norman, OK (2014).
- 42. Researched, wrote report, and testified in court on synthetic cannabinioid case, Stan Monroe/Rob Nigh, Tulsa, OK (2014).
- 43. Researched, wrote report on use of diazepam/alprazolam and driving, Allen Smallwood, Tulsa, OK (2014).
- 44. Researched, wrote report on methamphetamine use in workmens comp case, Thomas Mortensen, Tulsa, OK (2014).
- 45. Researched, wrote report, testifed on use of zolpidem and disinhibition behavior, Dustin Phillips, OkCity, OK (2015).
- 46. Researched, wrote report, prescription drug use and accident in new home attic, Jennings & Teague, OkCity, OK (2015).

### LITIGATION CONSULTANT/EXPERT WITNESS CASES (CONT.)

- 47. Researched, wrote report on prescription drugs in workmens comp case, Mike Jones Law Firm, Bristow, OK (2015)
- 48. Researched, wrote report, accident involving drug use in prison, Maples, Nix & Diesselhorst, Edmund, OK (2015).
- 49. Researched, wrote report, testified on blood levels of methamphetamine, Stan Monroe Law Firm, Tulsa, OK (2015).
- 50. Researched, wrote report on motor vehicle accident while taking zolpidem, Schroeder & Associates, Tulsa, OK (2015).
- 51. Researched, wrote report on truck accident and antidepressant and hypnotic use, Mark Bonner, OKC, OK (2015)
- 52. Researched, wrote report (ongoing) wrongful death lawsuit due to opioid overdose, Rode Law Firm, Tulsa, OK (2015)
- 53. Researched, wrote report (ongoing) impaired driver and fatal motor vehicle accident, McAfee & Taft, OkCity, OK (2015)
- 54. Researched, wrote report (ongoing) impaired driving and fatal motor vehicle accident, Jennings & Teague, OkCity, OK (2015).

### GRANT STUDY SECTIONS

Reviewer for NIH grants, Special Emphasis Pain Study Sections (1998-present)

Grant consultant for the AAAS, Univ of Michigan, Centers of Research Excellence project (2003)

Grant Reviewer for National Science Foundation (1996-2002)

Grant Reviewer for the Veterans Administration (1995- present)

Chair (1999), Member (1997) Biological Sciences Panel, Texas State Granting Program-Advanced Research Proposals

Grant Reviewer (2008) for Neuroscience and Mental Health Grants, The Wellcome Trust

### EDITORIAL & ADVISORY BOARDS/PEER-REVIEWER FOR THE FOLLOWING SCIENTIFIC JOURNALS

Peer-Reviewer for J. Pharmacol. Exp. Ther., Brain Research, Life Sciences, Neuroscience Letters, Eur. J. Pharmacology,

J. Neuroscience, Pain, American Journal of Physiology, Journal of Pain, Laboratory Animals

Editorial Advisory Board, Pharmacology Online (Italy), Editor: Anna Capasso.

Editorial Advisory Board, Computational Biology and Chemistry: Advances and Applications, Editor: Bruno Villoutreix

Advisory Board Member, Tobacco-Free Zone, Tulsa, OK

Consultant, Reuters News Service, Insight Service

## COMPUTER CONSULTING

SigmaPlot for Windows,  $\beta$ -tester, Jandel Scientific, CA, 1992-1999.

Reference Manager for Windows,  $\beta$ -tester, Research Information Systems, Inc., CA, 1993-1999.

Institute for Scientific Information (ISI), focus group meeting, San Francisco, CA, April, 1998.

Knowledge Acquisition Consultant for Ingenuity.com (2001).

β-tester for JPET Online Review and Submission website (2001).

## COMMUNITY SCIENCE INITIATIVES

Science Fair Judge at School (Carver and Elliot) and Regional (Tulsa County) Level, 1990-2010.

Institutional Representative for the Tulsa Biological and Clinical Research Alliance (TBCRA), 1998-2001

Science Enrichment for University of Tulsa-Gifted School, 1998-present, also at Trinity Episcopalian Day School.

Faculty Participant in High School Ambassador Program at OSU-CHS, 1994-2000

Workshop participant in "Speaking out for Science", sponsored by AAAS, March 28, 2009.

Member, Oklahomans for Excellence in Science Education.

