

No. _____

IN THE SUPREME COURT OF THE UNITED STATES

* * * * *

DAVID S. ZINK et al.,
Petitioners,

v.

GEORGE A. LOMBARDI, et al.
Respondents.

* * * * *

ON PETITION FOR WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

THIS IS A CAPITAL CASE

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PETITION FOR WRIT OF CERTIORARI

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ELIZABETH UNGER CARLYLE
(Counsel of Record)
P.O. Box 30418
Kansas City, Missouri
(816) 525-6540

Joseph W. Luby
Death Penalty Litigation Clinic
6155 Oak Street, Suite C
Kansas City, MO 64113
816-363-2795

John William Simon
Constitutional Advocacy, LLC
7201 Delmar Blvd., Suite 201
St. Louis, Missouri 63130-4106
314-604-6982

Counsel for Petitioners

QUESTIONS PRESENTED

In November 2012, the district court denied a motion to dismiss, ruling that *Baze v. Rees* does not require a prisoner to propose an alternative means of execution in order to state an Eighth Amendment claim attacking the state’s method of execution. That non-final order was, of course, not appealable. Thirteen months and four execution protocols later, however, the Eighth Circuit granted respondents’ mandamus petition, which sought relief from orders requiring them to disclose the identities of the compounding pharmacy that supplies Missouri’s execution drug and the laboratory that analyzes it. Respondents invoked a “state secrets” privilege against this disclosure. The Court of Appeals declined to reach the privilege issue, but instead held that the district court “clearly” abused its discretion in ordering disclosure because, back in 2012, it should have dismissed the Eighth Amendment claim for plaintiffs’ failure to plead an alternative means of their demise—a contention not raised by respondents when resisting the district court’s discovery rulings. This case presents the following questions:

- I. Whether *Baze v. Rees* requires a plaintiff alleging an Eighth Amendment violation predicated on one method of execution to allege an alternative to the challenged method in order to avoid dismissal?
- II. Whether the Court of Appeals lost jurisdiction over the mandamus action when the identities of the pharmacy and laboratory became publicly known?
- III. Whether the Court of Appeals wrongly encroached on the merits of a non-final order under the guise of resolving a petition for extraordinary relief?

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**PETITION FOR WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT**

The Petitioners, David S. Zink, Michael Worthington, John Winfield, Michael A. Taylor, Leon Taylor, Walter T. Storey, Herbert Smulls, William Rousan, Earl Ringo, Roderick Nunley, John C. Middleton, Paul T. Goodwin, Jeffrey R. Ferguson, Andre Cole, Reginald Clemons, Cecil Clayton, Mark Christeson, Russell Earl Bucklew, and David M. Barnett, respectfully pray that a writ of certiorari issue to review the judgment and opinion of the United States Court of Appeals, rendered in these proceedings on January 24, 2014.

OPINIONS BELOW

The Eighth Circuit Court of Appeals, en banc, granted the respondents' petition for writ of mandamus. The opinion is not yet published. It is reprinted in the appendix to this petition beginning at page 1a. Judges Bye, Murphy and Kelly dissented. The dissenting opinion begins at page 16a. The order of the panel of the Eighth Circuit Court of Appeals is reprinted in the appendix at page 25a. The order of granting rehearing en banc is reprinted in the appendix at p. 26a. The docket text orders of the U.S. District Court, Western District of Missouri, are reprinted in the appendix beginning at page 27a. The order of the Eighth Circuit Court of Appeals denying petitioners' petition for rehearing is reprinted in the appendix to this petition at page 29a.

JURISDICTION

The United States Court of Appeals, Eighth Circuit, en banc, entered judgment on January 24, 2014. That court denied a timely petition for rehearing en banc, on January 27, 2014.

The jurisdiction of this Court is invoked under 28 U.S.C. §1254.

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

U.S. Const. Amend. VIII

Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

U.S. Const. Amend. XIV, Section 1.

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.

28 U.S. Code §1651 Writs

(a) The Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law.

(b) An alternative writ or rule nisi may be issued by a justice or judge of a court which has jurisdiction.

Federal Rules of Civil Procedure 12(b) How to Present Defenses.

Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

. . .

(6) failure to state a claim upon which relief can be granted

STATEMENT OF THE CASE

This mandamus action arises out of a discovery dispute in the petitioners' 42 U.S.C. §1983 action contending that the method of execution used in Missouri violates the Cruel and Unusual Punishments Clause of the Eighth Amendment to the United States Constitution, along with other related claims of constitutional and statutory violations. A brief history of the litigation will assist the Court in deciding this petition.

On May 15, 2012, Missouri's Department of Corrections announced that it would conduct lethal injection executions by administering a massive dose of the anesthetic propofol. No execution using propofol had ever occurred before this announcement. On June 26, 2012, 42 days later, petitioners here¹ filed a civil action in the Circuit Court of Cole County, Missouri, alleging constitutional and statutory violations inherent in the new execution protocol. The respondents removed the action to federal court on August 1, 2012. On November 16, 2012, the U.S. District Court for the Western District of Missouri overruled the respondents' motion to dismiss the action as to the Eighth Amendment, *ex post facto*, and Missouri constitutional claims. *Zink v. Lombardi*, 2-12-CV-4209-BP, ECF 31 (included in the Appendix to this petition beginning at p. 32a). Specifically, the district court held that the plaintiffs' complaint was sufficient without alleging that a specific alternative method of execution that would pass constitutional muster.

The district court entered a scheduling order, directing that discovery be completed by April 25, 2013, and setting trial for October 7, 2013. On August 1, 2013 and September 24, 2013, well after the discovery deadline, the state issued two new execution protocols. Both protocols retained use of propofol, but they provided for different means of administering it and different drugs accompanying it.

¹ Joseph Paul Franklin and Allen Nicklasson were included as plaintiffs in the original action, but they have since been executed. Petitioner Herbert Smulls is scheduled for execution at 12:01 a.m. on January 24, 2014. Whether or not this execution occurs, the issues in this petition remain relevant to the remaining petitioners.

Despite the pending litigation, on August 14, 2013, the Missouri Supreme Court scheduled execution dates for Allen Nicklasson on October 23, 2013 and Joseph Paul Franklin on November 20, 2013. However, on October 11, 2013, facing mounting pressure from the medical community because the European manufacturers of propofol indicated that they would no longer export the drug to the United States if it were used in executions, Missouri Governor Jay Nixon withdrew the propofol protocol and postponed Mr. Nicklasson's execution.

On October 22, 2013, less than 30 days before Mr. Franklin's scheduled execution, the state announced yet another revised protocol (the third in as many months) using a different drug, pentobarbital, as the killing agent. In an accompanying press release, the Department indicated that the drug would be obtained from a compounding pharmacy, and that the identity of the pharmacy, as well as that of a physician who wrote purported prescriptions for the pentobarbital and the laboratory which tested the potency and sterility of the drug would be kept secret under a statute that subjects those who reveal the identity of members of the execution team to civil damages (Mo. Rev. Stat. 546.720.03), and under a "state secrets" privilege. Previous suppliers of execution drugs, including the firms which were initially willing to supply propofol, had not been kept secret, but had been freely disclosed in discovery and in response to open records requests. On November 8, 2013, the state again changed its protocol, this time by an affidavit purporting to change the means by which executioners would insert an IV line into the prisoner.

Mr. Franklin was executed on November 13, 2013, while a motion for stay of execution was pending in the district court.

As a result of the state's issuance of the pentobarbital protocol, the district court granted the petitioners leave to file an otherwise out-of-time amended complaint. The amended complaint, filed on December 3, 2013, alleged that the use of compounded pentobarbital, like propofol, violated the petitioners' rights under the Cruel and Unusual Punishments Clause of the Eighth Amendment. The amended complaint also alleged several other constitutional and statutory grounds for relief, including numerous claims under the Missouri Administrative Procedure Act and Missouri pharmacy regulations.

The respondents moved the district court for a protective order allowing them to keep the identities of the compounding pharmacy, prescribing doctor, and laboratory secret. App. p. 53a *et seq.* The district court denied the motion. App. p. 27a-28a. On December 6, 2013, the respondents filed a petition for mandamus in the court of appeals seeking to vacate the district court order denying the protective order.

Mr. Nicklasson was executed on December 10, 2013, while a petition for rehearing of the denial of a motion for stay based on this case was pending in the Eighth Circuit.

On December 20, 2013, while the mandamus petition was pending in the court of appeals, the respondents filed in the district court a motion to dismiss the amended complaint, alleging among other grounds that the plaintiffs were required

to allege an alternative method of execution in order to prove an Eighth Amendment violation in a method of execution challenge.

On December 27, 2013, the Eighth Circuit panel granted mandamus as to the identity of the prescribing physician, but directed the identities of the laboratory and pharmacy be disclosed. App. p. 25a. On the same day, the Eighth Circuit en banc recalled the mandate and stayed the district court's discovery orders pending respondents' petition for rehearing en banc. On January 17, 2014, the Court of Appeals issued an order granting rehearing en banc and stating that the stay of December 27 remained in effect.

On January 21, 2014, the Kansas City newspaper *Pitch Weekly*, using publicly available documents, identified The Apothecary Shoppe of Tulsa, Oklahoma as Missouri's supplier of compounded pentobarbital. (The *Pitch* determined that, of the three Oklahoma pharmacies that were licensed on a particular date that was displayed on a redacted document provided under the Missouri Sunshine Law, only the Apothecary Shoppe has the ability to compound sterile injectable drugs such as pentobarbital.) The story, filed in the Court of Appeals as Exhibit 1 to the petitioners' petition for rehearing, is reprinted in the appendix beginning at p. 128a.

On January 24, 2014, the Louisiana Department of Corrections revealed documents that it was "in the process" of obtaining pentobarbital, and it disclosed a draft of a "non-disclosure agreement" sent to it by the Apothecary Shoppe. The press report of this release is included in the appendix beginning at p. 136a, and the

non-disclosure agreement is found beginning at p. 141a.² The non-disclosure agreement suggests that The Apothecary Shoppe had reached a similar contract to supply execution drugs to the State of Georgia, which also uses compounded pentobarbital in executions.

Petitioners' expert was able to determine the identity of the laboratory, Analytical Research Laboratories, using test reports that the respondents filed as exhibits supporting their opposition to stays of execution sought by Mr. Franklin and Mr. Nicklasson³, and published reports including examples of reports from the same laboratory. Those exhibits bore the initials "ARL," which the expert recognized from his experience in the field of compounded pharmaceuticals. The identity of the laboratory was published by news media on January 24, 2014, before the Eighth Circuit issued its opinion.

At 7:52 p.m. on the evening of January 24, 2014, the Eighth Circuit issued its opinion on rehearing, granting the petition for mandamus in its entirety. The Eighth Circuit held that the district court erred in requiring the very limited disclosure of the identities of the pharmacy, laboratory and prescribing physician because these identities were not "relevant" to any claim raised by the petitioner that should survive a motion to dismiss. It also went on to rule that the Eighth Amendment claim in the original, superseded complaint should have been

² These documents were filed as exhibits 2 and 3 to petitioners' petition for rehearing in the Eighth Circuit.

³ The reports, with ECF notations showing the date of filing, are included in the Appendix beginning at p. 144a. They were filed in the Court of Appeals as Exhibit 4 to the petitioners' petition for rehearing.

dismissed because the complaint failed to allege a constitutional means by which the State of Missouri could execute their clients.

The Eighth Circuit denied a timely motion for rehearing on January 27, 2014. This petition follows.

REASONS FOR GRANTING THE WRIT

I. The holding that an Eighth Amendment claim concerning manner of execution must be dismissed unless it alleges an available alternative manner of execution misreads *Baze v. Rees* and contradicts *Jones v. Bock* and *Hill v. McDonough*.

Reaching back to a 13-month-old ruling entered by the district court upholding a superseded complaint concerning a superseded execution protocol, the Eighth Circuit Court of Appeals granted a writ of mandamus because;

In denying a motion to dismiss the original complaint, and thus allowing discovery to proceed, the district court ruled that “Plaintiffs are not required to propose an alternative method of execution as an element of their Eighth Amendment claim.” R. Doc. 31, at 7. In our view, this is a plain misreading of the Supreme Court’s decision in *Baze v. Rees* and the Eighth Amendment.

App. p. 12a.

This holding itself misreads *Baze v. Rees*, 553 U.S. 35 (2008). In *Jones v. Bock*, 549 U.S. 199, 213 (2007), this Court held,

In *Hill v. McDonough*, 547 U.S. 573 (2006), we unanimously rejected a proposal that §1983 suits challenging a method of execution must identify an acceptable alternative: “Specific pleading requirements are mandated by the Federal Rules of Civil Procedure,

and not, as a general rule, through case-by-case determinations of the federal courts” *Id.*, at 582).

But *Baze* did not distinguish, or even cite, *Jones* or *Hill*. The Court in *Baze* was confronted with the specific claim that Kentucky’s execution protocol violated the Eighth Amendment ***because*** the state could easily change to a one-barbiturate method or at least discontinue the use of the paralytic agent pancuronium bromide. *Id.* at 56-57. That specific claim required the prisoner to show that the proposed alternative was feasible, available, and likely to reduce a significant risk of pain. *Id.* at 52, 61. The *Baze* opinion simply addressed the claim before this Court. It did not erect a new standard for pleading or proving ***every*** Eighth Amendment claim relating to manner of execution. In order to do so, it would have had to overrule *Jones* and *Hill*.

This Court has repeatedly held that there is a presumption that it does not overrule previous precedent *sub silentio*, and that the courts of appeals should not presume that it has done so. *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, (2000) (“This Court does not normally overturn, or so dramatically limit, earlier authority *sub silentio*.”); *Agostini v. Felton*, 521 U.S. 203, 237 (1997); *Quijas v. Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989) (“If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions.”)

Petitioners' complaint is materially different than that in *Baze*. Their claim is that the Missouri execution protocol violates the Eighth Amendment because it creates "a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment,'" ⁴ because of the state's use of unreliable and illegal drugs, not because of the state's failure to use an alternative method. *Baze* simply did not hold that the *only* way to demonstrate a "substantial risk of serious harm" is to show that there is an available alternative. That was one argument advanced by the Kentucky plaintiffs, but it was not held to be dispositive, because the Court approved the *existing* Kentucky protocol.

In its order denying rehearing, the Eighth Circuit implicitly conceded that *Hill v. McDonough*, 547 U.S. 573 (2006), is still good law, but attempted to distinguish *Hill* by noting that in that case, the petitioner had stated that "the challenged procedure presents a risk of pain the State can avoid while still being able to enforce the sentence ordering a lethal injection." *Id.* at 482, App. p. 30a. Petitioners' pleadings never suggested that the State cannot constitutionally use lethal injection to execute them. Their prayer for relief in each of their complaints requests a declaratory judgment that the lethal injection *protocol* issued by respondents violates their constitutional rights, and an injunction against the use of *that protocol*. Like the petitioners in *Hill* and for that matter in *Baze*, petitioners

⁴ *Baze v. Rees*, 553 U.S. 35, 50 (2008), quoting *Farmer v. Brennan*, 511 U.S. 825, 842, 846 & n.9 (1994).

here have never denied that the state can use lethal injection to execute them. The Eighth Circuit's attempt to circumvent the clear language of *Hill* is a distinction without a difference.

Moreover, the effect of the Eighth Circuit's erroneous construction of *Baze* is to deny petitioners discovery in their civil suit. As the dissenting judge there observed,

The challenge of proposing a readily available alternative method seems nearly impossible if the prisoners are denied discovery and, thus, unable to ascertain even basic information about the current protocol. The proposition that a plaintiff must propose an alternative method for his own execution in order to state a claim for relief under the Eighth Amendment is unreasonable.

App. p. 20a, Bye, J., dissenting.

Effectively, then, the Eighth Circuit's construction overrules *Baze* itself. If a plaintiff, *before conducting discovery*, must allege an available alternative to the current protocol, then it will in effect be impossible to prosecute an Eighth Amendment claim against *any* method of execution. Since *Baze* (as well as *Hill v. McDonough*, 547 U.S. 573 (2006)) recognized that such a claim is permissible under §1983, the Eighth Circuit's reading is contrary to this Court's opinions in both cases.

As the dissent notes, before this opinion, the Eighth Circuit itself had not required plaintiffs bringing Eighth Amendment method-of-execution challenges to allege an alternative method of execution. In *Clemons v. Crawford*, 585 F.3d 1119 (8th Cir. 2009), the court addressed the sufficiency of pleadings under the motion to

dismiss standard. The opinion did not require plaintiffs to plead an alternative method of execution to meet that standard. *See also Noonan v. Norris*, 594 F.3d 592 (8th Cir. 2010). Similarly, the Ninth Circuit opinions in *Cook v. Brewer*, 637 F.3d 1002 (9th Cir. 2011), and *Cook v. Brewer*, 649 F.3d 915 (9th Cir. 2011), also declined to require the allegation of an alternative method of execution.

The Courts of Appeals are divided on this issue; the Fifth and Sixth circuits have expressly held that in order to prevail on a manner of execution challenge under the Eighth Amendment, the plaintiff must show that the risk of pain is “substantial when compared to the known and available alternatives.” *Raby v. Livingston*, 600 F.3d 552, 560-61 (5th Cir. 2010) (affirming summary judgment); *Cooey v. Strickland*, 589 F.3d 210, 220 (6th Cir. 2009) (denying stay of execution). Although these two decisions were not decided on the liberal pleading standard of a motion to dismiss, the fact that they espouse a requirement that a successful plaintiff prove the absence of an alternative shows that they have misapprehended *Baze*.

The ruling below makes the Eighth Amendment all but inoperable in lethal injection cases:

The pleading standard advanced by the majority would require the prisoners to identify for the Director a readily available alternative method . . . for their own executions. Now, any individual wishing to challenge a state’s execution method as unconstitutional must identify a readily available alternative method for their own deaths before any discovery has been conducted to survive a Rule 12(b)(6) motion to dismiss. The challenge of proposing a readily available alternative method seems nearly

impossible if the prisoners are denied discovery and, thus, unable to ascertain even basic information about the current protocol.

App. 20a (Bye, J., dissenting). The Eighth Circuit's requirement is unworkable, because the prisoner cannot obtain discovery of the elaborate facts he is required to plead. The ruling below "cries out for review and reversal by the Supreme Court before another court in another state adopts the dubious reasoning applied by the majority here." Andrew Cohen, "The Secrecy Behind the Drugs Used to Carry Out the Death Penalty," THE ATLANTIC, Jan. 26, 2014.

This Court should grant certiorari to clarify the issue for other circuits and to correct the Eighth Circuit's erroneous reading of *Baze*. In the alternative, this Court should grant certiorari, vacate the judgment of the Eighth Circuit Court of Appeals and remand for reconsideration in light of *Baze v. Rees*, 553, U.S. 35, 50 (2008); *Jones v. Bock*, 549 U.S. 199, 213 (2007), and *Hill v. McDonough*, 547 U.S. 573 (2006).

II. The Court of Appeals improperly resolved a moot discovery dispute in order to reach the merits of petitioners' underlying claims.

As this Court has long held,

The exercise of judicial power under Art. III of the Constitution depends on the existence of a case or controversy. As the Court noted in *North Carolina v. Rice*, 404 U.S. 244, 246. . . (1971), a federal court has neither the power to render advisory opinions nor to decide questions that cannot affect the rights of litigants in the case before them.

Preiser v. Newkirk, 422 U.S. 395, 401 (1975).

Petitioners now have the information they sought in discovery, and they had it before the Eighth Circuit issued its opinion. Nothing in that opinion can put the toothpaste back into the tube and allow the respondents to suppress that information. Respondents are like the petitioner in *Murphy v. Hunt*, 455 U.S. 478, 482 (1982), who was no longer entitled to bail once he had been convicted and could therefore not benefit from a favorable court decision, and the petitioners in *Alvarez v. Smith*, 558 U.S. 87, 92 (2009), who had resolved all of the property issues in the case with the respondents. They will not benefit from the Eighth Circuit's decision on their mandamus petition.

In its order denying rehearing, the Court of Appeals attempted to avoid the petitioners' mootness argument by stating that the published information might not be accurate, and that the respondents had not withdrawn their request to suppress the identities of the pharmacy and laboratory. But whether or not that request is granted now makes no difference. Petitioners were the ones seeking this information. They are confident that the information IS accurate, and they now have no reason to seek discovery of that information from respondents. Thus, the Court's judgment "cannot affect the rights of litigants in the case before" it. *Ibid*. This Court reached a similar conclusion in *Alvarez v. Smith*, 558 U.S. 87, 92 (2009), where the parties continued "to dispute the lawfulness of the State's hearing procedures." However, the Court declined to decide that dispute because: "[T]hat

dispute is no longer embedded in any actual controversy about the plaintiffs' particular legal rights. Rather, it is an abstract dispute about the law, unlikely to affect these plaintiffs any more than it affects other Illinois citizens." *Id.* at 93. As this Court put it most recently in *Genesis Healthcare Corp. v. Symczynk*, 133 S.Ct. 1523, 1528 (2013),

If an intervening circumstance deprives the plaintiff of a "personal stake in the outcome of the lawsuit," at any point during litigation, the action can no longer proceed and must be dismissed as moot. *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477–478. . . (1990) (internal quotation marks omitted).

The Eighth Circuit's judgment about the respondents' right to keep secret the identities of the pharmacy and laboratory might affect the respondents in *future* cases, but those cases are not before the Court. The respondents here have no "personal stake in the outcome of the lawsuit." The sole stated purpose of the lawsuit here—a mandamus petition—was to protect members of the "execution team" from "harassment, intimidation, and harm" because members of the public or even the prisoners' attorneys might threaten or boycott these individuals' businesses, and thus, respondents might be unable to carry out executions and to ensure the safety and security of those who assist executions. ["Petition for Immediate Writ of Prohibition or Mandamus" at 3-4, 11-12.]. But that interest had run its course by the time of the Eighth Circuit's opinion. Petitioners' counsel knew the information independently of the district court's orders, and the public already knew the very identities that respondents sought to withhold. An appeal becomes

moot when, as here, the court cannot provide effective relief for the claimed or threatened injury. *E.g.*, *Iron Arrow Honor Society v. Heckler*, 464 U.S. 67, 70-71 (1983); *Mills v. Green*, 159 U.S. 651, 653 (1895); *Pub. Util. Comm’n of the State of Cal. v. FERC*, 100 F.3d 1451, 1458 (9th Cir.1996); *In re Public Service Co. of New Hampshire*, 963 F.2d 469, 471 & n.4 (1st Cir. 1992).

This claim does not fall within the narrow exception to the mootness doctrine for questions “capable of repetition, yet evading review.” This “narrow exception” requires a party to show (1) a “demonstrated probability” that the complaining party will be subjected to the same action again, and (2) that the challenged action is of such short duration that “a similar future action could not be fully litigated before the case becomes moot.” *Murphy v. Hunt*, 455 U.S. 478, 482 (1982); *see also Weinstein v. Bradford*, 423 U.S. 147, 149 (1975) (*per curiam*). The exception applies only in exceptional circumstances. *Alvarez v. Smith*, 558 U.S. 87, 93 (2009).

Before the Eighth Circuit, the respondents argued that the case was not moot because “[I]f the current pharmacist leaves the execution team because of fear of harassment or other pressures, the underlying issue of the protection of the identity [of the] next pharmacist remains.” Supplemental Suggestions in Support of Petition for Rehearing En Banc, p. 6. But that speculation neither shows a “demonstrated probability” that the issue will recur nor that respondents could not litigate it in a similar future action.

First, as of the filing of this petition, the current pharmacy has not left the execution team despite news accounts revealing its identity and the fact that it sells

execution drugs to other states. Instead, it has simply denied its involvement in the press. Any suggestion that it will cease to sell execution drugs in the future is highly speculative. A “mere physical or theoretical possibility” is insufficient to avoid mootness. *Murphy v. Hunt*, 455 U.S. 478, 482 (1982).

Second, if in fact the state is required to secure a new pharmacy, and litigation ensues concerning *that* pharmacy’s identity, the district court and Court of Appeals will have a full opportunity to consider the issue at that time. The Court of Appeals refused, in its opinion, to decide the privilege claims that the respondents initially placed before it. (“The privilege issues are significant and complex, but we express no view on them. . . .” Appendix, p. 11a). Thus, the decision here is of absolutely no help to respondents in any future dispute about the disclosure of the identity of the pharmacy other than the free pass taken by the Court of Appeals to attack the merits of petitioners’ claims. But there is no reason to think that, in the future, the issue will evaporate before it can be resolved unless the respondents continue to be careless about their public disclosures.

Should this Court not choose to address the Eighth Circuit’s *ultra vires* attempt to overrule *Baze v. Rees*, 553 U.S. 35 (2008), this Court should grant certiorari, find the case moot, and remand to the Eighth Circuit with instructions to dismiss.

III. The Court of Appeals usurped the merits of the district court's non-final rulings.

Mandamus does not lie for mere error by the district court or an abuse of its discretion. Rather, “[O]nly exceptional circumstances amounting to a judicial usurpation of power or a clear abuse of discretion” will justify the invocation of the extraordinary remedy of mandamus. *Cheney v. U.S. Dist. Ct.*, 542 U.S. 367, 390 (2004). The aggrieved party must show that its right to mandamus is “clear and indisputable.” *Kerr v. U.S. Dist. Court for N.D. Calif.*, 426 U.S. 394, 403 (1976).

In support of their district court motion for a protective order suppressing the identities of the pharmacy, laboratory, and prescribing physician, the respondents relied *only* on their claim of privilege. (For the convenience of the Court, the motion is included in the Appendix beginning at p. 52a.) At no time in their written pleadings on this issue did they seek reconsideration of the district court’s November 16, 2012, order that the *original* complaint filed by the petitioners was sufficient without alleging an alternative method of execution which would pass constitutional muster. In fact, they did not file a motion to dismiss the amended complaint on this or any other ground until December 20, 2013, after the district court had denied their motion for protective order and they had filed their petition for mandamus.⁵ But the respondents did not argue the denial of their motion to dismiss in the district court as a basis either for the issuance of a protective order or

⁵ The motion to dismiss is still pending, but is now moot. On January 27, 2014, petitioners filed a motion for leave to file a second amended complaint, as permitted in the new scheduling order issued by the district court on January 13, 2014.

for their motion to stay the discovery order. Only in their petition for rehearing after the Eighth Circuit panel denied relief did the respondents argue, *for the first time*, that their motion for a protective order should have been granted because petitioners do not propose an alternative method of execution.

The standard for granting a writ of mandamus is “far more demanding” than the standard for relief on appeal. Wright & Miller, 16 FEDERAL PRACTICE & PROCEDURE § 3932.1 (2d ed. 1996). Since an *appellant* cannot prevail on arguments not raised in the court below, a mandamus petitioner cannot suddenly raise new arguments and obtain extraordinary appellate court relief. Thus, the Eighth Circuit’s ruling that the district court abused its discretion by denying a protective order because it improperly failed to dismiss an action 13 months earlier convicts the court of abusing discretion that it was never asked to exercise. “Permitting piecemeal, prejudgment appeals. . . undermines efficient judicial administration and encroaches upon the prerogatives of district court judges, who play a special role in managing ongoing litigation.” *Mohawk Industries v. Carpenter*, 558 U.S. 100, 106 (2009).

Responding to this contention in its order denying rehearing, the Court of Appeals relied on the fact that the respondents had raised the issue in their motion to dismiss the original complaint: “We do not think the Director was required to reargue the same points in his motion for a protective order to justify raising the issues in the court of appeals.” App. p. 30a. But this analysis permits exactly the type of “piecemeal, prejudgment appeal” that was condemned in *Mohawk Industries*

where this Court reversed the grant of mandamus. Allowing the court of appeals to reach back into the history of the case and review the district judge's prejudgment orders not only violates the collateral order doctrine (see *Firestone Tire & Rubber Co. v. Risjord*, 449 U.S. 368, 374 (1981)), it undermines "the independence of the district judge, as well as the special role that individual plays in our judicial system." (*Id.*) As this Court explained in *Richardson-Merrell, Inc. v. Koller*, 472 U.S. 424, 430 (1985): "Immediate review of every trial court ruling, while permitting more prompt correction of erroneous decisions, would impose unreasonable disruption, delay, and expense. It would also undermine the ability of district judges to supervise litigation." The same policy prevents the court of appeals from usurping the district judge's authority to decide motions to dismiss under the guise of deciding a mandamus petition addressed to a discovery issue.

Despite this Court's clear directives that circuit courts utilize the writ sparingly, the exact meaning of "clear abuse of discretion" and "usurpation of judicial power" has remained undefined by this Court. As a result, it has been subject to a variety of interpretations at the circuit level. In determining whether there was a "clear abuse of discretion" or usurpation of judicial power", some courts have based the decision on whether the district court gave the question presented an appropriate level of consideration. *See Roe v. United States*, 414 Fed.Appx. 327 (2d Cir. 2011) (holding that high standard for a writ of mandamus had not been met where the district court reviewed the documents in question and the voluminous submissions by the parties, conducted four days of hearings as to the question at

issue, and explained in detail its “well-reasoned decision” to issue the order for which review was sought); See e.g. *In re Whirlpool Corp.*, 597 F.3d 858 (7th Cir. 2010) (finding that the standard for a writ had not been met.)

Other courts have asked whether a well-established legal rule or standard was disregarded by the district court. See e.g. *In re Cooper Tire & Rubber Co.*, 568 F.3d 1180 (10th Cir. 2009) (holding that a writ should not issue because, contrary to the claims in the pleadings seeking a writ, the Court had properly considered Fed.Rule.Civ.Pro, 26 prior to issuing its order); *In re The City of New York*, 607 F.3d 923 (2d. Cir. 2010) (Issuing writ on the grounds that the district court “indisputably” adopted an erroneous view of the law and also made a clearly erroneous assessment of evidence).

Still other courts have taken the writ proceedings as an opportunity to re-explore every aspect of an order and make their own independent assessment of the facts in order to determine whether the trial court made any error in issuing the contested order. See e.g. *In re Volkswagen of America, Inc.* 545 F.3d 304 (5th Cir. 2008) (issuing a writ prohibiting the district court from enforcing its order on a transfer motion after applying the facts of the case to the factors that must be considered in determining transfer and deciding that the district court had decided the factors erroneously); *United States v. Fast*, 709 F.3d 712 (8th Cir. 2013) (Re-engaging in the analysis the district court had performed in order to determine that the amount of restitution had been properly calculated, and therefore denying the writ).

In this case, the Eighth Circuit went beyond even the standards adopted in *Fast* and *Volkswagen* and took the mandamus petition as an opportunity to issue an advisory order as to what the court should (or should have) ruled on a motion to dismiss, an issue that was not even before the court on mandamus. Far from remedying a “judicial usurpation of power,” *Cheney v. U.S. Dist. Ct.*, 542 U.S. 367, 390 (2004), the ruling below creates one. The Court should grant certiorari to enforce the limited scope of extraordinary writ proceedings, and thus to minimize appellate disruption of non-final orders and district court prerogatives. The orderly conduct of litigation requires nothing less. “Perhaps there is always some hardship caused by the application of the ‘final decision’ rule. Yet the rule is beneficial in most applications.” *In re Heddendorf*, 263 F.3d 887, 888-89 (1st Cir. 1959).

CONCLUSION

The petition for writ of certiorari should be granted..

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Elizabeth Unger Carlyle', with a stylized, cursive script.

ELIZABETH UNGER CARLYLE

(Counsel of Record)

P.O. Box 30418

Kansas City, Missouri 64112

(816) 525-6540

Joseph W. Luby

Death Penalty Litigation Clinic

6155 Oak Street, Suite C

Kansas City, MO 64113

816-363-2795

John William Simon

Constitutional Advocacy, LLC

7201 Delmar Blvd., Suite 201

St. Louis, Missouri 63130-4106

314-604-6982

Counsel for Petitioners

ATTORNEYS FOR PETITIONERS

United States Court of Appeals
For the Eighth Circuit

No. 13-3699

In re: George A. Lombardi,

Petitioner.

Appeal from United States District Court
for the Western District of Missouri - Jefferson City

Submitted: January 17, 2014

Filed: January 24, 2014

Before RILEY, Chief Judge, WOLLMAN, LOKEN, MURPHY, BYE, SMITH,
COLLTON, GRUENDER, SHEPHERD, and KELLY, Circuit Judges, En Banc.¹

COLLTON, Circuit Judge, with whom RILEY, Chief Judge, and WOLLMAN,
LOKEN, SMITH, GRUENDER, and SHEPHERD, Circuit Judges, join.

George Lombardi, Director of the Missouri Department of Corrections,
petitions for a writ of mandamus or prohibition directed to the district court in an
underlying civil action concerning Missouri's method for carrying out the death
penalty. *See Zink v. Lombardi*, No. 2:12-cv-04209 (W.D. Mo. filed Aug. 1, 2012).
Lombardi seeks to prohibit the district court from enforcing orders that Lombardi
must disclose in civil discovery, for use by opposing counsel, the identities of (1) the

¹Judge Benton did not participate in the consideration or decision of this
matter.

physician who prescribes the chemical used in Missouri executions, (2) the pharmacist who compounds the chemical, and (3) the laboratory that tests the chemical for potency, purity, and sterility. Citing reports that “many manufacturers and suppliers have barred the use of drugs used for executions or refused, under pressure from death-penalty opponents, to sell or manufacture drugs for use in execution,” the Director avers that disclosure of these identities “would prevent the Department from obtaining lethal chemicals needed to perform its state obligations.” R. Doc. 189-1, at 2. Consistent with the Director’s affidavit, the plaintiffs themselves allege that maintaining confidentiality of the identities “prevents the suppliers’ associations, customers, and prescribing or referring physicians from censuring or boycotting them,” and unreasonably restricts the associations of health-care professionals “from de-certifying or otherwise censuring them or boycotting them.” R. Doc. 183, at 94-95.

A three-judge panel of this court granted a writ with respect to discovery of the identity of the physician, but denied a writ as to discovery of the identities of the pharmacy and the laboratory. On rehearing en banc, we conclude that a writ should issue to vacate the orders requiring discovery of all three identities.

I.

A.

In Missouri, first-degree murder is punishable by death or life imprisonment. Mo. Rev. Stat. § 565.020.2. When the trial court imposes a penalty of death, Missouri law provides that “[t]he manner of inflicting the punishment of death shall be by the administration of lethal gas or by means of the administration of lethal injection.” Mo. Rev. Stat. § 546.720.1. The statute further authorizes the Director to provide “the necessary appliances for carrying into execution the death penalty by means of the administration of lethal gas or by means of the administration of lethal

injection.” *Id.* State law thus places the matter of selecting a lethal-injection protocol in the discretion of the Director. *Taylor v. Crawford*, 487 F.3d 1072, 1081 (8th Cir. 2007). The governing statute also provides that the Director will select an “execution team,” consisting of “those persons who administer lethal gas or lethal chemicals” and “those persons, such as medical personnel, who provide direct support for the administration of lethal gas or lethal chemicals.” Mo. Rev. Stat. § 546.720.2.

As of 2010, Missouri’s lethal-injection protocol involved the administration of three drugs: “sodium thiopental to anesthetize the prisoner and render him unconscious, pancuronium bromide to paralyze him and stop his breathing, and potassium chloride to stop the prisoner’s heart.” *Ringo v. Lombardi*, 677 F.3d 793, 795 (8th Cir. 2012). But Missouri’s supply of sodium thiopental expired on March 1, 2011, and the State was unable to acquire more of the drug. The only domestic manufacturer of sodium thiopental had ceased to produce it, and the Food and Drug Administration had not approved the drug for importation. *Id.* at 797. In late 2011, moreover, the European Union announced strict regulations on the export of sodium thiopental to countries that authorize the death penalty. Press Release, European Commission, Commission Extends Control over Goods Which Could Be Used for Capital Punishment or Torture (Dec. 20, 2011), *available at* http://europa.eu/rapid/press-release_IP-11-1578_en.pdf (last visited Jan. 24, 2014).

In light of these developments, Director Lombardi issued a new execution protocol in May 2012 that called for the injection of two grams of propofol. R. Doc. 133-1. In October 2013, however, “in light of the issues that have been raised surrounding the use of propofol in executions,” Governor Nixon directed the Department of Corrections to modify the execution protocol to employ a different form of lethal injection. R. Doc. 183-1. The “issues” raised in the public domain included the potential that if propofol were used in lethal injections, then the European Union would forbid or restrict the exportation of propofol to the United States, and the drug would be unavailable for continued use in this country as a

common anesthetic in surgical procedures. *See, e.g.*, R. Doc. 126, at 4; R. Doc. 126-1, at 3-4; R. Doc. 126-3, at 2-3; Mo. Soc’y of Anesthesiologists, Statement on the Use of Propofol in Lethal Injections (Sept. 2013), *available at* <http://www.msahq.com/wp-content/uploads/2013/09/MSA-Statement-on-Use-of-Propofol-in-Lethal-Injections.pdf> (last visited Jan. 24, 2014).

In response, the Director changed the lethal-injection protocol on October 18, 2013. The new protocol eliminates the use of propofol and provides for the injection of five to ten grams of pentobarbital. R. Doc. 144, at 1; R. Doc. 144-1, at 1. The Department also announced that it had added a compounding pharmacy to its execution team, and that the pharmacy would be responsible for providing pentobarbital for executions carried out under the new protocol. R. Doc. 183-3. Missouri applied the October 2013 protocol in the executions of Joseph Paul Franklin on November 20, 2013, and Allen Nicklasson on December 11, 2013.

B.

The litigation underlying the petition for writ of mandamus began in June 2012 and was removed to federal court in August 2012. A group of prisoners sentenced to death in Missouri sued the Director, seeking a declaration that the lethal-injection protocol using propofol was unconstitutional. The complaint alleged that the protocol violated the Eighth and Fourteenth Amendments of the Constitution of the United States and the comparable prohibition on cruel and unusual punishment in the Missouri Constitution, the Ex Post Facto Clauses of the federal and state constitutions, the Supremacy Clause of the federal Constitution, and the separation of powers guaranty of the Missouri Constitution. R. Doc. 1-1; R. Doc. 1-2. On the Director’s motion to dismiss the complaint, the district court allowed the claims based on the Eighth Amendment and the Ex Post Facto Clauses to proceed, but dismissed the others for failure to state a claim. R. Doc. 31.

After the Director modified the lethal-injection protocol in October 2013 to eliminate propofol and to use pentobarbital, the Director moved to dismiss the complaint for lack of jurisdiction. The district court denied the motion, reasoning that despite the change in lethal-injection protocol, “there is clearly an overarching controversy concerning the Department’s method of execution,” and that even if the complaint were dismissed, the plaintiffs “could and would immediately file a new lawsuit alleging violations involving the latest version of the protocol.” R. Doc. 163, at 3. The court concluded that even if the plaintiffs were required to file a new lawsuit, “[t]he same controversy would remain: whether the Department’s current execution protocol is in violation of the Eighth Amendment.” *Id.*

On November 26, 2013, the district court granted the plaintiffs leave to file an amended complaint alleging violations of several federal and state constitutional, statutory, and regulatory provisions. Although this court recently had vacated the district court’s order staying the execution of Joseph Paul Franklin based on challenges to the method of execution, *Zink v. Lombardi*, No. 13-3505, Order (8th Cir. Nov. 19, 2013), *vacating* R. Doc. 163, the district court ruled that the proposed amendment was not futile, because this court’s decision in Franklin’s case did not mean that the plaintiffs could never develop sufficient evidence to support their claims with adequate discovery procedures. R. Doc. 181. On December 3, 2013, the plaintiffs filed an amended complaint that challenged the current protocol and the use of pentobarbital. R. Doc. 183.

The discovery orders at issue here were entered on December 12, 2013. Having denied the Director’s motion to dismiss the original complaint, rejected the Director’s contention that amendment of the complaint would be futile, and disagreed with the Director’s invocation of an evidentiary privilege, the district court ordered the Director to disclose to counsel for the plaintiffs, no later than December 16, the identities of the physician who provides a prescription for the compounded pentobarbital, the pharmacist who compounds the pentobarbital used in executions,

and the laboratory that tests the compounded drug. R. Doc. 203; R. Doc. 204. The district court also denied the Director's motion for a protective order regarding members of the execution team. R. Doc. 205.

The district court permitted only two attorneys for the plaintiffs to learn the identities and required those attorneys to "refrain from directly identifying to any other person the pharmacist, physician, or laboratory as individuals who are assisting the state in the execution of prisoners." R. Doc. 203. Counsel for the plaintiffs, however, expressed concern that it could be very difficult to investigate the physician, pharmacist, and laboratory without disclosing their roles in the execution process, and suggested there were "many ways in which investigating the pharmacy might place the pharmacy's identity, status, and role at issue before whoever we would be talking to." R. Doc. 224, at 14-16. The district court acknowledged that "it may be that there's just no way given the circumstances to keep it confidential because of the central nature of these people to the current dispute," and asked only that counsel keep the identities confidential, "other than as needed to do the investigation." *Id.* at 16.

The Director then petitioned this court for a writ of mandamus or prohibition that would prohibit the district court from enforcing the three disputed orders. Late in the afternoon on December 16, the district court denied the Director's motion for a stay of the discovery orders pending a decision from this court. The Director promptly moved for a stay in this court. On December 17, the Director delivered to the district court (but not to opposing counsel) a document identifying the prescribing physician, compounding pharmacy, and testing laboratory. Later that day, this court granted a temporary stay of the district court's orders.

On December 27, a three-judge panel of this court (Bye, Gruender, and Kelly, JJ.) granted a writ of mandamus and prohibited the district court from ordering the Director to disclose the identity of the prescribing physician. The panel denied,

however, the petition for writ of mandamus as to discovery of the identities of the compounding pharmacy and the testing laboratory. The panel dissolved the temporary stay entered on December 17 and issued the mandate immediately. The district court then ordered the Director to disclose to opposing counsel the identities of the compounding pharmacist and the testing laboratory by 5:00 p.m. on December 27. The Director promptly petitioned this court for rehearing en banc. He also moved this court to recall the mandate and to stay temporarily the district court's discovery orders pending disposition of the petition for rehearing. The Director informed the district court of these filings and again provided the identities of the compounding pharmacy and testing laboratory to the district court, but not to opposing counsel.

The three-judge panel denied the motions to recall the mandate and for temporary stay by a vote of 2-1, with Judge Gruender dissenting. The full court, on its own initiative, ordered rehearing en banc of the motions by a vote of 7-2, with two judges not participating, and then granted both motions. The clerk entered the appropriate orders on this court's docket by 7:36 p.m. on December 27.

There followed some unusual procedural developments. On Saturday, December 28, the district court entered an order stating that no stay of the district court's order of December 27 had been issued by the Eighth Circuit, and that the district court, "exercising its inherent authority to protect the jurisdiction of the Court and to ensure fairness, has sent to Cheryl Pilate and Joe Luby [counsel for the plaintiffs] the information voluntarily provided to the Court by the Defendants." R. Doc. 242, at 2. This information included the identities of the compounding pharmacy and the testing laboratory. Later that day, however, the district court entered a second order stating:

Since entering its Order, [Doc. 242], the Court learned that the Eighth Circuit stayed its judgment filed on December 27, 2013. In light of this

stay, Ms. Pilate and Mr. Luby have been instructed to take no action concerning the information provided them until a phone conference can be arranged with the parties at the earliest possible time.

R. Doc. 243.

On December 30, the district court convened a telephone conference and ordered Ms. Pilate and Mr. Luby “to completely delete the email sent by the Court from their system and to delete any information obtained from that email from their files.” R. Doc. 251. The court further ordered that counsel and their staff “are . . . not to disclose the information provided in the email, are not to conduct investigations regarding the contents of the email, and are ordered to delete any trace of the contents of the emails and of the information contained within it.” *Id.* The Director moved during the telephone conference for recusal of the district judge. The district judge later entered an order recusing herself from further proceedings in this matter, R. Doc. 253, and the case was reassigned to another district judge. R. Doc. 254.

II.

The principal matter before the en banc court is Director Lombardi’s petition for a writ of mandamus to prohibit the district court from enforcing its orders that the Director disclose to opposing counsel the identities of the physician who prescribes the pentobarbital used in Missouri executions, the pharmacist who compounds the chemical, and the laboratory that tests the chemical for potency, purity, and sterility. Although the district court disclosed to counsel for plaintiffs the identities of the pharmacist and laboratory on December 28, despite this court’s entry of a temporary stay on December 27, the petition is not moot. The Director has not disclosed the identities to opposing counsel, and the district court took remedial action to foreclose use of the information that the court disclosed to counsel. There is still a live

controversy over whether the Director must disclose the identities for active use by opposing counsel.

Extraordinary writs like mandamus are “useful safety valves for promptly correcting serious errors,” *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 111 (2009) (internal quotation and alteration omitted), but “only exceptional circumstances amounting to a judicial usurpation of power or a clear abuse of discretion” will justify the invocation of the extraordinary remedy of mandamus. *Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380 (2004) (internal quotations and citation omitted). To obtain a writ of mandamus, the petitioning party must satisfy the court that he has “no other adequate means to attain the relief he desires,” and that his entitlement to the writ is “clear and indisputable.” *Id.* at 380-81 (internal quotations omitted). “[I]f the first two prerequisites have been met, the issuing court, in the exercise of its discretion, must be satisfied that the writ is appropriate under the circumstances.” *Id.* at 381.