### VISITING SCIENTIST/RESEARCH CONSULTANT/OUTSIDE COLLABORATION

- 1994 Laboratory of Tony L. Yaksh, Ph.D., Vice Chair for Research, Dept. of Anesthesiology, UCSD, La Jolla, CA. Project entailed characterization of met-enkephalin extended sequences in *Rana pipiens* and presentation to research group.
- 1996 Laboratory of George Wilcox, Ph.D., Professor of Pharmacology, University of Minnesota Medical School, Minneapolis, MN. Training of intrathecal catheterization to research group and general lab QC.
- 1999 Laboratory of Howard Gutstein, M.D./Ph.D., Director of Research, Dept. of Anesthesiology, MD Anderson Cancer Center, Houston, TX. Training of intrathecal catheterization and analgesic modeling techniques to research group.
- 2000 Research consultant for Ligand Pharmaceuticals, San Diego, CA.
- 2000 Laboratory of Dr. Sandra Roerig, Professor of Pharmacology/Associate Dean for Research, LSU Medical Center, Shreveport, LA. Training of intrathecal catheterization and analgesic modeling techniques to research group.
- 2000 Laboratory of Dr. James Zadina, Professor of Pharmacology/ Director of Neurosciences Program, Tulane University School of Medicine, New Orleans, LA. Training of intrathecal catheterization to research group.
- 2001 Visiting Professor, Neuroscience Lab Course, Dr. George Wilcox, co-director, University of Minnesota Neuroscience Program.

  Amphibian model for testing analgesics used in a live laboratory course (also subsequent years).
- 2001 Laboratory of Ken McCarson, Ph.D., Associate Professor of Pharmacology, University of Kansas Medical Center, Kansas City, KS. Training and collaboration on vanilloid-like receptor function in *Rana pipiens*.
- 2002 Laboratory of Paul Prather, Ph.D., Associate Professor of Pharmacology. University of Arkansas for Medical Sciences, Little Rock, AR. Collaboration on transfection of frog opioid receptors in cell lines.
- 2002 Visiting Professor, Dept. of Neuroscience, University of Minnesota Medical School, March 12-14, 2002.
- 2003 Visiting Professor, Dept. of Neuroscience, University of Minnesota Medical School, April 8 to 10, 2003.
- 2003 Visiting Professor, Dept. of Medicinal Chemistry, University of Mississippi, Oxford. MI, May 7-9, 2003.
- 2004 Visiting Professor, Dept. of Neuroscience, University of Minnesota Medical School, April 12-15, 2004.
- 2005 Visiting Professor, Dept. of Neuroscience, University of Minnesota Medical School, April 11-13, 2005.