In a summary order, the three-judge panel issued a writ of mandamus to prohibit the district court from enforcing its order to disclose the identity of the prescribing physician, but denied the Director’s request to prohibit disclosure of the pharmacy and testing laboratory. In his petition for rehearing, the Director urged two principal reasons why a writ should issue not only as to the physician’s identity, but to prohibit discovery of all three identities.

First, the Director relies on his invocation of a privilege to protect information designated as confidential by Missouri statute or common law. *See generally* Fed. R. Evid. 501; *In re Hampers*, 651 F.2d 19, 21-23 (1st Cir. 1981); *Am. Civil Liberties Union of Miss., Inc. v. Finch*, 638 F.2d 1336, 1343-44 (5th Cir. Unit A Mar. 1981). Throughout this litigation, the Director has urged that the Department properly designated the physician, pharmacist, and laboratory as part of its “execution team,” and has relied on a state statute that says “identities of members of the execution

team, as defined in the execution protocol of the department of corrections, shall be kept confidential.” Mo. Rev. Stat. § 546.720.2. On this basis, the Director contends that the information is privileged from disclosure. *See generally* Model Code of Evidence, Rule 228 (1942); *Taylor v. Nix*, 451 F. Supp. 2d 1351, 1352-54 (N.D. Ga. 2006). The Director also has adverted, *e.g.*, R. Doc. 224, at 8-9, to common law privileges that apply independent of any statute that specifically requires confidentiality. *See generally* *State ex rel. Mo. Ethics Comm’n v. Nichols*, 978 S.W.2d 770, 773 (Mo. Ct. App. 1998); *Pack v. Beyer*, 157 F.R.D. 226, 231-33 (D.N.J. 1994). Second, the Director argues that the plaintiffs in the underlying litigation have failed to state a claim as to which discovery of the identities is relevant, and that the discovery of such sensitive information is therefore unjustified. *See* Fed. R. Civ. P. 26(b)(1).

In addition to these arguments on the merits, the Director asserts that no other adequate means is available to attain the requested relief. He argues that if discovery proceeds and an appeal is allowed only after judgment, then it is likely that active investigation of the physician, pharmacy, and laboratory will lead to further disclosure of the identities. These disclosures, he contends, would trigger collateral consequences that would prevent the Director from obtaining the lethal chemicals necessary to carry out the capital punishment laws of the State. He cites, as an example, a letter dated October 2013 from a compounding pharmacy in Texas that demanded the Texas Department of Criminal Justice return a supply of compounded pentobarbital sold for use in executions, because of a “firestorm,” including “constant inquiries from the press, the hate mail and messages,” that resulted from publication of the pharmacy’s identity. R. Doc. 189-1, at 6-7. *See Landrigan v. Brewer*, 625 F.3d 1132, 1143 (9th Cir. 2010) (Kozinski, C.J., dissenting from denial of rehearing en banc) (“Certainly Arizona has a legitimate interest in avoiding a public attack on its private drug manufacturing sources . . .”).

The privilege issues are significant and complex, but we express no view on them, because it is clear and indisputable that the discovery ordered by the district court is not relevant to any claim that should survive a motion to dismiss, and that the Director has no other adequate means to attain the relief he desires. Although denial of a motion to dismiss ordinarily is not appealable, a writ of mandamus to correct an erroneous denial may be warranted in extraordinary circumstances where continued litigation would have significant unwarranted consequences. *See Abelesz v. OTP Bank*, 692 F.3d 638, 650-53 (7th Cir. 2012). Discovery orders likewise are not ordinarily appealable, but mandamus may issue in extraordinary circumstances to forbid discovery of irrelevant information, whether or not it is privileged, where discovery would be oppressive and interfere with important state interests. *See Sanderson v. Winner*, 507 F.2d 477, 479-80 (10th Cir. 1974). These propositions taken together, along with the unavailability of alternative means for the Director to attain relief, lead us to conclude that a writ should issue.

The plaintiffs' principal claim in the underlying litigation is based on the Eighth Amendment. Our analysis must begin with a basic proposition: "[C]apital punishment is constitutional. It necessarily follows that there must be a means of carrying it out." *Baze v. Rees*, 553 U.S. 35, 47 (2008) (plurality opinion) (citation omitted). Any allegation that all methods of execution are unconstitutional, therefore, does not state a plausible claim under the Eighth Amendment.

The plaintiffs complain that Missouri's use of compounded pentobarbital in its execution protocol creates a substantial risk of severe pain or an objectively intolerable risk of severe pain, and thus constitutes cruel and unusual punishment in violation of the Eighth Amendment. In furtherance of that claim, they seek to investigate the physician, pharmacy, and laboratory involved in the execution process. But the plaintiffs do not allege that the risk of harm arising from the State's current lethal-injection protocol is substantial when compared to known and available alternatives. They do not allege that a different lethal-injection protocol, or a

different method of execution (*e.g.*, lethal gas, electrocution, or firing squad), is more humane. In denying a motion to dismiss the original complaint, and thus allowing discovery to proceed, the district court ruled that “Plaintiffs are not required to propose an alternative method of execution as an element of their Eighth Amendment claim.” R. Doc. 31, at 7.

In our view, this is a plain misreading of the Supreme Court’s decision in *Baze v. Rees* and the Eighth Amendment. Where, as here, there is no assertion that the State acts purposefully to inflict unnecessary pain in the execution process, the Supreme Court recognized only a limited right under the Eighth Amendment to require a State *to change* from one feasible method of execution to another. The controlling opinion of the Chief Justice in *Baze* provides that if a State refuses to adopt a readily available alternative method of execution that would significantly reduce a substantial risk of severe pain, then “a State’s refusal *to change its method* can be viewed as ‘cruel and unusual’ under the Eighth Amendment.” 553 U.S. at 52 (plurality opinion) (emphasis added). In sum: “A stay of execution may not be granted on grounds such as those asserted here unless the condemned prisoner establishes that the State’s lethal injection protocol creates a demonstrated risk of severe pain. *He must show that the risk is substantial when compared to the known and available alternatives.*” *Id.* at 61 (emphasis added). The concurring opinions in *Baze* reflect the same understanding. *Id.* at 63 (Alito, J., concurring) (explaining that the plurality opinion “concludes that ‘a State’s refusal to change its method [of execution] can be viewed as “cruel and unusual” under the Eighth Amendment’ *if the State, ‘without a legitimate penological justification,’ rejects an alternative method that is ‘feasible’ and ‘readily’ available and that would ‘significantly reduce a substantial risk of severe pain’*”) (alteration in original) (emphasis added) (quoting *id.* at 52 (plurality opinion)); *id.* at 94 (Thomas, J., concurring in the judgment) (“As I understand it, [the plurality] opinion would hold that a method of execution violates the Eighth Amendment if it poses a substantial risk of severe pain *that could be significantly reduced by adopting readily available alternative procedures.*”)

(emphasis added); *see also Raby v. Livingston*, 600 F.3d 552, 560-61 (5th Cir. 2010) (“Because we find that Raby has failed to establish that the Texas lethal injection protocol creates a demonstrated risk of severe pain, *we do not reach the second step of the Baze test, whether the risk created by the current protocol is substantial when compared to the known and available alternatives.*”) (emphasis added); *Cooey v. Strickland*, 589 F.3d 210, 220 (6th Cir. 2009) (“To demonstrate that Ohio seeks to impose ‘cruel and unusual’ punishment, U.S. Const. amend. VIII, *Biros* must show that its protocol ignores a ‘*sure or very likely*’ risk of serious pain ‘and needless suffering,’ which ‘creates a demonstrated risk of severe pain’ *that is ‘substantial when compared to the known and available alternatives.* ’”) (second emphasis added) (quoting *Baze*, 553 U.S. at 50, 61 (plurality opinion)).²

Without a plausible allegation of a feasible and more humane alternative method of execution, or a purposeful design by the State to inflict unnecessary pain, the plaintiffs have not stated an Eighth Amendment claim based on the use of compounded pentobarbital. Nor have they stated a claim under Article I, Section 21 of the Missouri Constitution, which embodies the same standard as the Eighth Amendment. *Burnett v. State*, 311 S.W.3d 810, 814 n.3 (Mo. Ct. App. 2009). It was therefore a clear abuse of discretion for the district court to allow the claim to proceed and to order on that basis discovery of sensitive information, the disclosure of which Lombardi avers would prevent the State from acquiring lethal chemicals necessary to carry out the death penalty.

²This court’s decisions in *Nooner v. Norris*, 594 F.3d 592 (8th Cir. 2010), and *Clemons v. Crawford*, 585 F.3d 1119 (8th Cir. 2009), and the decisions of the Ninth Circuit in *Cook v. Brewer*, 649 F.3d 915 (9th Cir. 2011), and *Cook v. Brewer*, 637 F.3d 1002 (9th Cir. 2011), all rejected Eighth Amendment claims on the ground that a plaintiff failed to show a substantial risk of serious harm. None of those decisions held that an Eighth Amendment challenge to method of execution could succeed without a showing that the alleged risk is substantial when compared to known and available alternatives.

The plaintiffs also assert a violation of the Ex Post Facto Clauses of the federal and state constitutions, claiming that the use of compounded pentobarbital in the current execution protocol constitutes an unconstitutional increase in punishment over the former method of execution. The manner of punishment for capital murder in Missouri at all relevant times, however, has been death by lethal injection or lethal gas, with discretion granted to the Director of the Department of Corrections to establish the method of execution. Mo. Rev. Stat. § 546.720.1. The plaintiffs were on fair notice of this discretion when they committed their crimes, and the discretion was not later removed as was alleged in *Garner v. Jones*, 529 U.S. 244, 254 (2000). As the Supreme Court observed, “discretion, by its very definition, is subject to changes in the manner in which it is informed and then exercised.” *Id.* at 253.

In the context of the death penalty, moreover, the Court long ago ruled that “[t]he constitutional inhibition of *ex post facto* laws was intended to secure substantial personal rights against arbitrary and oppressive legislative action, and *not to obstruct mere alteration in conditions deemed necessary for the orderly infliction of humane punishment.*” *Malloy v. South Carolina*, 237 U.S. 180, 183 (1915) (emphasis added). Although *Malloy* involved a change in method of execution from hanging to electrocution, which several States considered more humane, the general proposition stated in that case is sound where the State has neither deliberately acted to inflict pain for the sake of pain nor ignored a readily available alternative that would substantially reduce a risk of severe pain.

The plaintiffs do not allege that the Director, in the exercise of his discretion, has employed anything other than the most humane method of execution available. That a former method of execution is no longer available does not mean that adoption of the next best method is an unconstitutional increase in punishment. The punishment—death—has not changed. The prisoners had fair notice of that punishment, and of the Director’s discretion to determine the method of execution, when they committed their crimes. Where “only the mode of producing” death has

changed, with no allegation of superadded punishment or superior alternatives, the Ex Post Facto Clauses are not implicated. *Id.* at 185; *see State v. Harris*, No. SC 93170, 2013 WL 5460639, at *2 (Mo. Oct. 1, 2013) (“The Missouri Constitution’s ban on ex post facto laws is coextensive with the United States Constitution’s ban on ex post facto laws.”).

As to the other claims raised by the plaintiffs, the identities of the prescribing physician, pharmacist, and laboratory are plainly not relevant. Citing various constitutional, statutory, and regulatory provisions, the plaintiffs challenge the Director’s authority to use pharmacist-compounded pentobarbital in executions at all, to carry out executions or modify the execution protocol during the pendency of this litigation, to name any prescribing physician, pharmacist, or laboratory to the execution team, and to shield the identities of execution team members like the physician, pharmacist, and laboratory from the plaintiffs and the public. They also complain that the execution team could use a central venous line to insert a catheter when it is not clinically indicated (despite a supervising official’s affidavit to the contrary), and that changes in the execution protocol create uncertainty that enhances anxiety for the prisoners. But the merits of these claims do not depend on the identities of the physician, pharmacist, or laboratory.

For these reasons, we grant the Director’s petition for a writ of mandamus and vacate the district court’s discovery orders, R. Doc. 203 and 204, dated December 12, 2013. In light of the issuance of this writ, the Director’s petition for a writ of mandamus directed to the district court’s order denying a motion for protective order, R. Doc. 205, is denied.

GRUENDER, Circuit Judge, concurring.

I concur in the opinion of the Court. However, I write separately to explain the discrepancy between my vote on the administrative panel and my vote upon rehearing

en banc. In Lombardi's petition for a writ of mandamus, filed on December 13, 2013, he did not raise the argument that mandamus should issue to prevent the disclosure of the identities at issue because the prisoners' relevant underlying claims fail to state a claim upon which relief can be granted. Instead, Lombardi relied solely on the state secrets privilege. On December 23, Lombardi moved for leave to file supplemental suggestions in support of his petition for a writ of mandamus. In that motion, he noted that he had filed a motion to dismiss in the district court on December 20, 2013—ten days *after* the district court entered the discovery orders challenged here—and argued that the substance of the motion provided a further basis for granting him mandamus relief. Because Lombardi relied exclusively on the December 20 motion to dismiss, I concluded that, regardless of whether his failure-to-state-a-claim argument had merit, he had not timely raised it. Even in his petition for rehearing en banc, Lombardi did not suggest that he had raised this argument before the district court prior to December 20. However, I have since determined that on August 8, 2012, Lombardi filed a motion to dismiss a prior iteration of the prisoners' complaint. In that motion, Lombardi advanced substantially the same argument that he presented in his December 20, 2013, motion to dismiss. Thus, this argument was before the district court prior to its entry of the discovery orders challenged here. And I find that argument—as articulated in the Court's opinion—to be persuasive. Accordingly, I concur in the opinion of the Court.

BYE, Circuit Judge, with whom MURPHY and KELLY, Circuit Judges, join, dissenting.

The Director is not entitled to the extraordinary remedy of a writ of mandamus. Such a remedy is proper only in cases of "a judicial usurpation of power or a clear abuse of discretion," and only if the party seeking mandamus relief "show[s] that his right to issuance of the writ is clear and indisputable." Cheney v. U.S. Dist. Court for D.C., 542 U.S. 367, 380-81 (2004) (internal quotations, brackets, and citations omitted). Because the district court did not clearly abuse its discretion in ordering the

Director to disclose the identities of the compounding pharmacist and the testing laboratory, the petition for a writ of mandamus should be denied.³

Here, the majority grants this extraordinary remedy after concluding the district court abused its discretion in failing to dismiss the prisoners' Eighth Amendment claim on a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss. The majority holds that, in order to survive a Rule 12(b)(6) motion, a plaintiff must now plead a "readily available alternative method" to the current method of execution the plaintiff is challenging. The majority inexplicably gleans this pleading requirement from a case which in no way addressed the pleading standard for an Eighth Amendment claim. In Baze v. Rees, 553 U.S. 35 (2008), Chief Justice Roberts issued a plurality opinion joined by Justices Kennedy and Alito. In Baze, multiple death row inmates brought suit against Kentucky's Department of Corrections Commissioner. They sought to have Kentucky's three-drug lethal injection protocol declared unconstitutional. Id. at 46. However, Baze did not involve a Rule 12(b)(6) motion to dismiss. Instead, the parties had engaged in extensive discovery and, ultimately, a seven-day bench trial during which the trial court received the testimony of approximately twenty witnesses. At the conclusion of the trial, the trial court issued a judgment upholding the execution protocol.

Chief Justice Roberts' plurality opinion did not establish a new pleading standard, nor did it purport to do so. Chief Justice Roberts was discussing alternative methods because the plaintiffs there had proposed several alternatives as a means of demonstrating the constitutional deficiency of Kentucky's execution protocol at the time. Baze, 553 U.S. at 56-57. Thus, Chief Justice Roberts' plurality opinion should not be read to create a more rigorous pleading requirement for an Eighth Amendment claim.

³Because the prisoners have not challenged the grant of mandamus relief as to the identity of the prescribing physician, I will not address that issue here.

The majority concludes the district court committed a "clear abuse of discretion" by declaring "Plaintiffs are not required to propose an alternative method of execution" even though the two decisions of this Court which addressed Baze in no way acknowledged any such requirement. In Clemons v. Crawford, 585 F.3d 1119 (8th Cir. 2009), this Court addressed whether Missouri's execution protocol violated the Eighth Amendment in the context of grant of judgment on the pleadings. The Clemons court noted the grant of judgment on the pleadings is reviewed "under the same standard used to address a motion to dismiss for failure to state a claim under [Fed. R. Civ. P.] 12(b)(6)." Clemons, 585 F.3d at 1124 (internal quotations and citation omitted).

The Clemons court outlined the standard for establishing an Eighth Amendment claim, stating:

"[T]he Constitution does not demand the avoidance of all risk of pain in carrying out executions." [Baze, 553 U.S. at 36.] Instead, to establish an Eighth Amendment violation, "the conditions presenting the risk must be 'sure or very likely to cause serious illness and needless suffering,' and give rise to 'sufficiently imminent dangers.'" Id. at 50 (quoting Helling v. McKinney, 509 U.S. 25, 33, 34 (1993)). "[T]o prevail on such a claim there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment.'" Id. at 50 (quoting Farmer v. Brennan, 511 U.S. 825, 842, and 846 n. 9 (1994)). The mere fact "an execution method may result in pain, either by accident or as an inescapable consequence of death," does not amount to an Eighth Amendment violation. Id.

Clemons, 585 F.3d at 1125.

At no point does the Clemons court suggest a plaintiff is required to propose an alternative method of execution in order to sufficiently plead an Eighth

Amendment claim. This omission is instructive because the case specifically involved the pleading standard and the opinion extensively discussed Chief Justice Roberts' plurality opinion in Baze.

Likewise, in Nooner v. Norris, 594 F.3d 592 (8th Cir. 2010), this Court addressed whether Arkansas' execution protocol violated the Eighth Amendment in the context of a grant of summary judgment in favor of the State. Nooner articulated a standard very similar, if not identical, to the Clemons' standard. Nooner, 594 F.3d at 598-99. The Nooner court also cited extensively to Baze, but never mentioned a readily available alternative method of execution requirement. Id. at 598-608. Nor should it have, for no such requirement exists.

Other circuits have applied a similar standard post-Baze to our decisions in Clemons and Nooner. In Cook v. Brewer, 637 F.3d 1002 (9th Cir. 2011), and Cook v. Brewer, 649 F.3d 915 (9th Cir. 2011), the Ninth Circuit, in considering a Rule 12(b)(6) motion to dismiss, cited Baze repeatedly and stated a standard nearly identical to that set forth in Clemons and Nooner. See Cook, 637 F.3d at 1004-05; Cook, 649 F.3d at 917. Neither decision referenced a readily available alternative method as a pleading requirement for an Eighth Amendment claim.

Because this Court has previously read Baze not to have modified the pleading requirement for an Eighth Amendment claim, it is unclear how the majority can now conclude the district court "clearly abused its discretion" by reaching the same conclusion as this Court did in both Clemons and Nooner. Indeed, the district court was bound to follow the Clemons and Nooner decisions. Those decisions were properly decided, and they properly articulate this Court's pleading requirement for an Eighth Amendment claim. To say the district court clearly abused its discretion in following those decisions is misguided.

In addition, the majority mysteriously finds error with the district court's denial of a motion to dismiss, even though that motion involved the prisoners' original complaint which is no longer relevant. The original complaint addressed an earlier execution protocol instituted by Missouri which utilized propofol. The district court's December 12, 2013, discovery order, the order at issue here, addressed the prisoners' amended complaint attacking Missouri's use of compounded pentobarbital. The December 12, 2013, discovery order in no way concerned Missouri's use of propofol. The district court's denial of the Directors' earlier motion to dismiss is irrelevant to our present inquiry, and, thus, the majority's reliance on it is misplaced.

Next, the majority elects to adopt a reading of Baze which places an absurd burden on death row inmates. The pleading standard advanced by the majority would require the prisoners to identify for the Director a readily available alternative method for *their own* executions. Now, any individual wishing to challenge a state's execution method as unconstitutional must identify a readily available alternative method for their own deaths before any discovery has been conducted to survive a Rule 12(b)(6) motion to dismiss. The challenge of proposing a readily available alternative method seems nearly impossible if the prisoners are denied discovery and, thus, unable to ascertain even basic information about the current protocol. The proposition that a plaintiff must propose an alternative method for his own execution in order to state a claim for relief under the Eighth Amendment is unreasonable.

Assuming, for the sake of argument, the dicta in Chief Justice Roberts' plurality opinion in Baze is the new pleading standard, the prisoners have still sufficiently alleged a claim under the Eighth Amendment. The prisoners seek an alternative protocol to Missouri's current method of producing and testing compounded pentobarbital. They desire a method which ensures the chemical composition, purity, efficacy, and safety of compounded pentobarbital. The prisoners have never argued properly compounded and tested pentobarbital would not be an alternative method. Instead, the prisoners' argument is the use of a compounded substance purported to

resemble pentobarbital, acquired from a non-traditional, non-FDA-approved compounding pharmacy which likely lacks the ability to test chemicals for identity, potency, purity, and contamination, is what violates the Eighth Amendment. It is clear the readily available alternative method here is one which guarantees the chemicals used in Missouri's executions do not cause "serious illness and needless suffering" and "give rise to 'sufficiently imminent dangers.'" Baze, 553 U.S. at 50.

The Director next raises the question of privilege. The Director has characterized his asserted privilege as a "state secrets" privilege. This comparison is inapt, as the state secret privilege has a narrow applicability limited to cases involving national security, diplomatic secrets, and military intelligence. See Black v. United States, 62 F.3d 1115, 1118-19 (8th Cir. 1995). No such issue is before the Court now. Instead, the Director seeks to avoid disclosure, asserting the compounding pharmacist and testing laboratory face the threat of harassment, intimidation, and harm. These assertions are largely unsupported. See Cal. First Amendment Coal. v. Woodford, 299 F.3d 868, 880 (9th Cir. 2002) (noting the State's fear execution team members would be identified and retaliated against was speculative). In addition, execution team members are protected by Missouri law. Mo. Rev. Stat. § 546.720.4 provides any "licensing board or department shall not censure, reprimand, suspend, revoke, or take any other disciplinary action against the person's license because of his or her participation in a lawful execution." This provision further minimizes any concerns of reprisal against members of the execution team.

Although the Director's state secrets privilege argument is misguided, some courts have recognized it may be appropriate to apply state law privileges as part of the federal common law of privilege pursuant to Federal Rule of Evidence 501. See Am. Civil Liberties Union of Miss., Inc. v. Finch, 638 F.2d 1336, 1343-44 (5th Cir. 1981). The Finch court outlined a two-step balancing test to determine whether to apply a state-law privilege in a case based on federal question jurisdiction. First, the court asks whether a state court would apply the privilege. Id. at 1343. If so, then the

court must determine "whether the privilege is intrinsically meritorious in [the court's] independent judgment." Id. This inquiry requires "balancing the policies behind the privilege against the policies favoring disclosure." Id.