### INVITED TALKS/SEMINARS/KEYNOTE PRESENTATIONS

- 1. "Opioid antinociception in amphibians", Satellite Symposium: Behavioral Biology of Nociception: Comparative, Developmental, and Sexual Aspect, Society for Neuroscience, New Orleans, LA, November, 1987.
- 2. "An amphibian model for the assessment of opioid action", Annual Meeting of the College on Problems in Drug Dependence (CPDD), Richmond, VA, June, 1989.
- "Alternatives to the use of mammals for pain research", OSU College of Veterinary Sciences, Annual Research Symposium, Stillwater OK, May 1991.
- "An amphibian model for pain research", Northeastern State University, Science and Technology Seminar Series, Tahlequah OK, October, 1991.
- "An amphibian model for pain research", Children's Medical Center, Chapman Research Institute Seminar Series, Tulsa OK, November, 1991.
- "An amphibian model for pain research", Oklahoma State University, Dept. of Zoology Seminar Series, Stillwater OK, January, 1992.
- "Alternatives to the use of mammals for opioid research", OSU College of Veterinary Sciences, Annual Research Symposium, Stillwater OK, May 1992.
- 8. "An amphibian pain model for opioid research", University of Tulsa Biology Department Colloquium, Tulsa, OK, September 1992.
- 9. "An amphibian pain model for opioid research", University of Oklahoma Health Sciences Center, Dept. of Anatomy, Oklahoma City, OK, October, 1992.
- "Studies of opioid tolerance in an amphibian pain model", 1st Annual Young Investigators Symposium, College on Problems in Drug-Dependence (CPDD), Toronto, June, 1993.
- 11. "Relative analgesic potency of mu and kappa opioids in amphibians: a unique assay for kappa opioid action?", College on Problems of Drug Dependence (CPDD), Palm Beach, FL, 1994.
- 12. "An amphibian pain model for opioid research", UCSD, Anesthesiology Research Lab Group, April, 1994.
- 13. "An amphibian model for pain research", Pharmacology Dept., LSU Med Center, New Orleans, 9/27/94.
- "Alternatives to the use of mammals for pain research", NIH/OPPR/LSU sponsored workshop, New Orleans, September 29-30, 1994.
- 15. "Alternatives to the use of mammals for pain research: an amphibian model", SCAW/CCAC Conference, Toronto, Canada, September 28, 1995.
- 16. "An amphibian model for studies of opioid action", University of Minnesota Medical School, Dept. of Pharmacology Seminar Series, Minneapolis, MN, January 19, 1996.
- 17. "An alternative model for testing of opioid analgesics and pain research using amphibians", 2nd World Congress on Alternatives and Animal Use in the Life Sciences, Utrecht, Netherlands, October 21, 1996.
- 18. "From Pond to Pain: An Amphibian Model for Opioid Analgesia", Anatomy/Physiology Seminar Series, University of Oklahoma Health Sciences Center, Oklahoma City, OK, May 20, 1997.
- 19. "From Pond to Pain: An Amphibian Model for Opioid Analgesia", invited Symposium speaker, Annual Meeting of the Midwest Pain Interest Group (PIG), Medical College of Wisconsin, Milwaukee, WI, June 6, 1997.
- 20. "Studies of selective mu opioid antagonism after spinal administration of beta-FNA in amphibians", invited Symposium speaker, College on Drug Dependence (CPDD) Annual Meeting, Nashville, TN, June 16, 1997.
- 21. "The unireceptor hypothesis of opioid antinociception in amphibians: implications for the evolution of opioid receptors", invited Symposium speaker, International Narcotics Research Conference (INRC), Munich, Germany, July 20-25, 1998.
- 22. "An Amphibian Whole-Animal Alternative for the Study of Pain", invited participant for symposium, All Creatures Weird and Wonderful: Revolutionary Approaches to Medical Discovery, AAAS Meeting, Anaheim, CA, Jan, 23, 1999.
- "Perspectives on Opioid Tolerance from Basic Research", MD Anderson-University of Texas Medical Center, Dept. of Anesthesiology and Critical Care, Houston, TX, November 18, 1999.
- 24. "An Alternative Model for Pain and Analgesia Research Using Amphibians", invited Symposium speaker, Scientists Center for Animal Welfare (SCAW), Spring Meeting, Baltimore, MD, May 19, 2000.
- 25. "From Pond to Pain: Investigating Mechanisms of Opioid Analgesia Using Amphibians", OSU, Zoology, Stillwater, OK, 9/22/00.
- 26. "Investigating Mechanisms of Opioid Analgesia in Amphibians", LSU-Medical Center, Dept. of Pharmacology, Shreveport, LA, December 5, 2000.
- 27. "An Amphibian Model for the Study of Opioid Analgesics", University of Kansas Medical Center, Dept. of Pharmacology, Toxicology and Therapeutics, Kansas City, KS, September 11, 2001 (re-scheduled and presented on December 11, 2001).
- "An Amphibian Model for Analgesia Testing", Univ. of Oklahoma Dental School, Student Research Society Annual Banquet, Myriad Convention Center, Oklahoma City, OK, April 12, 2002.
- 29. "Mechanisms of Opioid Analgesia in Amphibians", Dept. of Neuroscience, Univ. of MN, Minneapolis, MN, April 16, 2002.
- 30. "An Amphibian Model for Investigation of Opioid Analgesia and Pain-processing", at the Cross-Species Approach to Pain and Analgesia conference, sponsor: Mayday Fund, Airlie Conference Center, Warenton, VA, Sept. 19, 2002.
- 31. "An Amphibian Model for Opioid Research", Dept. of Pharmacology and Toxicology, University of Arkansas for Medical Sciences, Little Rock, AR, October 16, 2002.
- "Opioid research using amphibians and the evolution of opioid receptors", Dept. of Medicinal Chemistry, University of Mississippi, Oxford. MI, May 8, 2003.
- "Opioid research using amphibians and the evolution of opioid receptors", invited Symposium speaker, British Society for Experimental Biology, Edinburgh, Scotland, April 2, 2004.
- 34. "Opioid research using amphibians and the evolution of opioid receptors", invited Symposium speaker, European Opioid Conference, Budapest, Hungary, April 8, 2004.