Applying the first step, a state court likely would not apply the privilege to the compounding pharmacist or the testing laboratory. Mo. Rev. Stat. § 546.720 governs the execution team privilege here. Section 546.720.2 defines the execution team as:

those persons who administer lethal gas or lethal chemicals and those persons, such as medical personnel, who provide direct support for the administration of lethal gas or lethal chemicals.

Mo. Rev. Stat. § 546.720.2.

The plain meaning of section 546.720.2 limits the execution team to those individuals administering or providing "direct support" for the administration of lethal chemicals. The statute thus limits confidentiality protection to those members who are directly involved in administration of the execution. The execution team must be defined more narrowly than suggested by the Director, otherwise the "direct" in "provide direct support for the administration" would be rendered superfluous. Further, the terms "administer" and "administration" must be read in context. See United States v. Behrens, 713 F.3d 926, 929 (8th Cir. 2013) ("Statutory language must be read in context and a phrase gathers meaning from the words around it."). Because "administer" clearly refers to the actual injection of lethal chemicals, this strongly suggests "administration" similarly refers to assistance of the actual injection. The phrase "such as medical personnel" further bolsters a narrow reading of the statute. As the affidavit submitted by Larry D. Sasich states, "[n]on-traditional compounding pharmacy practice resembles drug manufacturing more than it does the practice of pharmacy." Because compounding pharmacists function more as drug manufacturers than medical personnel, they should not fall within the sweep of the

statute. Testing laboratories are even less likely to be deemed analogous to "medical personnel."

For these reasons, Missouri's execution team privilege is inapplicable here. Yet, even assuming a state court would apply the privilege, balancing the underlying policies would favor disclosure. Accordingly, the district court did not commit a clear abuse of discretion. Although speculative, the disclosure of the compounding pharmacist's identity – and, to a lesser extent, the testing laboratory's identity – may result in reprisals or harassment which could impair Missouri's ability to obtain a compounded mixture of pentobarbital in the future.

However, with regards to Missouri's policies behind this privilege, the prisoners' interests are much more significant. The prisoners have a significant interest in obtaining the identities of these parties to assert their constitutional right against being subjected to "serious illness and needless suffering" during execution. Baze, 553 U.S. at 50. The prisoners' claims revolve around the chemical composition, purity, potency, and safety of the compounded mixture of pentobarbital used by Missouri. The prisoners cannot adequately investigate their claims unless the Director discloses these identities. The supplemental declarations submitted by Mr. Sasich underscore the deficiencies of relying on the reports of the testing laboratory. Without disclosure, neither the prisoners nor the district court can effectively assess the accuracy and significance of these reports. This consideration is important because the Director has relied heavily on the testing laboratory's reports in its efforts to demonstrate its execution protocols do not threaten serious and needless suffering.

Further, identifying the compounding pharmacist appears to be essential in determining the process used to compound these chemical mixtures. Mr. Sasich's affidavit extensively highlights the potential problems associated with largely unregulated compounding pharmacies and the need to fully investigate their procedures to ensure the final product comports with the stringent requirements of the

Eighth Amendment. Aside from disclosure, the Director has not shown how the prisoners can obtain critical information about the chemical composition, purity, potency, and safety of the compounded pentobarbital which Missouri uses in its executions.

Although the Director has some interest in keeping the identities of the testing laboratory and the compounding pharmacist confidential, that interest is outweighed by the significant interests of the prisoners in disclosure. Without this information, it is unclear whether they can adequately investigate and litigate these important claims. Thus, the Director has not carried his heavy burden of demonstrating clearly and indisputably the district court abused its discretion in ordering disclosure of the identities of the testing laboratory and the compounding pharmacist.

For the foregoing reasons, I respectfully dissent.

**UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT**

No: 13-3699

In re: George A. Lombardi

Petitioner

Appeal from U.S. District Court for the Western District of Missouri - Jefferson City
(2:12-cv-04209-NKL)

JUDGMENT

The order entered on December 27, 2013 is vacated.

The Petition for Writ of Mandamus or Prohibition filed by the State of Missouri is granted in part as to the identity of the prescribing physician. The petition is denied in part as to the identities of the compounding pharmacist and the testing laboratory.

The temporary stay granted by this court on December 17, 2013, is now vacated.

Petitioner's motion for leave to file supplemental suggestions in support of the petition is denied.

December 27, 2013

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

**UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT**

No: 13-3699

In re: George A. Lombardi

Petitioner

Appeal from U.S. District Court for the Western District of Missouri - Jefferson City
(2:12-cv-04209-NKL)

ORDER

Petitioner's petition for rehearing en banc is granted. The stay entered on December 27, 2013 will remain in effect pending further order of the court. Judge Duane Benton did not participate in the consideration or decision in this matter.

January 17, 2014

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

APPEAL

**U.S. District Court
Western District of Missouri (Jefferson City)
CIVIL DOCKET FOR CASE #: 2:12-cv-04209-BP**

Zink et al v. Lombardi et al

Assigned to: District Judge Beth Phillips

Case in other court: Circuit Court of Cole County, 12AC-
CC00396

Eighth Circuit, 13-03505

USCA, 13-03664

8th Circuit, 14-01187

Cause: 28:1441 Petition for Removal

Date Filed: 08/01/2012

Jury Demand: None

Nature of Suit: 550 Prisoner: Civil
Rights

Jurisdiction: Federal Question

Date Filed	#	Docket Text
12/12/2013	203	<p>MINUTE ENTRY. Teleconference held before Judge Nanette Laughrey on December 12, 2013. Time: 9:00 a.m. - 9:27 a.m. Comments: Teleconference held to resolve whether Defendants are required to reveal the identity of pharmacist who compounds the pentobarbital used in executions, the laboratory that tests the compounded drug, and the doctor who provides a prescription for the compounded drug. Defendants assert the identities of these individuals are protected by the state secrets privilege and Missouri's death penalty statute, section 546.720 RSMo. Defendants are concerned with the safety of those involved, should their identities be revealed to the public. Plaintiffs argue the state secrets privilege is customarily used with issues of national security and the absence of protection of these individuals' identities in the death penalty statute is further support that their identities are not a state secret. The Court found section 546.720 RSMo does not prohibit disclosure of the identities of the compounding pharmacist, investigative laboratory, and prescribing physician. At the time the statute was passed there was no evidence the issues in this law suit existed; the state was acquiring drugs from foreign manufacturers. Additionally, the state secret privilege does not apply. The Court ordered Defendants to reveal the identities of the compounding pharmacist, the investigative laboratory, and the prescribing physician to Mr. Luby and Ms. Pilot only. If at some point Mr. Luby and Ms. Pilot need help from other attorneys, they must seek permission from the Court to disclose the identities of the pharmacist, laboratory, and physician to additional attorneys. Mr. Luby and Ms. Pilot must refrain from directly identifying to any other person the pharmacist, physician, or laboratory as individuals who are assisting the state in the execution of prisoners. The Court further ordered Defendants to work with Plaintiffs to maintain confidentiality when the investigation involves state organizations. The Court further ordered that on or before 12/19/2013, Defendants must provide to the Court a list identifying all people in the state government who are aware of the identity of the pharmacist, physician, and</p>

27a

		laboratory. This list shall be provided to the Court by email or in paper and it shall not be made public or filed on ECF or otherwise. Appearances: Plaintiff by: Elizabeth Carlyle, Joseph Luby, John Simon, Elizabeth Carlyle, Cheryle Pilot, and Kathryn Parish. Defendants by: Susan Boresi, Michael Spillane, Stephen Hawke, David Hansen and Andrew Bailey. Court Reporter. Gayle Wambolt. CRD: Renea Kanies (TEXT ENTRY ONLY - NO DOCUMENT ATTACHED). To order a transcript of this hearing please contact Gayle Wambolt, 816-512-5641. (Matthes, Renea) (Entered: 12/12/2013)
12/12/2013	204	ORDER entered by Judge Nanette Laughrey. During a teleconference on 12/12/2013, the Court ordered Defendants to disclose the identities of the compounding pharmacist, prescribing physician, and investigative laboratory. Defendants are ordered to produce to Mr. Luby and Ms. Pilot the identities of these individuals no later than 12/16/2013. The Court further orders that any time Plaintiffs seek information relating to the pharmacist, laboratory, or physician from a third party, Plaintiffs must secure a written agreement with that third party requiring the identity of the pharmacist, laboratory, or physician to remain confidential. Plaintiffs and Defendants shall confer on the wording of the confidentiality agreement, and if a dispute arises as to the contents of the agreement, the Parties should contact the Court by no later than 12/16/2013. This is a TEXT ONLY ENTRY. No document is attached. (Matthes, Renea) (Entered: 12/12/2013)
12/12/2013	205	ORDER entered by Judge Nanette Laughrey. Defendants' Motion for Protective Order [Doc. 189] is DENIED for the same reasons as discussed during the Court's teleconference with the Parties on 12/12/2013. This is a TEXT ONLY ENTRY. No document is attached. (Matthes, Renea) (Entered: 12/12/2013)

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United States Court of Appeals
For the Eighth Circuit

No. 13-3699

In re: George A. Lombardi,

Petitioner,

Appeal from United States District Court
for the Western District of Missouri - Jefferson City.

Filed: January 27, 2014

Before RILEY, Chief Judge, WOLLMAN, LOKEN, MURPHY, BYE, SMITH,
COLLTON, GRUENDER, SHEPHERD, and KELLY, Circuit Judges, En Banc.*

ORDER

The respondents in this matter, plaintiffs in the underlying litigation, *Zink v. Lombardi*, No. 2:12-cv-04209 (W.D. Mo. filed Aug. 1, 2012), petition for rehearing of this court's decision filed January 24, 2014, and to vacate the opinion on account of mootness. For the following reasons, we deny the petition.

The respondents argue that the issues before this court were moot at the time of the opinion's issuance, because the identities of the testing laboratory and

*Judge Benton did not participate in the consideration or decision of this matter.

compounding pharmacy used by the State have become known through media accounts and inferences made by one of respondents' experts from other filings in the case. We do not know whether the media sources and the expert have correctly identified the pharmacy and the laboratory. The issue before this court was whether the district court properly ordered the Director to disclose in discovery the identities of the prescribing physician, the compounding pharmacy, and the testing laboratory. The respondents never withdrew their request for the disputed discovery, and there was a live controversy over whether the Director was required to provide it. The petition for writ of mandamus was therefore not moot when the opinion issued.

The respondents next contend that this court wrongly granted mandamus relief on grounds that were not presented to the district court. We believe the grounds were adequately presented. In moving to dismiss the original complaint challenging a method of execution using propofol, the Director argued that the plaintiffs failed to state a claim under the Eighth Amendment because they did not allege the existence of a feasible, readily implemented alternative that significantly reduces risk of severe pain. R. Doc. 3, at 5. The Director also urged that the plaintiffs failed to state a claim under the Ex Post Facto Clause because the governing statute grants the Director discretion to establish the method of execution, the punishment of death for capital murder had not changed, and only the mode of producing this result had changed. *Id.* at 11-12. After the Department of Corrections changed its execution protocol to use compounded pentobarbital, the district court granted leave to amend the complaint, rejecting the Director's argument that amendment would be futile in light of *Baze v. Rees*, 553 U.S. 35 (2008), and circuit precedent applying the Ex Post Facto Clause. R. Doc. 181; R. Doc. 178, at 5-6. In a hearing on the discovery dispute, the Director, while advancing primarily an argument of privilege, cited *Baze* and the requirement of feasible alternatives under the Eighth Amendment. R. Doc. 224, at 9-10. The plaintiffs' amended complaint challenging the new protocol presented the same legal issues under the Eighth Amendment and Ex Post Facto Clauses that were raised with the district court in the first motion to dismiss, as the plaintiffs themselves later

acknowledged. R. Doc. 258, at 11, 14. We do not think the Director was required to reargue the same points in his motion for a protective order to justify raising the issues in the court of appeals.

The respondents urge that this court misread *Baze v. Rees* by holding that an Eighth Amendment claim challenging method of execution must allege that the risk of harm arising from the State's current lethal-injection protocol is substantial when compared to known and available alternatives. They cite the Supreme Court's statement in *Hill v. McDonough*, 547 U.S. 573 (2006), that there is no "[s]pecific pleading requirement[]" that a prisoner must identify "an alternative, authorized method of execution" to proceed in a § 1983 action. *Id.* at 582. In *Hill*, however, the plaintiff conceded that "other methods of lethal injection the Department could choose to use would be constitutional," *id.* at 580, and he alleged "that the challenged procedure presents a risk of pain the State can avoid while still being able to enforce the sentence ordering a lethal injection." *Id.* at 581. The plaintiffs in this case did not make such an allegation in the amended complaint. We therefore concluded that they failed to state a claim by failing to allege even the elements of an Eighth Amendment claim as defined in *Baze*. We were not required to address whether alleging that the current method of execution creates a substantial risk of harm when compared to known and available alternatives, without specifying an alternative, would be sufficient to state a claim in light of *Hill* and *Baze*. *Cf. Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The respondents finally assert that this court misread their state-law claims in concluding that the identities of the pharmacy and laboratory are plainly not relevant to their state-law claims. As they reiterate in the petition, however, the respondents alleged in their amended complaint that the Department violates state law by carrying out executions using compounding-pharmacy drugs. The Department admits that it acquires the drugs from a compounding pharmacy. As we read the complaint, the plaintiffs have not alleged that some uses of compounding-pharmacy drugs are lawful

and some uses are unlawful, such that investigation of the particular compounding pharmacy would be relevant to their claims under state law.

The petition for rehearing is denied.

Judge Shepherd votes to deny the petition for rehearing.

Judge Murphy, Judge Bye, and Judge Kelly would grant the petition for rehearing.

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

DAVID ZINK, et al.,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 2:12-CV-4209-NKL
)	
GEORGE A. LOMBARDI, et al.,)	
)	
Defendants.)	

ORDER

This case involves a challenge by twenty-one Plaintiffs, prisoners on death row in Missouri, to the execution protocol issued by the Missouri Department of Corrections on May 15, 2012. Plaintiffs filed a petition for declaratory and injunctive relief on June 26, 2012, and Defendants removed to federal court on August 1, 2012. Pending before the court is Defendants' Motion to Dismiss [Doc. # 3]. For the reasons set forth below, the Motion to Dismiss is DENIED in part and GRANTED in part.

I. Background

Plaintiffs, twenty-one prisoners under sentence of death due to convictions for first degree or capital murder in the state courts of Missouri, bring suit against the following Defendants in their official capacity: George Lombardi, Director of the Missouri Department of Corrections; David Dormire, Director of the Division of Adult Institutions at the Missouri Department of Corrections; Terry Russell, Warden of the Eastern Reception Diagnostic & Correctional Center, where Missouri executions are currently conducted; and John Does 2-40, Anonymous Executioners for the state of Missouri.

Plaintiffs allege that the execution protocol issued by Defendant Lombardi on May 15, 2012, which mandates execution via injection of 2 g of the anesthetic propofol and 10 cc of the pain-suppressant lidocaine, violates the state and federal Constitutions by creating an unprecedented, substantial likelihood of foreseeable infliction of excruciating pain during execution. Count I alleges that this method of execution, the first of its kind, violates the prohibition on cruel and unusual punishments of the Eighth and Fourteenth Amendments and the Missouri Constitution, Art. I § 21, by inflicting unconscionable pain without reliable mitigation. Count II alleges that administering lidocaine without a prescription, as required by the Food, Drug & Cosmetic Act, violates the Supremacy Clause of the United States Constitution, Art. VI clause 2. Count III alleges that application of the newly promulgated protocol to Plaintiffs violates the *Ex post facto* Clauses of the Missouri Constitution, Art. I § 13, and the United States Constitution, Art. I § 10, by creating a significant risk of increased punishment. Finally, Count IV alleges that Missouri statute § 546.720, which authorizes Defendant Lombardi to prescribe the means by which the Department of Corrections carries out executions by lethal injection or lethal gas, violates the separation of powers guaranty of the Missouri Constitution, Art. II § 1.

Defendants have moved to dismiss for failure to state a claim.

II. Discussion

A. Facts

The facts in this section are taken from Plaintiffs' Complaint and attached documentation [Doc. # 1]. Plaintiffs allege that 1) propofol causes pain on injection in

the overwhelming majority of instances, even as used in ordinary medical practice; 2) the defendants' protocol calls for a rapid injection of a massive dosage of propofol far exceeding what is used in surgical settings; and 3) the lidocaine defendants plan to inject will not provide sufficient or reliable mitigation of the pain caused by the propofol.

In support of these allegations, Plaintiffs have submitted the sworn affidavit of Dr. Mark Heath, Assistant Professor of Clinical Anesthesiology at Columbia University. Dr. Heath attests that although propofol is widely used to induce general anesthesia, a subset of patients experience significant pain at the time of injection. Dr. Heath also states that the two grams of propofol called for in the new lethal injection protocol is fifteen times the dose normally given to adult patients to induce anesthesia. He avers that as it is unlikely that a dosage this large has ever been deliberately injected into a conscious person, clinical studies documenting the severity of pain caused by this amount of propofol have likely not been performed. Dr. Heath also attests that based on his research, the Missouri Department of Corrections is the first and currently only such entity to propose the administration of propofol in lethal injections.

Plaintiffs also include in their pleadings a peer-reviewed article, *Prevention of pain on injection of propofol: systematic review and medical analysis*, by L. Jalota, et al., published by the British Medical Journal in 2011. According to this article, the overall risk of pain caused by propofol injection is 60%. Although the article states that lidocaine has been effective in reducing this pain, Dr. Heath avers that the amount of lidocaine called for in the protocol is not sufficient to reliably prevent the occurrence of pain from such a large dose of propofol.

In addition, Plaintiffs submit the deposition of Dr. Mark Dershwitz taken in the case of *Jackson v. Danberg*, in the District Court of Delaware. Dr. Dershwitz was the expert used by the Missouri Department of Corrections in the lethal injection challenge presented in *Taylor v. Crawford*, 487 F.3d 1972, 1076 (8th Cir. 2007). In his deposition in the Delaware case, Dr. Dershwitz testified that propofol causes pain in two-thirds to three-quarters of patients, and that a subset of patients “literally scream at the top of their lungs as they are falling asleep” because “propofol burns.” [Doc. # 1, Ex. 4].

Finally, Plaintiffs contend that Defendants know, or in the exercise of reasonable diligence should know, that propofol causes pain and that the amount of lidocaine in the protocol is insufficient to anesthetize Plaintiffs from that pain.

B. Standard of Review

To survive a motion to dismiss, a pleading must present “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). For the purposes of a motion to dismiss, a court is required to construe the allegations in a complaint broadly and in the light most favorable to the nonmoving party. *Ritchie v. St. Louis Jewish Light*, 630 F.3d 713, 716 (8th Cir. 2011). Plaintiffs must assert sufficient facts in their pleading that, if accepted as true, would “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 1974 (2007); *see also Northstar Indus., Inc. v. Merrill Lynch & Co., Inc.*, 576 F.3d 827, 832 (8th Cir. 2009). District courts should rely on their own “judicial experience and common sense” in making the “context-specific” determination of whether factual allegations make a right to relief plausible. *Ashcroft v. Iqbal*, 556 U.S.

662, 679, 129 S. Ct. 1937, 1950 (2009). A complaint that fails to satisfy these requirements may be dismissed for failure to state a claim on which relief can be granted. Fed. R. Civ. P. 12(b)(6).

C. Discussion

1. *Eighth Amendment*

Defendants contend that Plaintiffs fail to state a claim under the Eighth Amendment because they have not alleged facts that present an objectively intolerable risk of harm.

There are two components to an Eighth Amendment challenge, which is applied to the States through the Fourteenth Amendment: “First, the punishment must not involve the unnecessary and wanton infliction of pain. Second, the punishment must not be grossly out of proportion to the severity of the crime.” *Taylor v. Crawford*, 487 F.3d 1072, 1079 (8th Cir. 2007). The Eighth Circuit has concluded that an “unnecessary risk of causing the wanton infliction of pain” may satisfy the first prong. *Taylor v. Crawford*, 487 F.3d 1072, 1079 (8th Cir. 2007). A plurality of the Supreme Court has similarly held that “subjecting individuals to a risk of future harm—not simply actually inflicting pain—can qualify as cruel and unusual punishment,” but that “the risk must be ‘*sure or very likely* to cause serious illness and needless suffering,’ and give rise to ‘*sufficiently imminent dangers.*’” *Baze v. Rees*, 553 U.S. 35, 49-50, 128 S. Ct. 1520, 1530-31 (2008) (quoting *Helling v. McKinney*, 509 U.S. 25, 33, 34–35, 113 S. Ct. 2475 (1993)) (emphasis in original); see also *Farmer v. Brennan*, 511 U.S. 825, 834, 114 S. Ct. 1970, 1977 (1994). When assessing the constitutionality of a written lethal injection protocol,

the court must determine whether it “presents a substantial risk of inflicting unnecessary pain.” *Nooner v. Norris*, 594 F.3d 592, 599 (8th Cir. 2010) *cert. dismissed*, 130 S. Ct. 2432 (U.S. 2010), *cert. denied*, 131 S. Ct. 569 (U.S. 2010) (quoting *Taylor*, 487 F.3d at 1080).

Defendants read Plaintiffs’ complaint to assert that the risk of pain must be zero under the Eighth Amendment. However, Plaintiffs do not make that claim. Rather, Plaintiffs allege that the Department of Corrections’ protocol creates a substantial, objectively intolerable risk of severe pain. They have offered expert affidavits attesting that pain experienced as a result of the injection of propofol is widely acknowledged by the medical community, and that whereas lidocaine has been found to mitigate this pain, it is unlikely to be effective here given the untoward amount of propofol the protocol requires. In contrast to the lethal injection protocols challenged in recent similar litigation, the Plaintiffs’ challenge addresses the risk of pain inherent in the execution method itself, not the risk of pain that could possibly result from maladministration of the protocol. *See, e.g., Baze*, 553 U.S. at 49; *Clemons v. Crawford*, 585 F.3d 1119, 1127 (8th Cir. 2009); *Nooner*, 594 F.3d at 603; *Taylor*, 487 F.3d at 1080. As the Eighth Circuit has explained, “The cruelty against which the Constitution protects a convicted man is cruelty inherent in the method of punishment . . .” *Taylor*, 487 F.3d at 1080 (quoting *Louisiana ex rel. Francis v. Resweber*, 329 U.S. 459, 464, 67 S. Ct. 374, 376 (1947) (plurality opinion)). Unlike *Taylor*, in the instant case there is no admission by Plaintiffs that if the procedure is properly administered, the risk of pain is virtually nil. *Id.* at 1083.