### INVITED TALKS/SEMINARS/KEYNOTE PRESENTATIONS (CONT.)

- 35. "Opicid research using amphibians: a unique perspective on the evolution of vertebrate opicid receptors", Seminar for the Center for Pain Research, University of Minnesota, Minneapolis, MN, April 15, 2004.
- 36. "An Evolutionary Approach to Understanding Vertebrate Opioid Reeptors", Veterinary Biomedical Sciences Seminar Series, OSU-College of Veterinary Medicine, Stillwater, OK, January 27, 2005.
- 37. "Opioid research using amphibians: An Evolutionary Approach to Understanding Vertebrate Opioid Receptors", Seminar for the Department of Neuroscience, University of Minnesota Medical School, Minneapolis, MN, April 12, 2005.
- 38. "Opioid analgesia research in amphibians: from behavioral assay to cloning opioid receptor genes", Keynote speaker, Annual meeting of the Association of Reptile and Amphibian Veterinarians, Baltimore, MD, April 23-26, 2006.
- 39. "Insights on the Molecular Evolution of Vertebrate Opioid Receptors: From Frog to Man", Physiology Seminar Series, University of Oklahoma Health Sciences Center, Oklahoma City, OK, January 25, 2007.
- 40. "Evolution of opioid receptors: why the mu opioid receptor would make Darwin proud" INRC Annual Meeting, Charleston, SC, USA, July 15, 2008.
- 41. "Evolution of Opioid Receptors: Why the Mu Opioid Receptor Would Make Darwin Proud", Veterinary Biomedical Sciences Seminar Series, OSU-Center for Veterinary Medical Sciences, OSU-Stillwater, Stillwater, OK, March 5, 2009.
- "Evolution of Opicid Receptors", AAAS-SWARM Meeting, Tulsa, OK, March 30, 2009.
- 43. "Molecular Evolution of Vertebrate Opioid Receptors", Invited speaker, Genetics Group, St. Francis Hospital, March 15, 2012.
- 44. "Molecular Evolution of Opioid Receptors", Seminar Speaker, Human Anatomy and Physiology Society (HAPS) Annual Meeting, University of Tulsa, May 28, 2012.
- 45. "Ethical Issues of an Amphibian Pain Model", La souffrance animale: de la science au droit (Animal suffering: the science and the law) World Organization for Animal Health (OIE) Paris, France, October 18-19, 2012.

### SCIENTIFIC PRESS

- Stevens, C.W., "No Pain, Some Gain: A New Model for Neuropathic Pain", Journal of NIH Research, May, 1990, p.33-35.
- Stevens, C.W., "Funding for Young Investigators", Letters to the Editor, Science, Vol. 255, p. 142, 1992.
- Stevens, C.W., Response to "Letters from the Editor", Lab Animal, Vol. 25, p. 42, 1996.
- Stevens, C.W.; Response to Protocol Review Column, Lab Animal, Vol. 26, p 23-24, October, 1997.
- Stevens, C.W., "Evolution and Faith: Empathy Is Misplaced", Letters to the Editor, Science, Vol. 320, p. 745, 9 May 2008.

### MEDIA ARTICLES/INTERVIEWS/PRESS CONFERENCES

- "Northern grass frog helps Tulsan gig research grants", Tulsa World Newspaper, August 21, 1992.
- "Research Grants", op-ed page, Tulsa World Newspaper, September 7, 1992 (Animal rights response).
- 3. "Get Priorities Straight", op-ed page, Tulsa World Newspaper, September 20, 1992. (support of research)
- "Animal Research Needed", op-ed page, Tulsa World Newspaper, September 20, 1992. (support)
- "Who Suffers? Children or the Frogs?", op-ed page, Tulsa World Newspaper, September 27, 1992. (support) 5.
- "The Frogman", Tulsa People Magazine, March, 1994. (profile)
- "Success by Six" Interview on brain activity in children, KGRH, Tulsa 6pm Evening News, August 10, 1996 7.
- "State's Share of Funds Short, Researchers Say", interviewed & (mis)quoted, The Daily Oklahoman, January 11, 1999.
- "State's Research Fund Malnourished", interviewed & (mis)quoted, Tulsa World, Jan. 15, 1999, p A10
- "All Creatures Weird and Wonderful: Revolutionary Approaches to Medical Discovery", Press Conference, American Association for the Advancement of Sciences (AAAS) Anaheim, CA, Jan 23, 1999.
- 11. "Research Report", radio interview for Radio Netherlands, Jan 23, 1999.
- "Animals Hold Key to Cures: Medical Science Plumbs Secrets of Scorpions, Fish, Frogs" SF Examiner, Jan. 25, 1999.
- "What will ease the pain? Ask a frog", Science News, Vol. 155, p. 91, February 6, 1999.
- 14. "Painful Choices", New Scientist Online Conference Reports, Feb. 6, 1999.
- "Notebook: Frog Simplicity", The Scientist, Vol. 13 (4), p. 32, February 15, 1999.
   "Suffer the little amphibians", The London Times-Higher Education Supplement, Issue 1379, pp. 22-23, April 9, 1999.
- "Heat, Some Medicines Don't Mix", Tulsa World Newspaper, p A-9, August 4, 1999.
- 18. "OSU grant allows pain medicine study", The Daily Oklahoman, p. 3-B, August 27, 2001
- 19. "Research frogs may lead to medical leaps and bounds", The Tulsa World, Sept. 5, 2001.
- 20. "OSU researchers to study pain relief", The Tulsa World, p. D-7, Aug. 22, 2002.
- 21. "Of Frogs and Pain Weird Lab Recognized", Tulsa Business Journal, Vol 12 (#36), p. 10, Sept 6-12, 2002.
- 22. "Oklahoma Innovations Radio Show", invited guest to talk about OSU-CHS and OCAST-funded research, 3/4/03.
- 23. "Oklahoma Scientists and the Human Genome", article about Dr. Stevens' lab, Oklahoma Magazine, Oct., 2003.
- 24. "OSU Professor Receives Grant", The Daily O'Collegian, OSU Newspaper, September 8, 2004.
- 25. "The Other O.C. (Oxycontin)", The Tulsa World Newspaper, Feb, 17, 2005, D-1 (cont. D-6). CWS is the "voice of reason".
- 26. "Do Boiling Lobsters Feel Pain?" interviewed for ABC news special series on pain, May 10, 2005. http://abcnews.go.com
- 27. "Tough times add to panic, anxiety disorders", Tulsa World Newspaper interview, D-3, April 2, 2009.
- 28. "Take pains to excercise", Tulsa World Newspaper interview, D-3, July 18, 2009.
- 29. "OSU medical students say juggling is great for the brain", Dr. Stevens' Med School juggling club and video interview by Rick Wells from Newson6.com, August 25, 2010 (video at: http://www.youtube.com/watch?v=BCFqa0D8BY8)
- 30. "OSU Jugglers: Fox 23 Daybreak Show", Kristin Talent interview and juggling by Dr. Stevens, Feb. 11, 2011 (video at: http://clipsyndicate.com/video/playlist/0/2208385?wpid=9601)

### MEDIA ARTICLES/INTERVIEWS/PRESS CONFERENCES (CONT.)

- 31. "Juggle Heads: Keeping both sides of brain active is key to a healthy mind", Tulsa World article by Kim Brown featuring interview and photos of Dr. Stevens and the Med School Chapter of the T-Town Juggling Club. Jan. 27, 2011.
- 32. "Innovations Radio Show", interview with Dr. Stevens about his research on opioids. Oklahoma City, OK. April 6, 2011.
- 33. "Letters to the Editor: Research Supported", The Tulsa World Newspaper, Aug. 28, 2011.
- 34. "Turning to Frogs for Illegal Aid in Horse Races", The New York Times Newspaper Front Page, June 20, 2012. 35. "Secrets still shroud Clayton Lockett's execution", The Tulsa World Newspaper, May 11, 2014.
- 36. "Questions, inconsistencies about Clayton Lockett execution remain unanswered", The Tulsa World, August 31, 2014.
- 37. "Federal nursing home comparison website receives updates", The Tulsa World Newspaper, February 21, 2015.