Defendants also assert that Plaintiffs have failed to offer a reasonable alternative to propofol, citing *Baze*. However, Plaintiffs are not required to propose an alternative method of execution as an element of their Eighth Amendment claim. The Chief Justice's opinion in *Baze* simply stated that where the contested method creates a substantial risk of serious harm and the plaintiffs proffer a feasible, readily-implemented alternative, the state's refusal to adopt the alternative may constitute "cruel and unusual punishment" under the Eighth Amendment. *Baze v. Rees*, 553 U.S. 35, 52, 128 S. Ct. 1520, 1532. There is no requirement that Plaintiffs propose an alternative as part of their pleadings.

Plaintiffs have pled sufficient facts that, taken as true, indicate that a substantial risk of pain is likely to result from administration of the propofol-lidocaine cocktail. As such, dismissal prior to discovery is improper.

2. *Supremacy Clause Claim*

In their second claim, Plaintiffs allege that the use of lidocaine in the execution protocol is not prescribed by a doctor in contravention to the Food, Drug & Cosmetic Act ("FDCA"), and is therefore a violation of the Supremacy Clause. Both parties acknowledge, however, that the Food, Drug & Cosmetic Act ("FDCA") does not provide a private right of action to enforce the terms of the FDCA. Yet Plaintiffs seek a declaratory judgment that the execution protocol adopted by Defendants which uses a drug that has not been prescribed pursuant to Missouri statutory authority conflicts with the FDCA, and therefore violates the Supremacy Clause. The Court need not address the

viability of such a claim which is questionable, because it finds the Plaintiffs have no standing to raise it.

a. Standing

Defendants assert that Plaintiffs lack standing to bring their Supremacy Clause claim. A plaintiff has standing when she has a) suffered a “concrete and particularized” injury, which is b) “actual or imminent, not conjectural or hypothetical,” and c) “fairly traceable to the challenged action of the defendant” such that limiting the defendant will remedy the injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 2136 (1992) (internal quotes omitted). “At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice.” *Lujan*, 504 U.S. at 561, 112 S. Ct. at 2137.

Defendants contend that Plaintiffs have not shown injury because they have not alleged that lidocaine causes pain or any other injury. The Court agrees. This is not a case where the prescription drug is being used to cause death or that the administration of the drug requires supervision by a physician to avoid an unintended result. The only allegation is that the lidocaine is not sufficient to prevent pain under these circumstances. But that merely suggests that another drug should be used, not that the use of lidocaine is causing injury because it is not prescribed. In addition, Plaintiffs have not suggested that another doctor would in fact choose a different pain killer which would be sufficient to meet the pain concerns that they raise. Likewise, they have not alleged that if the drug were prescribed, a doctor would increase the dose of lidocaine to address the concerns raised by the Plaintiffs. In other words, Plaintiffs have not raised any facts to show that

the absence of a prescription is somehow responsible for the wrong drug or dose being chosen.

As previously said, district courts should rely on their own “judicial experience and common sense” in making the “context-specific” determination of whether factual allegations make a right to relief plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 679, 129 S. Ct. 1937, 1950 (2009). With that in mind, Plaintiffs’ Supremacy Clause claim is dismissed.

3. *Prohibition on Ex Post Facto or Retrospective Laws*

Plaintiffs argue that changing from the three-chemical sequence previously used in Missouri executions to the lidocaine-propofol protocol would increase the likelihood of excruciating pain experienced by Plaintiffs, and therefore constitutes an increased punishment in violation of the federal and state *ex post facto* prohibitions and Missouri’s retrospective operation prohibition. U.S. Const. Art. I § 9, cl. 3, and Art. I, § 10 cl. 1; Mo. Const. Art. I, § 13. Defendants contend that Plaintiffs have failed to state an *ex post facto* claim on the ground that a change in method of execution cannot be a violation of the *ex post facto* clause.

An *ex post facto* penal law is one that retroactively “disadvantages the offender affected by [it].” *Collins v. Youngblood*, 497 U.S. 37, 41 (1990). In other words it is a change in the law post-conviction that disadvantages the defendant. *R.W. v. Sanders*, 168 S.W.3d 65, 68 (Mo. 2005) (quoting *Cooper v. Mo. Bd. of Prob. & Parole*, 866 S.W.2d 135, 137–38 (Mo. banc 1993)); *see also Williams v. Hobbs*, 658 F.3d 842, 848 (8th Cir. 2011) *cert. dismissed*, 2012 WL 1803326 (U.S. Sept. 20, 2012) (internal quotes omitted)

(Holding that to state an *ex post facto* claim, the prisoner must allege that a new law or regulation “creates a significant risk of increased punishment.”).

Defendants rely on two cases, *Malloy v. S. Carolina*, 237 U.S. 180, 185, 35 S. Ct. 507, 509 (1915), and *State v. Brown*, 112 S.W.2d 568, 571 (Mo. 1937), to support their claim that a change in method of execution does not violate the *ex post facto* clause. In *Malloy*, the Supreme Court noted that the statute changing the method of execution from hanging to electrocution “did not change the penalty – death – for murder, but only the mode of producing this The punishment was not increased, and some of the odious features incident to the old method were abated.” *Malloy*, 237 U.S. at 185, 35 S. Ct. at 509. The Court emphasized that the purpose of the change of execution method in *Malloy* was to find “the most humane and practical method of inflicting the death sentence.” *Id.* Similarly, when Missouri changed the execution method from hanging to lethal gas for the purpose of providing a more “humane” death penalty, the Supreme Court of Missouri asked, “why should the new statute not apply to those cases pending at the time the change went into effect?... The changes are intended to be a benefit and not a detriment.” *State v. Brown*, 112 S.W.2d at 571.

In contrast to *Malloy* and *Brown*, in the instant case there is no indication that the new lidocaine-propofol protocol was adopted in order to make the administration of the death penalty more “humane” or to abate “odious features incident to the old method.” Taking Plaintiff’s allegations as true, the Defendants’ new method of execution would substantially increase the risk of pain Plaintiffs would endure. *Malloy* and *Brown*

therefore do not stand for the proposition that a change in method of execution cannot be a violation of the *ex post facto* clause.

Defendants also argue that there has been no change in the law because the applicable statute, Mo. Rev. Stat. § 546.720.1, has always given the Department of Corrections the responsibility to choose the protocol for an execution. However, the Supreme Court has made it clear that in some circumstances a change in a regulation or policy can be an *ex post facto* violation. There does not have to be a change in a statute. *See, Garner v. Jones*, 529 U.S. 244 (2000); *Levine v. Meniffee*, 2005 WL 1384021 (S.D.N.Y. June 9, 2005). Defendants have failed to address the issues raised in *Jones*, and the Court declines to engage in that analysis *sua sponte*.

Further, the retrospective operation clause in the Missouri Constitution “is broader than the federal proscription of *ex post facto* laws.” *Rentschler v. Nixon*, 311 S.W.3d 783, 788 (Mo. 2010) (en banc), *as modified on denial of reh'g* (May 11, 2010). It applies the *ex post facto* prohibition not only to laws enacted by the legislature, but also to regulations promulgated by an agency. *Miller v. Mitchell*, 25 S.W.3d 658, 663 (Mo. Ct. App. 2000); *Davis v. Kempker*, 167 S.W.3d 721, 728 (Mo. Ct. App. 2005). This is so, the court in *Miller* explained, “because in promulgating regulations, the agency is exercising delegated legislative authority; thus, the rules are as if made by the legislature.” *Miller*, 25 S.W.3d at 663 (internal quotes omitted). The retrospective operation clause prohibits any law or regulation that “creates a new obligation, imposes a new duty, or attaches a new disability with respect to transactions or considerations already past.” *F.R. v. St.*

Charles County Sheriff's Dep't, 301 S.W.3d 56, 61 (Mo. 2010) (quoting *Squaw Creek Drainage Dist. v. Turney*, 235 Mo. 80, 138 S.W. 12, 16 (1911)).

Plaintiffs have alleged that the change in the execution protocol¹ promulgated by the Department of Corrections will result in a significant risk of increased pain compared to the prior method of execution. Taking this allegation as true and considering the arguments that have been raised by the Defendants, Plaintiffs have stated a plausible *ex post facto* claim.

4. Separation of Powers

Plaintiffs have alleged that the statutory delegation to the Department of Corrections to determine the method of execution is unconstitutional because it grants Defendants unbounded authority unconstrained by meaningful guidance from the legislature, and thus constitutes an exercise of legislative power in violation of the Missouri Constitution's guarantee of separation of powers. Article II § 1 of the Missouri Constitution states,

The powers of government shall be divided into three distinct departments—the legislative, executive and judicial—each of which shall be confided to a separate magistracy, and no person, or collection of persons, charged with the exercise of powers properly belonging to one of those departments, shall exercise any power properly belonging to either of the others, except in instances in this constitution expressly directed or permitted.

¹ Whether the Department of Corrections protocol is considered an alteration of “substantial personal rights” or a mere change in “modes of procedure which do not affect matters of substance,” *State v. Lawhorn*, 762 S.W.2d 820, 824 (Mo. 1988), has not been raised by the Defendants, and the Court will not address it *sua sponte*.

Missouri's statute delegating authority to the director of the Department of Corrections to formulate death penalty policies is as follows:

The manner of inflicting the punishment of death shall be by the administration of lethal gas or by means of the administration of lethal injection. And for such purpose the director of the department of corrections is hereby authorized and directed to provide... the necessary appliances for carrying into execution the death penalty by means of the administration of lethal gas or by means of the administration of lethal injection.

Mo. Rev. Stat. § 546.720.1.

The Missouri Supreme Court has not addressed the issue of the constitutionality of delegating the method of execution to agency officials. However, Missouri has addressed issues of delegation to executive officials in other contexts. *Lux v. Milwaukee Mechanics Ins. Co.*, 322 Mo. 342, 15 S.W.2d 343 (1929) set out the “general rule” that any law “which attempts to clothe an administrative officer with arbitrary discretion, without a definite standard or rule for his guidance, is an unwarranted attempt to delegate legislative functions to such officer, and for that reason is unconstitutional.” *Lux*, 15 S.W.2d at 345 (finding an ordinance unconstitutional because it gave a city official the power to condemn a building without providing guides, tests, or standards to protect the property owner from arbitrary action); *see also State v. Bridges*, 398 S.W.2d 1, 5 (Mo. 1966) (a law delegating authority “is constitutional if a definite standard is provided and no arbitrary discretion is involved.”); *Menorah Med. Ctr. v. Health & Educ. Facilities Auth.*, 584 S.W.2d 73, 83 (Mo. 1979) (“An ordinance or a statute which vests discretion in administrative officials must, generally stated, include standards for their guidance in order to be constitutional.”) (internal quotes omitted). The standard by which the

executive officer exercises discretion need not be explicitly laid out; rather, depending on “the nature and purpose of the legislation,” “the legislature may enact the basic purpose or rule, leaving matters of detail in administering the act to the board or executive, although an exercise of discretion by the latter may thus be involved.” *State ex rel. Priest v. Gunn*, 326 S.W.2d 314, 320-21 (Mo. 1959); *see also Menorah Med. Ctr*, 584 S.W.2d at 83. Where a statute establishes “a sufficiently definite public policy” and “merely leaves to the director the administrative duty of filling in the details of the policy in implementation of the law,” there has been no constitutional violation. *State v. Cushman*, 451 S.W.2d 17, 21 (Mo. 1970) (holding that a statute allowing the director of revenue to set the standards for protective headgear with no guidelines except that the standards be “reasonable” was constitutional). Delegation is constitutional where the executive agency possesses “particular areas of expertise,” *State Tax Comm'n v. Admin. Hearing Comm'n*, 641 S.W.2d 69, 74 (Mo. 1982), or where it is impracticable to “lay[] down a definite, comprehensive rule in the legislation itself.” *Priest*, 326 S.W.2d at 321 (internal quotes omitted); *see also Lux*, 15 S.W.2d at 345; *Cushman*, 451 S.W.2d at 20; *Menorah Med. Ctr*, 584 S.W.2d at 83-84; *State ex rel. Mackey v. Hyde*, 315 Mo. 681, 286 S.W. 363, 366 (1926).

Texas, Idaho, Florida, Nebraska, and Arizona state courts have considered whether delegation of execution protocols to an executive official violates their state separation of powers principles, and have determined that it does not. *Ex parte Granviel*, 561 S.W.2d 503 (Tex. Crim. App. 1978); *State v. Osborn*, 102 Idaho 405, 631 P.2d 187 (1981); *Sims v. State*, 754 So. 2d 657 (Fla. 2000); *State v. Ellis*, 281 Neb. 571, 799 N.W.2d 267 (Neb.

2011) *cert. denied*, 132 S. Ct. 463 (2011); *Cook v. State*, 230 Ariz. 185, 281 P.3d 1053 (Ct. App. 2012).²

The separation of powers jurisprudence of these states is fairly similar. The standard in Texas is that “a legislative body may, after declaring a policy and fixing a primary standard, delegate to an administrative tribunal or officer the power to fill up the details so as to carry out and effectuate the legislative purpose.” *Margolin v. State*, 151 Tex. Crim. 132, 138, 205 S.W.2d 775, 778 (1947). Florida jurisprudence provides that “the Legislature may enact a law, complete in itself, designed to accomplish a general public purpose, and may expressly authorize designated officials within definite valid limitations to provide rules and regulations for the complete operation and enforcement of the law within its expressed general purpose.” *Sims*, 754 So. 2d at 668 (internal quotes omitted). Nebraska’s separation of powers principles provide that “[w]here the Legislature has provided reasonable limitations and standards for carrying out the delegated duties, there is no unconstitutional delegation of legislative authority.” *Yant v. City of Grand Island*, 279 Neb. 935, 945, 784 N.W.2d 101, 109 (2010) (internal quotes

² Defendants also point to the Delaware case of *State v. Deputy*, 644 A.2d 411, 420 (Del. Super. 1994) *aff’d*, 648 A.2d 423 (Del. 1994) in support of their argument. However, this case involved an Eighth Amendment challenge to the state death penalty statute, which permitted the Department of Corrections to promulgate the execution protocol. The Petitioner argued that the statute was unconstitutional because it failed “to provide guidelines concerning the appropriate selection and training of the people administering the lethal injection,” and as such would constitute cruel and unusual punishment. *Deputy*, 644 A.2d at 420. The state court dismissed the argument without citing sources on the grounds that “[n]o requirement exists that the state statute itself must establish detailed procedures for the administration of the death penalty,” and that the procedures promulgated by the Department of Corrections were “conventional and well-planned,” “reliable,” and there was no evidence that Defendant’s “execution will involve unnecessary torture, degradation, terror, pain or disgrace so as to render the Delaware statute unconstitutional.” *Id.* at 420-21.

omitted). The Arizona Supreme Court has stated that “[a] statute need establish no more than a sufficient basic standard, i.e., a definite policy and rule of action which will serve as a guide for the administrative agency, in order for the delegation of legislative power to be deemed valid.” *State v. Arizona Mines Supply Co.*, 107 Ariz. 199, 205-06, 484 P.2d 619, 625-26 (Ariz. 1971). While the Arizona separation of powers jurisprudence appears to be slightly less stringent than Missouri’s, the Texas, Nebraska, and Florida standards for delegation align substantially with the contours of Missouri’s jurisprudence, as detailed above.³

In upholding the death penalty delegation statutes, these state courts considered the following factors:

- 1) Whether the statute established a general policy to guide administrative action, such that the agency official could reasonably fill in the details. *Granviel*, 561 S.W.2d at 514; *Osborn*, 102 Idaho at 419, 631 P.2d at 201; *Sims*, 754 So. 2d at 668; *Ellis*, 281 Neb. at 593, 799 N.W.2d at 289;
- 2) Whether the agency official is better qualified to make the determination, and requiring the legislature to detail the policy would be impracticable, as where “the relations to be regulated are highly technical or where regulation requires a course of continuous decision.” *Ellis*, 281 Neb. at 592-93, 799 N.W.2d at 289; *see also Sims*, 754 So. 2d at 670; *Cook*, 281 P.3d at 1056.

Because of the similarities between Missouri’s separation of powers jurisprudence and that of the above states, the Court concludes that consideration of these factors is likewise appropriate in the instant case.

³ The Idaho court in *Osborn* did not rely on any state law for its nondelegation analysis, only *Granviel*, and so the Court will not discuss Idaho’s separation of powers jurisprudence. *Osborn*. 102 Idaho at 419.

Plaintiffs rely on a recent outlier case in support of their claim that the death penalty delegation statute violates separation of powers principles, *Hobbs v. Jones*, 2012 Ark. 293, 2012 WL 2362712 (Ark. 2012). Arkansas' separation of powers jurisprudence provides that "discretionary power may be delegated by the legislature to a state agency as long as reasonable guidelines are provided," including "appropriate standards by which the administrative body is to exercise this power... A statute that, in effect, reposes an absolute, unregulated, and undefined discretion in an administrative agency bestows arbitrary powers and is an unlawful delegation of legislative powers." *Hobbs*, 2012 WL 2362712 at *10. Applying this standard, the Arkansas Supreme Court found the death penalty delegation statute unconstitutional on the grounds that the statute "provides no guidance and no general policy with regard to the procedures for the [corrections official] to implement lethal injections," and "plainly gives absolute and exclusive discretion to the [corrections official] to determine what chemicals are to be used." *Id.* at *15, *14. The dissent in *Hobbs* argued that the delegation of authority in the Arkansas statute was constitutional because it involved "details with which it is impracticable for the legislature to deal directly." *Hobbs*, 2012 WL 2362712 at *28 (Baker, J., dissenting).

Plaintiffs contend that the Missouri Supreme Court gives special weight to the decisions of the Arkansas Supreme Court; however, in support of this claim, they reference only one Missouri case involving a nondelegation challenge to a statute granting commissions the authority to construct and lease buildings, which cites two Arkansas cases in a footnote. *See Menorah Med. Ctr*, 584 S.W.2d at 84 n.3. This is not a sufficient basis for holding that the Arkansas decision is controlling, especially when

other state decisions have come to the contrary conclusion. Plaintiffs also point out that the Arkansas death penalty delegation statute, which required lethal injection and enumerated a list of possible chemicals, was more detailed than the Missouri statute in the instant case, which permits either lethal injection or lethal gas and does not recommend specific chemicals to be used. However, this alone is insufficient to merit relying on Arkansas' outlier decision, when there is no indication that Arkansas case law carries any special weight in Missouri.⁴

The Court applies the factors set out in the Texas, Idaho, Nebraska, Florida, and Arizona courts to the instant case. First, the statute in question establishes a general policy – execution shall be conducted via lethal gas or injection – the details of which could be reasonably filled in by the agency official. *See Sims*, 754 So. 2d at 670. The next question is whether the agency official is better qualified to make the policy, and whether it would be impracticable to require a detailed policy of this sort from the legislature. Nebraska's approach to this inquiry, which focuses on whether “the relations to be regulated are highly technical” or the “regulation requires a course of continuous decision,” is instructive. *Ellis*, 281 Neb. at 592, 799 N.W.2d at 289. Execution is a highly technical process involving complex drug combinations, to which this case is

⁴ Compare Ark. Code Ann. § 5-4-617(a) (Supp. 2011) (“The sentence of death is to be carried out by intravenous lethal injection of one (1) or more chemicals, as determined in kind and amount in the discretion of the Director of the Department of Correction The chemical or chemicals injected may include one (1) or more of the following substances: (A) One (1) or more ultra-short-acting barbiturates; (B) One (1) or more chemical paralytic agents; (C) Potassium chloride; or (D) Any other chemical or chemicals, including but not limited to saline solution.”) with Mo. Ann. Stat. § 546.720(1) (“The manner of inflicting the punishment of death shall be by the administration of lethal gas or by means of the administration of lethal injection . . .”).

testament. Decisions regarding the method of execution are also ongoing, as drugs become less available or new drugs enter the market. Furthermore, as other state courts have noted, Department of Corrections officials are better qualified to make these assessments than the legislature. *See Sims*, 754 So. 2d at 670. Therefore, Missouri's death penalty delegation statute is not unconstitutional under this test.

Additionally, Missouri law makes clear that a statute is to be presumed to be valid “unless it clearly contradicts a constitutional provision.” *State Auditor v. Joint Comm. on Legislative Research*, 956 S.W.2d 228, 231 (Mo. 1997). “Statutes must, if possible, be construed as consistent with the Constitution.” *State Tax Comm'n*, 641 S.W.2d at 73. In light of this canon of statutory interpretation and the state cases upholding death penalty delegation to executive officials, including the similarities between their separation of powers provisions and that of Missouri, the Court finds that Missouri's delegation of execution methods to the Defendant does not violate separation of powers principles. As such, Defendant's Motion to Dismiss on this claim is GRANTED.

5. Estoppel

Finally, Defendants contend that Plaintiffs are estopped from raising a separation of powers challenge on the grounds that one Plaintiff, Plaintiff Taylor, challenged the constitutionality of § 546.720 under the Eighth Amendment in a previous litigation, as a result of which the district court required the Department of Corrections to submit a written lethal injection protocol implementing § 546.720. *See Taylor v. Crawford*, 2006 WL 1779035 at *8 (W.D. Mo. June 26, 2006) (not reported in F. Supp. 2d). The written protocol was found not to violate the Eighth Amendment on appeal. *Taylor*, 487 F.3d at

1083. However, at no time was the issue of the constitutionality of the delegation of power under § 546.720 raised or litigated. Furthermore, Defendants introduce no case law showing that any form of estoppel would be appropriate in this instance. Thus, there is no basis for estopping Plaintiffs from proceeding with their claim.

IV. Conclusion

As the Supreme Court has made clear, “[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft*, 556 U.S. at 678, 129 S. Ct. at 1949 (internal quotes omitted). The Plaintiffs have met their burden at this stage with regards to their Eighth Amendment claim, and their *Ex Post Facto* and retrospective law claims. But the Motion to Dismiss must be granted as to their Supremacy Clause claim and their separation of powers claim. For the above stated reasons, Defendants’ Motion to Dismiss is GRANTED in part and DENIED in part.

s/ NANETTE K. LAUGHREY
NANETTE K. LAUGHREY
United States District Judge

Dated: November 16, 2012
Jefferson City, Missouri

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

DAVID S. ZINK, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:12-CV-4209-NKL
)	
GEORGE A. LOMBARDI, et al.,)	
)	
Defendants.)	