### PEER-REVIEWED PRIMARY PUBLICATIONS

- 1. Stevens, C.W. and Pezalla, P.D., A spinal site mediates opiate analgesia in frogs. Life Sci. 33: 2097-2013, 1983.
- Stevens, C.W. and Pezalla, P.D., Naloxone blocks the analgesic action of levorphanol but not dextrorphan in the leopard frog. Brain Research 301: 171-174, 1984.
- 3. Pezalla, P.D., and Stevens, C.W., Behavioral effects of morphine, levorphanol, dextroophan, and naloxone in Rana pipiens. Pharm. Biochem. Behavior 21: 213-217, 1984.
- 4. Yaksh, T.L., and Stevens, C.W., Simple catheter preparation permitting bolus intrathecal administration during chronic intrathecal infusion, Pharmacology, Biochemistry and Behavior, 25: 483-485, 1986.
- 5. Stevens, C.W. and Yaksh, T.L., Spinal action of dermorphin an extremely potent opioid peptide from frog skin, Brain Research, 385: 300-304, 1986.
- Stevens, C.W. and Yaksh, T.L., Dynorphin A and related peptides administered intrathecally in the rat: A search for putative kappa opiate receptor activity. J. Pharmacol. Exp. Ther., 238: 833-838, 1986.
- Stevens, C.W. Pezalla, P.D., and Yaksh, T.L., Spinal antinociceptive action of three representative opioids in frogs. Brain Research, 402: 201-203, 1987.
- Stevens, C.W., Weinger, M.B. and Yaksh, T.L., Intrathecal dynorphins suppress hindlimb electromyographic activity in rats. Eur. J. Pharmacol., 138: 299-302, 1987.
- Stevens, C.W. and Yaksh, T.L., Chronic antagonist infusion does not increase morphine antinociception in rat spinal cord. Brain Research, 425; 388-390, 1987.
- 10. Stevens, C.W., Monasky M.S. and Yaksh, T.L., Spinal infusion of opiate and alpha-2 agonists in rats: Tolerance and crosstolerance studies, J. Pharmacol, Exp. Ther. 244; 63-70, 1988.
- 11. Schick, R.R., Stevens, C.W., Yaksh, T.L. and Go, V.L.W., Chronic intraventricular administration of CCK octapeptide suppresses feeding in rats. Brain Research, 448:294-298, 1988.
- 12. Stevens, C.W., and Yaksh, T.L., Potency of infused spinal antinociceptive agents is inversely related to magnitude of tolerance after continuous infusion. J. Pharmacol. Exp. Ther. 250: 1-8, 1989.
- 13. Sosnowski, M., Stevens, C.W., and Yaksh, T.L., Assessment of the role of A1/A2 adenosine receptors mediating the purine antinociceptive, motor, and autonomic function in rat spinal cord. J. Pharmacol. Exp. Ther. 250: 915-922, 1989.
- 14. Stevens, C.W., and Yaksh, T.L., Time course characteristics of tolerance development to continuously infused antinociceptive agents in rat spinal cord. J. Pharmacol. Exp. Ther. 251: 216-233, 1989.
- 15. Stevens, C.W., and Yaksh, T.L., Magnitude of opioid dependence after continuous intrathecal infusion of mu and delta opioids in the rat. Eur. J. Pharmacol. 166: 467-472, 1989.
- 16. Morón, M.A., Stevens, C.W., and Yaksh, T.L., Diltiazem enhances and flunarizine inhibits nimodipine's antiseizure effects. Eur. J. Pharmacol. 163: 299-307, 1989.
- 17. Stevens, C.W. and Pezalla, P.D., Endogenous opioid system down-regulation during hibernation in amphibians. Brain Research, 494: 227-231, 1989.
- 18. Yanez, A., Sabbe, M.B., Stevens, C.W., and Yaksh, T.L., Interaction of midazolam and morphine in the rat spinal cord. Neuropharmacology 29: 359-364, 1990.
- 19. Morón, M.A., Stevens, C.W., and Yaksh, T.L., The antiseizure activity of dihydropyridine calcium channel antagonists in the conscious rat. J. Pharmacol. Exp. Ther. 252: 1150-1155, 1990.
- 20. Monasky, M., Zinsmeister, A., Stevens, C.W., and Yaksh, T.L., The interaction of intrathecal morphine and ST-91 on antinociception in the rat. J. Pharmacol. Exp. Ther. 254: 383-392, 1990.
- 21. Stevens, C.W., Lacey, C.B., Miller, K.E., Elde, R.P., and Seybold, V.S., Biochemical characterization and regional quantification of mu, delta, and kappa opioid binding sites in rat spinal cord. Brain Research 550: 77-85, 1991.
- 22. Stevens, C.W., Kajander, K.C., Bennett, G.J., and Seybold, V.S., Bilateral and differential changes in spinal mu, delta and kappa opioid binding in rats with a painful, unilateral neuropathy. Pain 46: 315-326, 1991.
- 23. Stevens, C.W. and Yaksh, T.L., Studies of morphine and DADLE cross-tolerance after continuous intrathecal infusion in the rat. Anesthesiology 76: 596-603, 1992.
- 24. Stevens, C.W. and Kirkendall, K., Time course and magnitude of tolerance to the analgesic effects of systemic morphine in amphibians, Life Sciences 52: PL111-116, 1993.
- 25. Stevens, C.W., Alan J. Klopp, and J. Anthony Facello, Analgesic potency of mu and kappa opioids after systemic administration in amphibians. J. Pharmacol. Exp. Ther. 269: 1086-1093, 1994.