**MOTION FOR PROTECTIVE ORDER REGARDING THE
IDENTITIES OF MEMBERS OF MISSOURI'S EXECUTION TEAM**

Summary of Argument

The Director of the Missouri Department of Corrections (the Director), is charged with selecting the members of the execution team, and the identities of the team members are protected by the state secrets privilege under the federal common law and Federal Rule of Evidence 501. Missouri law requires the Director to select an execution team and mandates the identities of the members of the execution team defined in the execution protocol remain confidential. Section 546.720.2, RSMo Cum.Supp, 2012. This provision specifically states “any portion of a record that could identify a person as being a current or former member of an execution team shall be privileged and shall not be subject to discovery.” Section 546.720.2, RSMo Cum.Supp. 2012. Missouri law creates a private cause of action on behalf of

any member of the execution team against any individual who discloses the identity of a current or former execution team member or a record that could identify them. Section 546.720.3, Cum. Supp. 2012. The Missouri Legislature has chosen to afford broad protection to the identities of the execution team as selected by the Director. The State of Missouri has a compelling and justifiable interest in invoking and preserving the state secrets privilege to protect the identities of the execution team. This privilege is well established in federal common law.

Statement of Exhibits

Defendants submit the following as exhibits in support of this motion:

1. Exhibit 1 is an affidavit by the Director of the Missouri Department of Corrections invoking the privilege.
2. Exhibit 2 is the Missouri execution protocol dated October 18, 2013.
3. Exhibit 3 are the docket sheet and court order in *Whitaker v. Livingston*, Case No. 4:13-CV-02901.
4. Exhibit 4 are the lab tests from the chemical used in the Franklin execution dated November 6, 2013 through November 11, 2013.
5. Exhibit 5 is the lab test from the chemical to be used in the Nicklasson execution dated December 5, 2013.
6. Exhibit 6 is the proposed protection order in this case.

7. Exhibit 7 is §546.720, Cum. Supp. 2012.

I. A federal common law privilege protects state secrets and it applies to secrets maintained by state departments of corrections.

The Federal Rules of Evidence govern which privileges a litigant may invoke in federal courts. Federal Rule of Evidence 501 states that the common law, as interpreted by federal courts, governs claims of privilege. The United States Supreme Court identified the state secret privilege in *United States v. Reynolds*, 345 U.S. 1, 5-6 (1953). The privilege is designed to protect official information from disclosure if doing so would endanger the public interest. *Id.* Other courts have stated that the asserted claim of state secret privilege should receive the utmost deference. *Kasza v. Browner*, 133 F.3d 1159, 1166 (9th Cir. 1998).

Federal courts have upheld this privilege when invoked by a state's department of corrections. *Taylor v. Nix*, 451 F.Supp.2d 1351 (N.D.Ga. 2006); *Pack v. Beyer*, 157 F.R.D. 226 (D.N.J. 1994). In *Taylor*, the plaintiff sought documents maintained by the Georgia Board of Probation and Parole. *Taylor v. Nix*, 451 F. Supp. 2d at 1352. Defendants asserted the state secret privilege and cited a Georgia law that prohibited disclosure of information received by the Board in performing its duty. *Id.* The federal court found that the state legislature had expressly conferred privileged status on the

information maintained by the Board, and that the state had a compelling interest in preserving the information under the state secrets privilege. *Id.* at 1354.

Similarly, the Missouri Legislature requires that the Director select the members of the execution team and that the identities of those individuals are to remain secret. Section 546.720.2, RSMo Cum. Supp. 2012. (Ex. 7). The legislature also proscribes discovery of material that could reveal the identities of that execution team. Section 546.720.2, RSMo Cum. Supp. 2012. (Ex. 7). The Legislature determined this privacy interest was so compelling that it created a private cause of action for execution team members whose identities have been made public. Section 546.720.3, RSMo Cum. Supp. 2012. (Ex. 7). The Legislature authorized both actual and punitive damages. *Id.* When considered together, these provisions show a clear intent by the Legislature to protect the identities of the execution team in the broadest possible terms. Like Georgia, the Missouri Legislature has conferred privileged status on execution team members.

In *Pack*, inmates sued New Jersey prison officials after they were segregated from other prisoners due to their affiliation with a dangerous criminal organization. *Pack v. Beyer*, 157 F.R.D. at 226. Inmates sought documents about their segregation from the general population, and prison officials asserted the state secrets privilege to protect the documents. *Id.* The

federal court balanced the need of the inmates to prove their case against the need for security of information and danger to the public interest. *Id.* at 232. As will be shown below, the State of Missouri has a similar compelling interest in maintaining the confidentiality of the identities of the execution team members. Unlike *Taylor*, the defendants in *Pack* did not have a state statute protecting the information on which to base the state secrets privilege. However, the court ruled that the prison officials' documents concerning the inmates were protected by the state secrets privilege because of the official's need to keep the information confidential. *Pack v. Beyer*, 157 F.R.D. at 232. The court noted the plaintiffs' ability to prove their case without the confidential information. *Id.*

II. The State of Missouri has properly invoked the privilege.

The United States Supreme Court outlined the method by which the government could invoke the state secret privilege in *United States v. Reynolds*, 345 U.S. 1, 5 (1953). To invoke the privilege the government must assert it. *Id.* The head of the department with control over the matter must invoke the privilege after personal consideration. *Id.* The court must then determine whether the privilege is appropriate without forcing disclosure of the thing the privilege has been invoked to protect. *Id.*

The Legislature directs the Director of the Missouri Department of Corrections to name the execution team members. Section 546.720.2, RSMo

Cum. Supp. 2012. (Ex. 7). The Director has defined the execution team to include department employees and contracted medical personnel including a physician, nurse, pharmacist, and anyone selected by the Director who provides direct support for the administration of lethal chemicals, including individuals who prescribe, compound, prepare, or otherwise supply the chemicals for use in the lethal injection procedure. (Ex. 2 ¶¶A). Therefore, the Director is the head of the department with control over the matter and has invoked the privilege after personal consideration. (Ex. 1). The Director has made the identities of the execution team confidential in the execution protocol in compliance with state law. Section 546.720.2, RSMo Cum. Supp. 2012; (Ex. 2), (Ex. 7).

The Director asserts the privilege in accord with state law and to prevent harassment of the execution team members. Tellingly, the plaintiffs assert that one of the reasons they need to know the identities of the execution team is so that they can promote censure and boycott of the compounding pharmacy and lab. (Amended Complaint, pp. 94-95). Plaintiffs cite to 2007 and 2008 articles in the St. Louis Post Dispatch as evidence that prior disclosures of execution team member identities has not resulted in harm to the individuals. (Amended Complaint, p. 95). Of course, the contention assumes that prior team members were correctly identified and it further assumes no censure, boycott or detriment over the past five years.

However, this one-dimensional view of the potential harm ensuing from disclosure of the execution team members' identities ignores the broader concerns justifying the Director's invocation of the state secrets privilege. In addition to the safety concerns of the execution team members, the Director is concerned about the Department's ability to employ execution team members and the security of correctional institutions. Moreover, the plaintiff's view belies steps taken by them to directly interfere with the state's ability to acquire drugs necessary to carry out executions.

The Director notes that revealing the identities of any execution team member, or records which could reveal their identities, would expose those individuals to "harassment, intimidation, and harm." (Ex. 1 pg. 3). One of the Director's concerns is for the personal and professional safety and well being of the members of the execution team who provide direct support by compounding lethal chemicals and testing those chemicals, as well as their family members. (Ex. 1 pg. 3). Specifically, the Director notes that indentifying these members of the execution team would prevent the Department from acquiring and testing proper chemicals, and it would prevent the Department from employing and contracting with individuals needed to perform the Department's lawful statutory obligations. (Ex. 1 pg. 4). Moreover, the Director states that revealing the identities of execution team members jeopardizes public safety and security of the correctional

institutions. (Ex. 1 pg. 4). The Director cites to other state's departments of corrections problems in carrying out their lawful obligations after chemical manufacturers and suppliers were harassed and intimidated. (Ex. 1 pg.2, Ex. A).

Before a recent Texas execution using a pharmacy-compounded pentobarbital, a federal district court noted that publicity surrounding the identity of the compounding pharmacy was interfering with the state's ability to carry out its execution laws. (Ex. 3, p. 13). Specifically, the court pointed out that harassment of the pharmacy had caused it to retreat from its direct support of the state's execution procedures. (Ex. 3, p. 13). Just because the St. Louis Post Dispatch reported that putative individual execution team members were not harmed years ago does not mean that there is not a present risk of harassment. (Amended Complaint, p. 95). Additionally, the Texas case shows a substantial risk that individuals will seek to harass and intimidate the compounding pharmacy into ceasing business with the State of Missouri. This is a risk the plaintiff's willfully admit they want to create. (Amended Complaint, pp. 94-95). Interference with the compounding pharmacy's direct support of the State of Missouri's executions also interferes with one of its core functions: The enforcement of laws that its elected officials have enacted.

Specifically in the area of corrections, courts have consistently recognized the need to give deference to correctional administrators in maintaining the security of their institutions. E.g. *Turner v. Safely*, 482 U.S. 78, 84 (1987). Other courts have determined that maintaining as confidential the identities of the execution team members is rationally related to the security needs of correctional institution. *See Thompson v. Department of Corrections*, 118 P.3d 1198, 1207 (Cal. 2001); *Bryan v. State*, 753 So.2d 1244, 1250 (Fla. 2000), (holding exemption of execution team identities from public disclosure laws valid in order to protect security of the prison). Maintaining the confidentiality of the execution team members is critical to the safety of the execution team members, the state's ability to employ execution team members and thereby carry out the validly enacted laws of the state, and the security of the correctional institutions.

III. The plaintiffs are not prejudiced.

In determining whether the state secrets privilege applies, the court should weigh the danger that exposure of the privileged information will pose to the public interest against the other party's need for the information. *United States v. Reynolds*, 345 U.S. 1, 5 (1953). Here the risk of harm to the public is great, as aforementioned. However, the plaintiffs have no need for the identities of the execution team members.

To the extent the plaintiffs argue that the identities of the compounding pharmacy and lab are necessary to determine the quality of the lethal chemical, the defendants have provided lab tests that establish the quality of the chemical used in the most recent execution. (Ex. 4). The tests show the chemical used in making the pentobarbital used in the Franklin execution tested in the proper ranges in all tests. (Ex. 4). The finished product tested in the proper range of potency, and no bacterial growth occurred in a sample of the finished product during the testing period. (Ex. 4). The pentobarbital used to during the Franklin execution was successful and public witnesses noted that Franklin “took a few breaths, swallowed once and then appeared to stop breathing.” (Doc. 178-3). Moreover, the chemical used in making the pentobarbital in Nicklasson’s execution also tested within the proper range for purity and no bacterial growth occurred in a sample of the finished product during the testing period. (Ex. 5). Plaintiffs’ contend the identities of the compounding pharmacy and lab are necessary to determine their track record of success with mixing the necessary chemicals. But this contention is allayed by tests proving the purity, potency, and sterility of the chemicals the state has used in its lethal injections. (Ex. 4, 5). Because the chemical tests within the proper ranges, it does not matter who made it. Additionally, the Director will not use a chemical that fails a lab test. (Ex. 1 pg. 4). The law presumes the Director will act correctly. The Director is

motivated to provide a humane execution. *See Williams v. Hobbs*, 658 F.3d 842 (8th Cir. 2011); *National Archives v. Favish*, 541 U.S. 157, 174 (2003).

To the extent the plaintiffs argue that maintaining the confidentiality of the compounding pharmacy and lab violates provisions of state, federal, and constitutional law, the identities of the execution team members are not essential to the adjudication of those claims. In fact, the only viable reason for revealing the identities of the execution team members is to subject them to harassment, as plaintiffs have indicated that they intend to do. (Amended Complaint, p. 95). There is no weighing of interests to be done under the *Reynolds* framework because the defendants have presented a substantial risk of harm to the public, whereas the plaintiffs make no showing of a need for the identities in order to adjudicate their claims.

Conclusion

Defendants ask this Court to issue the proposed protective order attached as Exhibit 6 to this motion or, in the alternative, to draft and issue a similar order protecting the identities of all members of Missouri's execution team from disclosure in this suit.

Respectfully submitted,

CHRIS KOSTER
Attorney General

\s\Andrew Bailey
ANDREW BAILEY
Assistant Attorney General
Missouri Bar No. 65758
P. O. Box 899
Jefferson City, MO 65102
(573) 751-0716
(573) 751-1336 FAX

Attorney for Respondent

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was electronically filed by using the CM/ECF system on 5 December, 2013. This Court's electronic filing system should serve counsel for the plaintiffs, as all are electronic filers.

\s\ *Andrew Bailey*

ANDREW BAILEY

Assistant Attorney General

AFFIDAVIT OF GEORGE A. LOMBARDI

I, George A. Lombardi, having been first duly sworn, state:

1. I am presently employed as the Director of the Missouri Department of Corrections ("Department"). I have been the Director since January 2009.

2. Prior to my appointment as Director, I served as the Director of the Division of Adult Institutions ("DAI") from 1986 until 2005. During my tenure as DAI Director, I was familiar with the Department's execution procedures.

3. Pursuant to §546.720, RSMo. Supp 2012, I am authorized and directed to establish the means by which the Department conducts lawful executions in the State of Missouri and am further authorized to select members of the execution team.

4. On October 18, 2013, the Department adopted a new execution protocol, which defines the execution team members as follows:

Department employees and contracted medical personnel including a physician, nurse, and pharmacist. The execution team also consists of anyone selected by the department director who provides direct support for the administration of lethal chemicals, including individuals who prescribe, compound, prepare, or otherwise supply the chemicals for use in the lethal injection procedure.

5. After personal consideration, I have determined that there is a reasonable danger that releasing the identities of the execution team

members, and any record which could reveal the identities of current or former execution team members, would interfere and prevent the Department's ability to carry out lawful executions as directed by the Missouri legislature, result in the potential harm, harassment or intimidation of execution team members, and impact public safety and institutional safety and security. I am therefore invoking the state secrets privilege.

6. Releasing the identity of execution team members would prevent the Department from obtaining lethal chemicals needed to perform its state obligations. Lethal chemicals used in the execution process are difficult, if nearly impossible, to obtain. This problem is not limited solely to Missouri, but is experienced by other death penalty states. It has been widely reported by the news media that many manufacturers and suppliers have barred the use of drugs used for executions or refused, under pressure from death-penalty opponents, to sell or manufacture drugs for use in execution. By ensuring the confidentiality of those individuals and entities who provide direct support for the administration of lethal chemicals by providing and testing those chemicals, the Department is able to procure necessary lethal chemicals.

7. Maintaining the confidentiality of the execution team members is also critical to the safety of the individuals and entities that assist the state

in carrying out lawful executions. Revealing the identities of any execution team member, or records which could reveal the identity of those individuals, would only expose that person or entity to harassment, intimidation and harm. (See Exhibit A, letter from pharmacist and related news articles).

8. Plaintiffs' articulate that they desire the identities of the "manufactures, suppliers, and others involved in supplying" the lethal chemicals so that "suppliers' associations, customers, and prescribing or referring physicians" can "censure" or "boycott" them. They further seek to identify the "licensed healthcare professionals" who "personally and directly engag[e] in the process of carrying out an execution" so that "their respective associations and colleagues" may "de-certify", "censure" or "boycott" these individuals. (Amended Complaint, pgs. 94-96). These actions only serve to harass and intimidate the individuals on the execution team, seeking to ultimately destroy their personal and professional lives, and possibly make them targets for individuals who may wish to harm them for their service to the State of Missouri in performing lawful executions.

9. By releasing the identity of the compounding pharmacy and testing lab, the information and records could identify the pharmacist who is currently a member of the execution team. As Director I believe it is important to have confirmation that the chemicals used in the lawful execution of the Plaintiffs are pure, potent and sterile. Any chemical that is

not pure, potent and sterile will not and shall not be used. However, releasing the identity of the compounding pharmacy and testing lab will only prevent the Department from acquiring proper chemicals and testing services.

10. Releasing the identity of execution team members would prevent the Department from employing and contracting with individuals and entities defined as execution team members. In my experience with obtaining and retaining execution team members confidentiality of their identities is a vital component of continued participation. Without ensuring the confidentiality of these individuals and entities, the Department would ultimately be prevented from being able to perform its lawful statutory obligations.


11. Lastly, revealing the identity of execution team members or releasing records which could disclose the identity of current or former execution team members would only serve to jeopardize public safety and the safety and security of the correctional institutions.

Further affiant sayeth not.

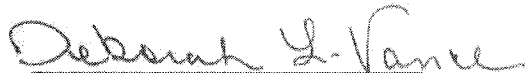
STATE OF MISSOURI)

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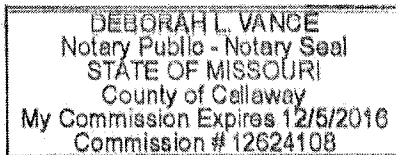
COUNTY OF _____)


George A. Lombardi

Subscribed to and sworn before me this 5 day of December 2013.


Notary Public

My Commission Expires: 12-5-2016



The Woodlands Compounding Pharmacy

3200 Research Forest Dr. Ste. A3

The Woodlands, TX 77381

Phone: 281-419-1340

Fax: 281-419-2181

October 4, 2013

Judge Larry Gist
Board Member, Texas Board of Criminal Justice
Fax 512.305.9398

Brad Livingston
Texas Department of Criminal Justice
Fax 936.437.2123

Bryan Collier
Deputy Executive Director, Texas Department of Criminal Justice
Fax 936.437.8925

Jason Clark
Information Director, Texas Department of Criminal Justice
Fax 936.437.6056

Region I Regional Director Richard Alford
Texas Department of Criminal Justice
Fax 936.437.2651

Region I Deputy Director Robert "Jay" Eason
Texas Department of Criminal Justice
Fax 936.437.2651

Katherine D. Hayes
Assistant Attorney General
Fax 512.320.8132

Dear Sirs and Madam:

I am the owner and pharmacist-in-charge of the Woodlands Compounding Pharmacy, the pharmacy that has provided TDCJ with vials of compounded pentobarbital.

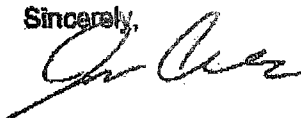
Based on the phone calls I had with Erica Minor of TDCJ regarding its request for these drugs, including statements that she made to me, it was my belief that this information

would be kept on the "down low" and that it was unlikely that it would be discovered that my pharmacy provided these drugs. Based on Ms. Minor's requests, I took steps to ensure it would be private. However, the State of Texas misrepresented this fact because my name and the name of my pharmacy are posted all over the internet. Now that the information has been made public, I find myself in the middle of a firestorm that I was not advised of and did not bargain for. Had I known that this information would be made public, which the State implied it would not, I never would have agreed to provide the drugs to the TDCJ.

I, and my staff, are very busy operating our pharmacy, and do not have the time to deal with the constant inquiries from the press, the hate mail and messages, as well as getting dragged into the state's lawsuit with the prisoners, and possible future lawsuits. For these reasons, I must demand that TDCJ immediately return the vials of compounded pentobarbital in exchange for a refund.

Please contact me immediately to arrange for the return of the drugs. Otherwise I may have to ask the Court in the prisoners' lawsuit to consider my concerns.

Sincerely,



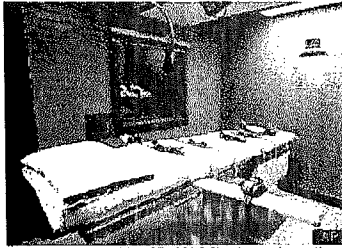
Jasper Lovoi, RPh.

December 5, 2013

HUFF
POST

CRIME

Texas Execution Drug Shortage: State Running Out Of Pentobarbital

By MICHAEL GRACZYK 08/01/13 08:57 PM ET EDT **AP**

This photo taken May 27, 2008 file photo shows the gurney in Huntsville, Texas, where Texas' condemned are strapped down to receive a lethal dose of drugs.

HUNTSVILLE, Texas -- The nation's most active death penalty state is running out of its execution drug.

The Texas Department of Criminal Justice said Thursday that its remaining supply of pentobarbital expires in September and that no alternatives have been found. It wasn't immediately clear whether two executions scheduled for next month would be delayed. The state has already executed 11 death-row inmates this year, and at least seven more have execution dates in coming months.

"We will be unable to use our current supply of pentobarbital after it expires," agency spokesman Jason Clark said. "We are exploring all options at this time."

Texas switched to the lethal, single-dose sedative last year after one of the drugs used in its three-drug execution process became difficult to obtain and the state's supply expired. Other death-penalty states have encountered similar problems after some drug suppliers barred the drugs' use for executions or have refused, under pressure from death-penalty opponents, to

sell or manufacture drugs for use in executions.

No executions in Texas were delayed because of that shortfall.

"When Texas raises a flag that's it having a problem, obviously numerically it's significant around in the country because like they're doing half the executions in the country right now," Richard Dieter, executive director of the Washington-based Death Penalty Information Center, an anti-death penalty organization, said Thursday.

"The states really scramble to go all over to get drugs," he said. "Some went overseas, some got from each other. But these manufacturers, a number them are based in Europe, don't want to participate in our executions. So they've clamped down as much as they can," Dieter said.

Some death penalty states, most recently Georgia, have announced they're turning to compounding pharmacies, which make customized drugs that are not scrutinized by the Federal Drug Administration, to obtain a lethal drug for execution use.

Missouri wants to use propofol, the anesthetic blamed for pop star Michael Jackson's 2009 death -- even though the drug hasn't been used to execute prisoners in the U.S. Its potential for lethal injection is under scrutiny by the courts and its first use isn't likely anytime soon. The Missouri Supreme Court has declined to allow execution dates to be set in that state until the legal issues are resolved.

Missouri Attorney General Chris Koster recently suggested that if a suitable execution drug can't be found, the state should consider the gas chamber. State law still allows for execution by lethal gas, though Missouri no longer even has a gas chamber.

A return to the gas chamber or electric chair anywhere would be difficult, Dieter suggested.

"Those things just raise the spectacle level and I don't think it's where states want to go," he said.

Pentobarbital, which has been used alone or in concert with other drugs in all executions in the U.S. the past two years, was more readily available because it was commonly used as a sedative.

"But I guess restrictions have been put on its distribution," Dieter said. "It's uncertain where all of this goes because it's inherently a medical kind of procedure involving some health professionals who are largely focused on keeping people alive. It runs into contradictions with executions -- people strapped to a table. Executions aren't exactly what the medical model is."

Texas has by far executed more inmates than any other state in the U.S. since the Supreme Court allowed executions to resume. Since 1982, six years after the high court's order, Texas has executed 503 inmates. Virginia is a distant second at 110.

As of May 2012, Texas had 46 of the 2.5-gram vials of pentobarbital, presumably enough to execute as many as 23 prisoners since each execution requires a 5-gram dose. The execution Wednesday of an inmate convicted in two road-rage killings was the 20th lethal injection since that disclosure.

Associated Press writer Jim Salter in St. Louis contributed to this story.

Filed by Hilary Hanson |

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Tennessee moves to single-drug executions despite pentobarbital shortage

Fri, Sep 27 2013

By Tim Ghianni

Sept 27 (Reuters) - Tennessee said on Friday that it will begin to use only pentobarbital to execute death row inmates despite a shortage of the drug.

The state will use the single-drug lethal injection method instead of the three-drug method it has used in the past, according to Tennessee Department of Correction spokeswoman Dorinda Carter.

"The Department of Correction had been unable to obtain the chemicals necessary to carry out an execution since 2011 due to a widespread shortage" of sodium thiopental, a drug used in the three-drug method, Carter said.

Sodium thiopental puts the prisoner to sleep, with another drug administered to paralyze the prisoner and a third to stop the heart.

In April 2011, Tennessee was among the states that turned over its supplies of sodium thiopental to authorities after concerns arose about how the supply of the drug was imported.

That move came after the company that produced sodium thiopental had bowed to European Union pressure to stop making the drug, creating a shortage. The death penalty has been abolished in all EU nations.

The sodium thiopental shortage forced U.S. states to switch to pentobarbital.

Seven states currently use pentobarbital alone for executions and more are planning to use it, according to Richard Dieter, executive director of the Death Penalty Information Center, a non-profit organization that provides information on capital punishment. Other states use it as part of the three-stage execution process.

Pentobarbital also is commonly used during surgeries and by veterinarians to euthanize animals.

"Given it's used by veterinarians and on humans for other purposes, there's probably a lot out there. But if you have to make a new order, it's hard to get for prisons," Dieter said.

Danish manufacturer Lundbeck and its American subsidiary, Akorn, are controlling the distribution of pentobarbital "and are not allowing its distribution if it is to be used for executions," Dieter said.

Dieter said some states that had been using pentobarbital were having to switch to other drugs or find new sources because of the shortage.

"Everybody that used (sodium thiopental) has switched and now they may have to switch again (from pentobarbital)," Dieter said.

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Untried sedative to be used in lethal injection tonight because of drug shortage

TU THANH HA

The Globe and Mail

Published Tuesday, Oct. 15 2013, 4:16 PM EDT

Last updated Tuesday, Oct. 15 2013, 5:27 PM EDT

Nearly a quarter of a century after he went to death row for rape and murder, William Happ was scheduled to be executed on Tuesday afternoon in controversial circumstances that underline how state executioners in the United States and Vietnam are now limited in their actions by a growing shortage of drugs for lethal injections.

More Related to this Story

- [With pentobarbital running out, Florida set to use untried drug for execution](#)
- [Vietnam Vietnam to try producing own lethal drugs for death sentences](#)

Mr. Happ is to be taken to a chamber of the Florida State Prison, where he will be strapped to a gurney and hooked to an intravenous saline bag. At 6 p.m., the executioner will pump 500 milligrams of the sedative midazolam hydrochloride to knock him unconscious before two other drugs are injected to kill him.

However, midazolam hydrochloride, known by the brand name Versed, has never been used before in executions, raising concerns about whether it can effectively make the execution painless.

Florida decided to use the untried midazolam because drug companies no longer want to provide the barbiturates traditionally used for capital punishment.

The American protocol for lethal injections, which has also been used by Vietnam, is typically a three-drug process: an anesthetic renders the prisoner unconscious, then a muscle relaxant paralyzes the inmate and finally a dose of potassium chloride stops the heart.

Since 2011, the European Union has banned exports of products that could be used for capital punishment such as gallows and guillotines, but also sodium thiopental and other similar barbiturates. The sole American maker of sodium thiopental, Hospira, ended production in January, 2011, because its plant was in Italy and it did not want to be held liable. Six months later, H. Lundbeck A/S, a Danish pharmaceutical firm that produced another lethal-injection

sedative, pentobarbital sodium, at a plant in Illinois, stopped selling to prisons in U.S. states carrying out the death penalty.

To keep executing inmates, "prisons now have to scramble and improvise," Maya Foa, an investigator for the British human-rights group Reprieve, said in an interview.

The uncertainty with the drug supplies has led some states to suspend executions. Missouri was going to circumvent the shortage by using the anesthetic propofol, but on Friday, its governor, Jay Nixon, halted the scheduled execution of a triple murderer, Allen Nicklasson.

"In light of the issues that have been raised surrounding the use of propofol in executions, I have directed the Department of Corrections that the execution of Allen Nicklasson, as set for October 23, will not proceed," Mr. Nixon said in a statement on Friday. "I have further directed the department to modify the State of Missouri's execution protocol to include a different form of lethal injection."

Other states have been trying to keep executing by relying on compounding pharmacies, which mix customized, small amounts of drugs.

This more artisanal approach has in turn raised concerns about quality controls and the reliability of these special-order drugs.

If the anesthetic does not work properly, the subsequent dose of muscle relaxant would leave prisoners lucid but unable to move while they are injected with potassium chloride, which causes excruciating pain, Ms. Foa said. "You'll be paralyzed and people won't be able to see that you are suffering, so it's quite insidious," she said.

In Georgia, Warren Hill, who was convicted of the murder of his girlfriend and subsequently of the murder of another inmate, was scheduled to be put to death on July 19. However, the day before, a judge of the Superior Court of Fulton County suspended Mr. Hill's execution after ruling that a new state law, which kept secret the identities of those who supply Georgia's lethal-injection drugs, was not constitutional.

"The plaintiff still, today, cannot possibly determine whether the pentobarbital in question was somehow contaminated or otherwise improperly compounded," Judge Gail S. Tusan wrote in the ruling.

Similar worries emerged after Vietnam adopted lethal injections in 2011, just three months before the start of European controls on the exportation of barbiturates. With a backlog of more than 560 inmates waiting on death row, the country announced in January that it would try to produce its own pharmaceuticals to carry out death sentences.

Vietnam's first lethal injection took place in August, with the execution of Nguyen Anh Tuan, for the fatal stabbing of a woman who was robbed of her cellphone and the equivalent of \$20 in her purse. The source of the lethal-injection drugs was not revealed.

"Some very tenacious states will try to find ways to kill people, no matter how underhanded," Ms. Foa said.

In Florida, when Mr. Happ was convicted in 1989, the state still relied on the electric chair and lethal injections would be introduced only in 2000.

Mr. Happ was found guilty of the murder and rape of Angela Crowley. She did not know him and had stopped to use a payphone when she was kidnapped from a parking lot in 1986. Her battered body was found in a canal in central Florida. Mr. Happ was arrested after police matched his fingerprints and shoe prints to those at the crime scene.

By the time Mr. Happ gave up on legal appeals last month, Florida was running out of its stockpile of lethal-injection barbiturates. According to a court filing [http://floridacapitalresourcecenter.org/media/uploads/news_attachments/ferguson_pento_inte], obtained by the Florida Capital Resource Center, the Aug. 5 execution of John Ferguson, convicted of eight murders, used pentobarbital sodium made by Lundbeck and acquired in June, 2011, just before the firm stop selling to prisons. The drug had an expiration date in the fall of 2013.

The plan to switch to midazolam was revealed in a September court filing. Several Florida death-row inmates have now challenged its use in a filing in U.S. federal court. According to the Florida Department of Corrections, the state currently has 400 men and five women on death row.

While state executioners still try to circumvent the drug shortage, the situation has fuelled a necessary debate on the issue, Ms. Foa said. "There may be some rogue states, but we are seeing some changes. ... This discussion is an important one."

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Lacking Lethal Injection Drugs, States Find Untested Backups

by NPR STAFF

October 26, 2013 5:19 PM

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Amber Hunt/AP

The U.S. is facing a shortage of a drug widely used for lethal injections. With few options, states are turning to new drugs and compounding pharmacies, rather than overseas companies.

The move is raising safety concerns, and in some cases delaying executions. Other executions are proceeding, however, and lawmakers are asking whether the use of new drugs violates the inmates' Eighth Amendment protection from cruel and unusual punishment.

A Witness To Lethal Injection

In 1989, William Hopp was sentenced to death for the murder and rape of 21-year-old Angie Coudry. For decades, Hopp appealed and lost.

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Phil Sandlin/AP

His death sentence remained, but the method of execution had changed since his conviction. Since 1924, Florida had used the electric chair to execute prisoners, but in 2000, facing pressure from the Supreme Court, the state switched to lethal injection.

More than a quarter century after Crowley's murder, Happ's execution date was finally set for Oct. 15, 2013. But the state had a problem: Supplies of pentobarbital, a drug commonly used for executions, were running low. As the execution date approached, the state ran out of the drug altogether.

So the Florida Department of Corrections decided to use a new drug -- a sedative called midazolam that had never been tested for execution. Nobody knew exactly how it would work.

Associated Press reporter Brendan Farrington was in the viewing room. "It's a very solemn, serious, quiet atmosphere. There's no talking," he tells *All Things Considered* host Arun Rath.

"They bring the witnesses in, and there's a screen across a long, rectangular window. And when they're ready to begin, the screen slowly rises," Farrington says. "The person conducting the execution will announce that the sentence is about to be carried out, tells this to the condemned, and asks if he has any last words."

Happ chose to speak, admitting to the crime and expressing shame for it. "[He said] he hopes God forgives him, and he realizes the family probably could not," Farrington says. "From there, the execution proceeds."

At 1 p.m. sharp, the execution began. Farrington had seen three other executions, none of which used midazolam. In those cases, he says, the prisoners' eyes closed "fairly quickly, and once their eyes closed, they usually stay closed."

"While it wasn't dramatically different than previous executions, it did seem like it took him longer to lose consciousness," Farrington says. "In Happ's case, his eyes were still opening two, three, four minutes into the process. Once they closed, about 10 minutes in, his head started moving kinda just around, and there was some motion."

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There's no way to know if Happ was in pain during his last moments. Some anesthesia experts have expressed concern that midazolam and other untested sedatives could fail to work properly during an execution. If that happened, condemned prisoners could die slowly or painfully, a violation of legal guidelines for executions.

Megan McCracken studies lethal injection drugs for the Death Penalty Clinic at the University of California, Berkeley, School of Law.

“If the first drug does not in fact deeply anesthetize the prisoner, then he or she could be conscious and aware of being both paralyzed and able to experience pain and the experience of cardiac arrest.”

- Megan McCracken, U.C. Berkeley Law School

"If the first drug does not in fact deeply anesthetize the prisoner," she says, "then he or she could be conscious and aware of being both paralyzed and able to experience pain and the experience of cardiac arrest."

In Search Of Drugs

NPR's Kathy Lohr has been covering the shortage of lethal injection drugs for years. She says the issue started when the drug company Hospira stopped making one of the most common drugs used in lethal injections, sodium thiopental. The anesthetic was used as part of a three-drug protocol.

"The company was the only maker of the drug in the United States," Lohr says. "But by 2011, the company stopped manufacturing it. In part, it really wanted to distance itself from executions."

The move caused a shortage, she says, "which basically led states to search for the drug wherever they could find it."

Some states began trading between themselves. Once the supply either runs out or expires, states are forced to come up with new protocols, find new drugs, or simply postpone the execution.

Missouri recently canceled an execution because it had planned to use propofol, a widely used anesthetic in U.S. hospitals. The drug is manufactured in Europe by the German company Fresenius Kabi. That potentially could have caused larger problems.

"The European Union has a statute that does not allow the export of any product that might be used in capital punishment," says company spokesman Matt Kuhn.

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Once On Death Row, He Now Fights To Defeat The Death Penalty

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Missouri announced Tuesday it would not use propofol; it's going to use pentobarbital instead.

Richard Dieter, who opposes the death penalty and directs the Death Penalty Information Center, says Missouri made the right decision in switching drugs.

"I think Missouri wisely got out of that whole crisis area and now finds a local pharmacy that will make a different drug, and joins Texas and some other states like Ohio and Georgia in this process," he says.

Compounding The Issue

But now there's another issue: Missouri and a number of states are now getting their drugs from compounding pharmacies. That bypasses the big European drug manufacturers altogether. The U.S. Food and Drug Administration doesn't regulate them, either.

"The drugs they're producing, including this pentobarbital, are not made specifically for executions and ... no court has actually reviewed this process," Lehr says. "So if the drugs cannot be validated as effective, this could be a violation of an inmate's Eighth Amendment right against cruel and unusual punishment."

If the drugs cannot be validated as effective, this could be a violation of an inmate's Eighth Amendment right against cruel and unusual punishment.

- NPR's Kathy Lohr

Texas, Ohio and Missouri all have announced plans to use compounding pharmacies just this month.

"I think we should be using the best practice — not what's available," Dieter says. "And that's what we've come down to: What can the states get a hold of from the backroom of local pharmacies, rather than what's recommended by medical experts."

In addition, states are withholding details about the compounding pharmacies. Georgia inmate Warren Lee Hill is challenging the state's claim that the information should be kept secret.

"His attorneys say they need this information about where the drug is coming from and how it's manufactured — even to know if they can mount a legal challenge," Lohr says.

The states argue that the pharmacies may not want to sell the drugs if it's made public that they're contributing to capital punishment. A lack of sellers — and therefore drugs — could get in the way of carrying out executions.

"So that issue is now making its way through the courts in Georgia, and the execution of an inmate here, Warren Lee Hill, is on hold," Lohr says. "Also, more legal challenges are expected on this issue across the country."



U.S.
Georgia Death
Penalty Under
Renewed Scrutiny
After 11th-Hour Stay

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NEWS

Drug Shortages Could Kill Lethal Injections

Court challenges say substitutes don't meet constitutional protections against inflicting unneeded pain and suffering

By Ron Word
Posted 12/4/13

NEWS

Fast-tracking Executions

NEWS

Life After Death Row?

For more than a dozen years, the state of Florida executed condemned inmates with a three-drug cocktail that first put them to sleep, then paralyzed their bodies and eventually stopped their hearts.

Now, the state is at another crossroads in implementing that protocol because one drug, pentobarbital, is no longer available from any source. Florida Department of Corrections switched to that drug in 2011 when sodium thiopental became scarce. The pentobarbital and sodium thiopental are designed to render inmates unconscious.

The same issue arose in the 31 other states that use lethal injection, when foreign suppliers refused to sell drugs for use in executions. Most of the problems have occurred since 2008, when the U.S. Supreme Court ruled that Kentucky's lethal injection method was constitutional.

Two death row inmates argued that Kentucky's three-drug lethal injection method would violate the

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Eighth Amendment prohibition of cruel and unusual punishment. By a 7-2 vote, the Supreme Court upheld Kentucky's method, which used the same drugs that almost all states used for lethal injections.

However, now that some of the chemicals have changed, some states, including Florida, are looking for new drugs that pass constitutional muster.

"States started panicking," said Deborah Denno, a Fordham University law professor and expert on the death penalty.

Hikma Pharmaceuticals PLC issued a press release out of London on May 15, which stated, "Hikma strongly objects to the use of any of its products in capital punishment. The company is putting in place concrete steps to restrict the supply of its products for unintended uses." The release continues, stating Hikma had ceased the sale of phenobarbital to U.S. departments of corrections.

Because of decisions made by foreign companies to forbid use of their drugs for executions, states are scrambling to come up with alternatives, which is prompting a new round of legal challenges, including one in federal court in Jacksonville from four death row inmates.

Florida switched to midazolam hydrochloride when it could no longer get pentobarbital for its three-drug cocktail on Oct. 15. When the state Department of Corrections abandoned the electric chair and first began using lethal injection in 2000, it used the same drugs as other states, including Texas and Oklahoma.

"Midazolam is not intended for use as an anesthetic," the federal lawsuit states. "Its use in this context is wholly untested."

U.S. District Court Judges Marcia Morales Howard and Timothy J. Corrigan in Jacksonville tossed out the federal challenge, but granted the inmates 60 days to file new briefs and gave the attorney general's office 30 days to respond.

Corrigan questioned the lack of medical evidence statements from both sides. Assistant Attorney General Scott Brown argued that the new drug was effective.

"If it's so great, why weren't they using it before?" Corrigan asked, as reported by the Associated Press.

In a letter to Gov. Rick Scott, Department of Corrections Secretary Michael D. Crews wrote, "The procedure has been reviewed and is compatible with evolving standards of decency that mark the progress of a maturing society, the concepts of the dignity of man, and advances in science, research, pharmacology and technology. The process will not involve unnecessary lingering or the unnecessary or wanton infliction of pain and suffering. The foremost objective of the lethal injection process is a humane and dignified death."

According to the Mayo Clinic website, the drug "is used to produce sleepiness or drowsiness and to relieve anxiety before surgery or certain procedures." It belongs to a group of medicines called central nervous system depressants, which slow down the nervous system.

"Florida used a drug that no state had ever used before," Denno said. "That execution did not go well."

Denno was referring to the Oct. 15 execution of William Hays, who had been on Death Row for 27 years. Reporters witnessing the execution said it appeared Hays remained conscious longer and made more body movements after losing consciousness than other people executed recently by lethal injection using the old formula.

One of the inmates challenging the new drugs is Etheria Verdel Jackson, who was sentenced to death for the Dec. 3, 1985, strangulation and stabbing death of 64-year-old Jacksonville furniture storeowner Linton Moody.

Richard Dieter, executive director of the Death Penalty Information Center in Washington, said the legal challenges may slow some Florida executions, though a new state law has increased the number from three last year to seven this year.

"There are challenges working their way through the courts which could be a roadblock," Dieter said. "Florida has gone off course with this drug."

For states, the problem is how to carry out an execution that's quick, effective and meets constitutional standards by not inflicting unneeded pain and suffering.

Mark Elliott, executive director of Floridians for Alternatives to the Death Penalty in Tampa, opposes all

Thursday	Dec 5
Job Fair	
University Center (Universi	5:00 pm
Open Mic	
Trade Winds Lounge	5:00 pm
Sound Effects: Music at MOCA	
MOCA - Museum of Conte	5:00 pm
Friday	Dec 6
Saturday	Dec 7

executions.

"There is no humane way to commit an inhumane act, no right way to do the wrong thing," Elliott wrote in an email.

"Florida executions are political 'dog and pony' shows designed to appear as approved medical procedures. The reality is that the executioner is paid \$150 to kill, and the state will find a way to do it," he continued.

"Our state officials like to claim it is 'humane,' 'dignified' and 'solemn.' It is none of that. It is legalized, premeditated murder."

An inmate who faces execution Dec. 27, Askari Muhammad, also known as Thomas Knight, lost an appeal Nov. 25 when Bradford County Circuit Judge Phyllis Rosier ruled the sedative midazolam hydrochloride is capable of preventing condemned inmates from experiencing pain during a lethal injection.

"There is no dispute that the dosage amount used in Florida's protocol is such that it would induce not only unconsciousness when properly administered, but also respiratory arrest and ultimately death," she wrote.

Knight's execution was originally scheduled for Dec. 3 but was delayed by the Florida Supreme Court. The case now goes back to the high court, which is scheduled to hear oral arguments Dec. 18.

Knight, 62, has been on Death Row for almost 40 years. He was convicted of fatally stabbing Corrections Officer Richard Burke with the sharpened end of a spoon in 1980. Knight was first convicted in the 1974 slaying of Sydney and Lillian Gans in Miami.

There are problems in other states where changes in lethal injection protocols have resulted in new legal challenges, Denno said.

Since 2010, 11 states have changed their protocols from three drugs to one drug, Denno said, while Florida continues to use three drugs.

"They have a very problematic procedure," Denno said of Florida's protocol.

The Missouri execution of white supremacist Joseph Paul Franklin was delayed for several hours Nov. 20 while his attorneys pressed their appeals, including the use of pentobarbital. His attorneys argued that its use would violate the constitutional ban on cruel and unusual punishment.

Missouri had planned to use the drug propofol, the surgical anesthetic made infamous by the death of pop star Michael Jackson. But there were concerns that European Union might halt shipments, leading to fears there would be an insufficient supply for medical purposes.

Missouri decided to use pentobarbital created by an unnamed compounding pharmacy, prompting Franklin's lawyers to argue it would raise the risk of contamination and a painful death.

Both Dieter and Denno believe new issues will continue to appear and be appealed as the death penalty becomes less popular.

"Death penalty opponents and medical professionals have long objected to lethal injection on the basis that the use of drugs to carry out executions links death to the practice of medicine," Denno wrote in an article to be published in 2014 in the Georgetown Law Journal. "Ironically, that reliance on drugs may end up accomplishing what countless legal challenges could not: Drug shortages have devastated this country's execution process to an unparalleled degree. Rather than masking the 'machinery of death,' the mimicry of medicine may end up dismantling it."

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**MISSOURI DEPARTMENT OF CORRECTIONS
PREPARATION AND ADMINISTRATION OF CHEMICALS
FOR LETHAL INJECTION**

A. Execution Team Members

The execution team consists of department employees and contracted medical personnel including a physician, nurse, and pharmacist. The execution team also consists of anyone selected by the department director who provides direct support for the administration of lethal chemicals, including individuals who prescribe, compound, prepare, or otherwise supply the chemicals for use in the lethal injection procedure.

B. Preparation of Chemicals

Medical personnel shall prepare the lethal chemicals. The quantities of these chemicals may not be changed without prior approval of the department director. The chemicals shall be prepared and labeled as follows:

1. Syringes 1 and 2: Five (5) grams of pentobarbital (under whatever name it may be available from a manufacturer, distributor or compounding pharmacy), 100 ml of a 50 mg/mL solution, shall be withdrawn and divided into syringes labeled "1" and "2."
2. Syringe 3: 30 cc of saline solution.
3. Syringes 4 and 5: Five (5) additional grams of pentobarbital (under whatever name it may be available from a manufacturer, distributor or compounding pharmacy), 100 ml of a 50 mg/mL solution, shall be withdrawn into syringes labeled "4" and "5."
4. Syringe 6: 30 cc of saline solution. This syringe is prepared in the event that additional flush is required.

C. Intravenous lines

1. Medical personnel shall determine the most appropriate locations for intravenous (IV) lines. Both a primary IV line and a secondary IV line shall be inserted unless the prisoner's physical condition makes it unduly difficult to insert more than one IV. Medical personnel may insert the primary IV line as a peripheral line or as a central venous line (e.g., femoral, jugular, or subclavian) provided they have appropriate training, education, and experience for that procedure. The secondary IV line is a peripheral line.
2. A sufficient quantity of saline solution shall be injected to confirm that the IV lines have been properly inserted and that the lines are not obstructed.

D. Monitoring of Prisoner

1. The gurney shall be positioned so that medical personnel can observe the prisoner's face directly or with the aid of a mirror.
2. Medical personnel shall monitor the prisoner during the execution.