PEER-REVIEWED PRIMARY PUBLICATIONS (CONT.)

- 26. Brenner, G.M., Deason, L. L, Klopp, A.J., and Stevens. C.W. Analgesic potency of alpha-adrenergic agents after systemic administration in amphibians J. Pharmacol. Exp. Ther. 270: 540-545, 1994.
- 27. Stevens, C.W., Sangha S. and Ogg, B., Analgesia produced by immobilization stress and an enkephalinase-inhibitor in amphibians, Pharm. Biochem. Behav. 50: 675-680, 1995.
- 28. Stevens, C.W. and Seybold, V.S., Changes of opioid binding density in the rat spinal cord following unilateral dorsal rhizotomy, Brain Research 687: 53-62, 1995.
- 29. Willenbring, B. and Stevens, C.W., Thermal, mechanical, and chemical peripheral sensation in amphibians: opicid and adrenergic effects. Life Sciences 58: 125-133, 1996.
- 30. Stevens, C.W. Relative analgesic potency of *mu*, *delta*, and *kappa* opioids after spinal administration in amphibians. J. Pharmacol. Exp. Ther. 276: 440-448, 1996.
- 31. Stevens, C.W. and Brenner, G.M., Spinal administration of adrenergic agents produces analgesia in amphibians, Eur. J. Pharmacol., 316: 205-210, 1996.
- 32. Stevens, C.W., and Rothe, K.S., Supraspinal administration of opioids with selectivity for μ-, δ- and κ-opioid receptors produces analgesia in amphibians, European Journal of Pharmacology, 331: 15-21, 1997.
- 33. Willenbring, B. and Stevens, C.W., Spinal mu, delta, and kappa opioids alter chemical, mechanical and thermal sensitivities in amphibians Life Sciences 61: 2167-2176, 1997.
- 34. Stevens, C.W., and Newman, L.C., Spinal administration of selective opioid antagonists in amphibians: evidence for an opioid unireceptor. Life Sciences-Pharmacology Letters 64: PL125-130, 1999
- 35. Newman, L. C., Wallace D.R. and Stevens, C.W., Characterization of [3H]-diprenorphine binding in Rana pipiens: observations of filter binding enhanced by naltrexone. J. Pharmacol. Toxicol. Meth. 41: 43-48, 1999.
- 36. Newman, L. C., Wallace D.R. and Stevens, C.W., Selective opioid agonist and antagonists displacement of [3H]-naloxone binding in amphibian brain, European Journal of Pharmacology, 397: 255-262, 2000.
- 37. Newman, L. C., Wallace D.R. and Stevens, C.W., Selective opioid agonist and antagonists competition for [3H]-naloxone binding in amphibian spinal cord, Brain Research, 884: 184-191, 2000.
- 38. Stevens, C.W., MacIver, D. N., Newman, L.C., Testing and comparison of non-opioid analgesics in amphibians, Cont. Topics in Lab. Animal Sciences 40: 47-51, 2001.
- 39. Newman, L. C., Sands, S.S., Wallace D.R. and Stevens, C.W., Characterization of selective μ, κ, and δ opioid radioligand binding in amphibian brain. Journal of Pharmacology and Experimental Therapeutics 301:364–370, 2002.
- 40. Mohan, S. and Stevens, C.W., Systemic and spinal administration of the *mu* opicid, remifentanil, produces antinociception in amphibians, European Journal of Pharmacology, 534: 89-94, 2006.
- 41. Stevens, C.W., Toth G., Borsodi A., Benyhe S., Xendorphin B1, a novel opioid-like peptide determined from a *Xenopus laevis* brain cDNA library, produces opioid antinociception after spinal administration in amphibians. Brain Res Bulletin., 71:628-632, 2007.
- 42. Stevens, C.W., Brasel, C.M. and Mohan, S.K., Cloning and bioinformatics of amphibian mu, delta, kappa, and nociceptin opioid receptors expressed in brain tissue: evidence for opioid receptor divergence in mammals. Neuroscience Letters, 419: 189-194, 2007
- 43. Davis, R.L., Buck, D.J., Saffarian, N. and Stevens, C.W., The opioid antagonist, β-funaltrexamine, inhibits chemokine expression in human astroglial cells. Journal of Neuroimmuunology 186: 141-149, 2007.
- 44. Davis, R.L., Buck, D.J., Saffarian, N., Mohan, S.K., Desilva, U., Fernando, S.C., Stevens, C.W., β-funaltrexamine inhibits inducible nitric-oxide synthase expression in human astroglial cells. J. Neuroimmune Pharm. 3: 150-153, 2008.
- 45. Brasel, C.M., Sawyer, G.W. and <u>Stevens, C.W.</u>, A pharmacological comparison of the cloned frog and human *mu* opioid receptors reveals differences in affinity and function. Bur J Pharmacol 599:36-43, 2008.
- 46. Stevens, C.W., Martin, K.K. and Stahlheber, B.W., Nociceptin produces antinociception after spinal administration in amphibians. Pharm Biochem Behav 91:436-440, 2009.
- 47. Mohan S.K., Davis R.L., Desilva U. and Stevens C.W., Dual regulation of mu opioid receptors in SK-N-SH neuroblastoma cells by morphine and interleukin-1 beta: Evidence for opioid-immune crosstalk. J Neuroimmunology 227:26-34, 2010.
- 48. Stevens, C.W., Aravind S., Das S., and Davis R.L., Pharmacological characterization of LPS and opioid interactions at the toll-like receptor 4. Br J Pharmacol. 168:1421-1429, 2013.
- 49. Davis R.L., Das S., Buck, D.J., and Stevens, C.W., β-funaltrexamine inhibits chemokine (CXCL10) expression in normal human astrocytes. Neurochem. Int. 62:478-485, 2013.
- 50. Stevens, C.W., New pathways for an old molecule: the role of the Na\*-K\* ATPase pump in peripheral neuropathy. J Neurol Sci. 340:3-4, 2014.
- 51. Davis, R.L., Das, S., Curtis, J.T., <u>Stevens, C.W.</u>, The opioid antagonist, β-funaltrexamine, inhibits NF-κB signaling and chemokine expression in human astrocytes and in mice. Eur J Pharmacol 762:193-201, 2015.
- 52. Vardy E, Sassano MF, Rennekamp AJ, Kroeze WK, Mosier PD, Westkaemper RB, Stevens CW, Katritch V, Stevens RC, Peterson RT, Roth BL. Single amino acid variation underlies species-specific sensitivity to amphibian skin-derived opioid-like peptides. Chem Biol. 22:764-75, 2015.

BOOKS, BOOK CHAPTERS, REVIEWS & CONFERENCE PROCEEDINGS

- 1. Yaksh, T.L., Durant, P., Onofrio, B. and Stevens, C.W., The effect of spinally administered agents on pain transmission in man and animals. In: Spinal Opioids and the Relief of Pain, J.M. Besson and J. Lazorthes (Eds.), INSERM 127: 317-332, 1984.
- 2. Yaksh, T.L., Durant, P.A.C., Gaumann, D.M., <u>Stevens, C.W.</u> and Mjanger, B., The use of receptor-selective agents as analgesics in the spinal cord: Trends and possibilities. J. Pain Sympt. Manag. 2: 129-138, 1987.
- 3. Stevens, C.W. and Yaksh, T.L., Opioid and adrenergic spinal receptor systems and pain control, In: *Problems of Drug Dependence 1987*, Harris, L.S. (Ed.), NIDA Research Monograph, 81: 343-352, 1988.
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