E. Administration of Chemicals

1. Upon order of the department director, the chemicals shall be injected into the prisoner by the execution team members under the observation of medical personnel. The lights in the execution support room shall be maintained at a sufficient level to permit proper administration of the chemicals.
2. The pentobarbital from syringes 1 and 2 shall be injected.
3. The saline solution from syringe 3 shall be injected.
4. Following a sufficient amount of time for death to occur after the injection of syringe 3, medical personnel shall examine the prisoner to determine if death has occurred. If the prisoner is still breathing, the additional five grams of pentobarbital will injected from syringes 4 and 5 followed by the saline from syringe 6.
5. At the completion of the process and after a sufficient time for death to have occurred, medical personnel shall evaluate the prisoner to confirm death. In the event that the appropriate medical personnel cannot confirm that death has occurred, the curtain shall be reopened until an appropriate amount of time has passed to reevaluate the prisoner.

F. Documentation of Chemicals

1. Medical personnel shall properly dispose of unused chemicals.
2. Before leaving ERDCC, all members of the execution team present at the execution shall complete and sign the "Sequence of Chemicals" form thereby verifying that the chemicals were given in the order specified in this protocol.
3. Before leaving ERDCC, one of the medical personnel present at the execution shall complete and sign the "Chemical Log" indicating the quantities of the chemicals used and the quantities of the chemicals discarded during the execution.
4. Within three days of the execution, the ERDCC warden shall submit the Sequence of Chemicals and the Chemical Log to the director of the Division of Adult Institutions (DAI). The DAI division director and the department director shall review the records. If they do not detect any irregularities, they shall approve the two documents. If any irregularities are noted, the DAI division director shall promptly determine whether there were any deviations from this protocol and shall report his findings to the department director.

Missouri Department of Corrections
Revised October 18, 2013

DEATH_PENALTY,PRIS

**U.S. District Court
SOUTHERN DISTRICT OF TEXAS (Houston)
CIVIL DOCKET FOR CASE #: 4:13-cv-02901**

Whitaker et al v. Livingston, Executive Director of the Texas Department of Criminal Justice et al
Assigned to: Judge Lynn N. Hughes
Cause: 42:1983 Civil Rights Act
Date Filed: 10/01/2013
Jury Demand: None
Nature of Suit: 550 Prisoner: Civil Rights
Jurisdiction: Federal Question

Plaintiff

Thomas Whitaker

represented by **Bobbie L Stratton**
Baker Donelson et al
1301 McKinney
Ste 3700
Houston, TX 77010
(713) 650-9700
Fax: (713) 650-9701
Email: bstratton@bakerdonelson.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Jessica Alison Hinkie
Baker Donelson et al
1301 McKinney
Ste 3700
Houston, TX 77010
713-650-9700
Fax: 713-650-9701
Email: jhinkie@bakerdonelson.com
ATTORNEY TO BE NOTICED

Maurie Amanda Levin
211 South Street
#346
Philadelphia, PA 19147
512-294-1540
Fax: 215-733-9225
Email: maurielevin@gmail.com
ATTORNEY TO BE NOTICED

Valerie Anne Henderson
Baker, Donelson, Bearman, Caldwell &
Berkowitz
1301 McKinney Street
Suite 3700
Houston, TX 77010

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Zink, et al. v. Lombardi, et al.
No. 2:12-CV-4209 NKL

Respondents' Exhibit 3

713-650-9700
Fax: 713-650-9701
Email: vhenderson@bakerdonelson.com
ATTORNEY TO BE NOTICED

Bradley E Chambers
Baker Donelson et al
1301 McKinney
Ste 3700
Houston, TX 77010
713-650-9700
Email: bchambers@bakerdonelson.com
ATTORNEY TO BE NOTICED

Plaintiff

Perry Williams

represented by **Bobbie L Stratton**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Jessica Alison Hinkie
(See above for address)
ATTORNEY TO BE NOTICED

Maurie Amanda Levin
(See above for address)
ATTORNEY TO BE NOTICED

Valerie Anne Henderson
(See above for address)
ATTORNEY TO BE NOTICED

Bradley E Chambers
(See above for address)
ATTORNEY TO BE NOTICED

Plaintiff

Michael Yowell
TERMINATED: 10/15/2013

represented by **Bobbie L Stratton**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Jessica Alison Hinkie
(See above for address)
ATTORNEY TO BE NOTICED

Maurie Amanda Levin
(See above for address)
ATTORNEY TO BE NOTICED

Valerie Anne Henderson
(See above for address)
ATTORNEY TO BE NOTICED

Bradley E Chambers
(See above for address)
ATTORNEY TO BE NOTICED

V.

Defendant

**Brad Livingston, Executive
Director of the Texas Department
of Criminal Justice**

represented by **Allan Kennedy Cook**
Office of the Attorney General
300 W 15th Street
7th Floor
Austin, TX 78701
512-475-1917
Fax: 512-495-9139
Email:
Allan.Cook@texasattorneygeneral.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Edward Larry Marshall
Office of the Attorney General
P O Box 12548
Capitol Station
Austin, TX 78711
512-936-1400
Fax: 512-320-8132
Email:
edward.marshall@texasattorneygeneral.gov

LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Adam Warren Aston
Texas Attorney General
209 W 14th St
7th Floor
Austin, TX 78701
512-936-1700
ATTORNEY TO BE NOTICED

David Alan Harris
Office of the Attorney General
P O Box 12548
Austin, TX 78711
512-463-2080
Fax: 512-495-9139

90a

Email:
david.harris@texasattorneygeneral.gov
ATTORNEY TO BE NOTICED

Katherine D Hayes
Office of Texas Attorney General
P O Box 12548
Austin, TX 78711-2548
512-936-1400
Fax: 512-320-8132
Email:
katherine.hayes@texasattorneygeneral.gov
ATTORNEY TO BE NOTICED

Defendant

**William Stephens, Director TDCJ-
CID**

represented by **Allan Kennedy Cook**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Edward Larry Marshall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Adam Warren Aston
(See above for address)
ATTORNEY TO BE NOTICED

David Alan Harris
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

James Jones

represented by **Allan Kennedy Cook**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Edward Larry Marshall
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Adam Warren Aston
(See above for address)
ATTORNEY TO BE NOTICED

David Alan Harris
(See above for address)

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*ATTORNEY TO BE NOTICED***Defendant****Unknown Executioners**

represented by **Allan Kennedy Cook**
 (See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Edward Larry Marshall
 (See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Adam Warren Aston
 (See above for address)
ATTORNEY TO BE NOTICED

David Alan Harris
 (See above for address)
ATTORNEY TO BE NOTICED

Movant**Edgar Tamayo Arias**

represented by **Maurie Amanda Levin**
 (See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
10/01/2013	<u>1</u>	COMPLAINT against James Jones, Brad Livingston, Executive Director of the Texas Department of Criminal Justice, William Stephens, Director TDCJ-CID, Unknown Executioners filed by Thomas Whitaker, Michael Yowell, Perry Williams.(Chambers, Bradley) (Entered: 10/01/2013)
10/01/2013	<u>2</u>	MOTION for Preliminary Injunction by Thomas Whitaker, Perry Williams, Michael Yowell, filed. Motion Docket Date 10/22/2013. (Stratton, Bobbie) (Entered: 10/01/2013)
10/01/2013	<u>3</u>	MOTION/APPLICATION to Proceed In Forma Pauperis by Thomas Whitaker, Perry Williams, Michael Yowell, filed. Motion Docket Date 10/22/2013. (Attachments: # <u>1</u> Affidavit, # <u>2</u> Proposed Order)(Stratton, Bobbie) (Entered: 10/01/2013)
10/01/2013	<u>4</u>	NOTICE of Appearance by Maurie Levin on behalf of Thomas Whitaker, filed. (Levin, Maurie) (Entered: 10/01/2013)
10/01/2013	<u>5</u>	NOTICE of Appearance by Maurie Levin on behalf of Perry Williams, filed. (Levin, Maurie) (Entered: 10/01/2013)
10/01/2013	<u>6</u>	NOTICE of Appearance by Maurie Levin on behalf of Michael Yowell, filed. (Levin, Maurie) (Entered: 10/01/2013)

10/02/2013	<u>7</u>	Scheduling ORDER. By 4:15 p.m. on 10/2/2013, the state of Texas's officers must tell the court which drugs it will use to execute Michael Yowell. Hearing on the motion for preliminary injunction set for 10/4/2013 at 03:00 PM in Courtroom 11C before Judge Lynn N. Hughes. Counsel must be prepared to discuss the facts, not legal posturing. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/02/2013)
10/02/2013	<u>8</u>	ORDER terminating <u>3</u> . The court will conditionally grant in forma pauperis status dependent on each plaintiff filing an affidavit of indigency. Defendants will file a response to the motion for a temporary injunction by 5:00 p.m. on 10/3/2013. Plaintiffs may file a reply by noon on 10/4/2013. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/02/2013)
10/02/2013	<u>9</u>	ADVISORY by Brad Livingston, Executive Director of the Texas Department of Criminal Justice, filed. (Attachments: # <u>1</u> Exhibit A: TDCJ Execution Procedure, # <u>2</u> Exhibit B: Purchase order and invoices, # <u>3</u> Exhibit C: Lab report)(Marshall, Edward) (Entered: 10/02/2013)
10/03/2013	<u>10</u>	NOTICE of Appearance by Katherine D. Hayes on behalf of Brad Livingston, Executive Director of the Texas Department of Criminal Justice, filed. (Hayes, Katherine) (Entered: 10/03/2013)
10/03/2013	<u>11</u>	RESPONSE in Opposition to <u>2</u> MOTION for Preliminary Injunction, filed by Brad Livingston, Executive Director of the Texas Department of Criminal Justice. (Attachments: # <u>1</u> Exhibit D: press release, # <u>2</u> Exhibit E: grievance, # <u>3</u> Exhibit F: Vernay letter, # <u>4</u> Exhibit G: Howell email)(Marshall, Edward) (Entered: 10/03/2013)
10/03/2013	<u>12</u>	MOTION for Adam W. Aston to Appear Pro Hac Vice for James Jones, Brad Livingston, Executive Director of the Texas Department of Criminal Justice, William Stephens, Director TDCJ-CID, Unknown Executioners, filed. Motion Docket Date 10/24/2013. (sguevara, 4) (Entered: 10/03/2013)
10/04/2013	<u>13</u>	REPLY to <u>11</u> Response in Opposition to Motion, <i>for Temporary Injunctive Relief</i> , filed by Thomas Whitaker, Perry Williams, Michael Yowell. (Attachments: # <u>1</u> Exhibit Plaintiff's Exhibit List, # <u>2</u> Exhibit A, # <u>3</u> Exhibit B, # <u>4</u> Exhibit C, # <u>5</u> Exhibit D, # <u>6</u> Exhibit E, # <u>7</u> Exhibit F, # <u>8</u> Exhibit G, # <u>9</u> Exhibit H, # <u>10</u> Exhibit I, # <u>11</u> Exhibit J, # <u>12</u> Exhibit K, # <u>13</u> Exhibit L, # <u>14</u> Exhibit M, # <u>15</u> Exhibit N, # <u>16</u> Exhibit O, # <u>17</u> Exhibit P, # <u>18</u> Exhibit Q, # <u>19</u> Exhibit R, # <u>20</u> Exhibit S, # <u>21</u> Exhibit T, # <u>22</u> Exhibit U, # <u>23</u> Exhibit V, # <u>24</u> Exhibit W, # <u>25</u> Exhibit X, # <u>26</u> Exhibit Y, # <u>27</u> Exhibit Z, # <u>28</u> Exhibit AA) (Stratton, Bobbie) (Entered: 10/04/2013)
10/04/2013	<u>14</u>	ORDER granting <u>12</u> Motion to Appear Pro Hac Vice as to Adam W. Aston. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/04/2013)
10/04/2013	<u>15</u>	AFFIDAVIT of Thomas Bartlett Whitaker re: <u>3</u> MOTION/APPLICATION to Proceed In Forma Pauperis, filed.(Stratton, Bobbie) (Entered: 10/04/2013)
10/04/2013	<u>17</u>	Minute Entry for HEARING held before Judge Lynn N. Hughes on 10/4/2013. Appearances: Maurie Levin, Bobbie Stratton, Valerie Henderson, Jennifer Moreno, Katherine Hayes, Adam Aston, Sharon Howell. Evidence taken.

		Argument heard on all pending motions. Order to be entered. (Court Reporter: G. Dye) (ghassan, 4) (Additional attachment(s) added on 10/7/2013: #(1) Plaintiff's exhibit 1, #(2) Plaintiff's exhibit 2). (ghassan, 4) (Entered: 10/05/2013)
10/05/2013	<u>16</u>	NOTICE by Michael Yowell, filed. (Attachments: # <u>1</u> Exhibit Woodlands Pharmacy Letter)(Levin, Maurie) (Entered: 10/05/2013)
10/05/2013	<u>18</u>	OPINION on Preliminary Injunction. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/05/2013)
10/05/2013	<u>19</u>	ORDER Denying Injunction and Emergency Relief. Plaintiffs' motion for a preliminary injunction is denied <u>2</u> . Yowell's emergency motion to stay his execution is denied. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/05/2013)
10/05/2013	<u>20</u>	ORDER Setting Conference. Pretrial Conference set for 10/17/2013 at 10:00 AM in Room 11122 before Judge Lynn N. Hughes. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/05/2013)
10/07/2013	<u>21</u>	Amended OPINION on Preliminary Injunction. (Amended to correct typographical error.) (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/07/2013)
10/07/2013	<u>22</u>	NOTICE OF APPEAL to US Court of Appeals for the Fifth Circuit by Michael Yowell, filed.(Levin, Maurie) (Entered: 10/07/2013)
10/07/2013	<u>23</u>	MOTION/Request to Proceed In Forma Pauperis by Thomas Whitaker et al, filed. This is a duplicate of document # <u>22</u> re-entered for case management purpose. Motion Docket Date 10/28/2013. (blacy, 4) (Entered: 10/07/2013)
10/07/2013	<u>24</u>	Notice of the Filing of an Appeal. DKT13 transcript order form attached to appellant (1 copies)to be returned. Fee status: Not Paid (IFP Pending). The following Notice of Appeal and related motions are pending in the District Court: <u>22</u> Notice of Appeal, filed.(blacy, 4) (Entered: 10/07/2013)
10/07/2013	<u>25</u>	ORDER. Thomas Whitaker, Perry Williams, and Michael Yowell may proceed on the appeal in forma pauperis <u>23</u> . (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/07/2013)
10/07/2013	<u>27</u>	AO 435 TRANSCRIPT ORDER FORM by Bobbie Stratton. This is to order a transcript of Hearing held on 10/04/2013 before Judge Lynn N. Hughes (original). Deposit amount \$\$370.00. Court Reporter/Transcriber: Gayle Dye, filed. (sroque, 4) (Entered: 10/07/2013)
10/08/2013	<u>28</u>	TRANSCRIPT re: Hearing held on October 4, 2013 before Judge Lynn N. Hughes. Court Reporter/Transcriber Dye. Release of Transcript Restriction set for 1/6/2014., filed. (gdye,) (Entered: 10/08/2013)
10/08/2013	<u>29</u>	NOTICE of Appearance by Valerie Henderson on behalf of Thomas Whitaker, Perry Williams, Michael Yowell, filed. (Henderson, Valerie) (Entered: 10/08/2013)
10/08/2013	<u>30</u>	NOTICE of Appearance by ^{94a} Jessica Hinkie on behalf of Thomas Whitaker,

		Perry Williams, Michael Yowell, filed. (Hinkie, Jessica) (Entered: 10/08/2013)
10/09/2013	<u>31</u>	Notice of Filing of Official Transcript as to <u>28</u> Transcript. Party notified, filed. (dhansen, 4) (Entered: 10/09/2013)
10/11/2013	<u>34</u>	Order of USCA re: <u>22</u> Notice of Appeal ; USCA No. 13-70031. The Order denying injunctive relief is Affirmed. Yowell's motion for stay of execution is denied, filed. (Attachments: # <u>1</u> Letter)(mmapps, 4) (Entered: 10/15/2013)
10/14/2013	<u>32</u>	NOTICE of Appearance by ALLAN K. COOK and DAVID A. HARRIS on behalf of James Jones, Brad Livingston, Executive Director of the Texas Department of Criminal Justice, William Stephens, Director TDCJ-CID, Unknown Executioners, filed. (Cook, Allan) (Entered: 10/14/2013)
10/15/2013	<u>33</u>	ORDER. The State of Texas killed Michael Yowell on 10/9/2013. Yowell is no longer a party to this lawsuit. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/15/2013)
10/17/2013	<u>35</u>	CONFERENCE MEMORANDUM: Pretrial conference held. Appearances: Bradley Chambers, Bobbie Stratton, David Harris, Allan Cook. Ct Reporter: G. Dye. Order to be entered. Internal review set for 11/18/2013. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/21/2013)
10/17/2013	<u>36</u>	Scheduling ORDER. By 11/01/2013, Whitaker and Williams may amend their complaint. By 11/15/2013, Livingston, Stephens, and Jones may respond. (Signed by Judge Lynn N. Hughes) Parties notified. (ghassan, 4) (Entered: 10/21/2013)
11/01/2013	<u>37</u>	First AMENDED Complaint against All Defendants filed by Perry Williams, Thomas Whitaker.(Stratton, Bobbie) (Entered: 11/01/2013)
11/01/2013	<u>38</u>	Order of USCA re: <u>22</u> Notice of Appeal; USCA No. 13-70031. The Petition for a Writ of Certiorari is DENIED, filed. (rnieto, 1) (Entered: 11/04/2013)
11/06/2013	<u>39</u>	MOTION to Dismiss by James Jones, Brad Livingston, Executive Director of the Texas Department of Criminal Justice, William Stephens, Director TDCJ-CID, Unknown Executioners, filed. Motion Docket Date 11/27/2013. (Attachments: # <u>1</u> Proposed Order)(Cook, Allan) (Entered: 11/06/2013)
11/08/2013		***Set/Reset Deadlines: Internal review set for 12/2/2013. (ghassan, 4) (Entered: 11/08/2013)
11/26/2013	<u>40</u>	RESPONSE to <u>39</u> MOTION to Dismiss filed by Thomas Whitaker, Perry Williams. (Henderson, Valerie) (Entered: 11/26/2013)
12/02/2013	<u>41</u>	Opposed MOTION to Intervene by Edgar Tamayo Arias, filed. Motion Docket Date 12/23/2013. (Attachments: # <u>1</u> Complaint Pleading Required by Rule 24, # <u>2</u> Exhibit Exhibit 1, # <u>3</u> Exhibit Exhibit 2, # <u>4</u> Exhibit Exhibit 3, # <u>5</u> Exhibit Exhibit 4)(Levin, Maurie) (Entered: 12/02/2013)

PACER Service Center

Transaction Receipt

12/03/2013 12:47:23			
PACER Login:	ag0032	Client Code:	ag
Description:	Docket Report	Search Criteria:	4:13-cv-02901
Billable Pages:	7	Cost:	0.70

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

Thomas Whitaker, et al.,

Plaintiffs,

versus

Brad Livingston, et al.,

Defendants.

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Civil Action H-13-2901

Opinion on Preliminary Injunction

I. *Background.*

Michael Yowell has asked the court to prevent the state of Texas from executing the death warrant from his conviction for three murders. He and two other people under death sentences want time to contest whether the drugs Texas intends to use will inflict constitutionally objectionable pain. Because Yowell will be executed on October 9, 2013, he seeks an emergency order stopping it.

People of goodwill can debate the merits of death as a penalty. The choices of the people of Texas are made law – public policy – by legislatures and governors chosen by voters. Courts may only review those choices to see whether they exceed the limits on all governments in the Constitution. The death penalty is constitutional. A constitutionally acceptable manner of killing the defendant necessarily must exist. The legal question is the cruelty of the means.

Thomas Whitaker, Perry Williams, and Michael Yowell – all inmates on death row – have complained that Texas's method of accomplishing their otherwise-constitutional death sentences is cruel under the Constitution. They ask the court to prevent officers of Texas from executing Yowell's sentence.

The defendants are three officials of the Texas prison system – Brad Livingston, William Stephens, and James Jones. They have been sued instead of the state itself for peculiar twists in American law. They will be called Texas. It concedes that the Supremacy

Clause of the United States Constitution requires Texas to punish criminals under the Eighth Amendment by avoiding "cruel and usual punishments."

To support this extraordinary remedy, they must show: (a) a substantial likelihood of success on the merits, (b) a substantial threat of irreparable injury if the injunction is not issued, (c) a threatened injury if the injunction is denied that outweighs the harm that will result if it is granted, and (d) the requested injunction is consistent with the public's interest.

The plaintiffs say that (a) the use of pentobarbital from a compounding pharmacy to execute is cruel, (b) the process does not allow them to prove that it is cruel, and (c) governmental regularity requires Texas to guarantee a painless death.

All of their arguments – even those based on their right to due process – depend on their challenge under the Eighth Amendment. Procedural issues aside, the complaint is that Texas has acquired its drug from a compounding pharmacy rather than a manufacturer. They say that this raises the risk that a prisoner's reaction to defective ingredients will cause him unconstitutional pain as he dies. The single issue is cruelty.

2. *Cruelty.*

Execution by injecting pentobarbital is no longer controversial at law. During the hearing, Yowell conceded that he has no objection to this drug. His only issue is whether Texas's current supply of pentobarbital has a demonstrated risk of severe pain because it was acquired from a compounding pharmacy rather than a manufacturer. This risk must be shown to be substantial compared to known alternatives.

Use of pentobarbital is not new. Twenty-three inmates in Texas have been executed this way. Since July 9, 2012, Texas has publicly disclosed that it executes prisoners by injecting them with five grams of pentobarbital – the exact dosage that it will use on Yowell.

He has shown no defect in the current supply of pentobarbital. Eagle Analytical Services – a testing laboratory – found that the potency of Texas's current supply is 98.8%.

Yowell speculates about the danger of drugs purchased from compounding pharmacies. He raises everything that could go wrong with an intravenous drug – under- and over-potency; allergic reactions; fungal, viral, and bacterial infections; and adulterants – all without technical data to support (a) the presence of impurities, (b) the level to be

dangerous, (c) their likelihood of causing pain, or (d) the severity of that pain while the party is conscious.

Yowell says that he has only had the specifics of the drug for a few days. That is partially true, but he has had years to get the foundational medical science about impurities. He needs to have serious support for his claim about painful impurities in addition to support for actual contamination.

He offers an affidavit from a case last year in Georgia. In that case, Georgia refused to disclose even basic information about the drug it planned to use for a lethal injection. The court held that data like the identity of the drug had to be disclosed. Without those facts, the state had effectively barred court review, and that violated the Constitution of the State of Georgia.¹ The affidavit was given by Larry D. Sasich, who holds a doctorate in pharmacy. Sasich repetitively assumes and generalizes for 17 pages without tethering it to the facts of the Georgia case much less this one.

Yowell also offers an incendiary press release from an advocacy group that did not bear on the issues here. He then urged that drugs from a compounding pharmacy in Massachusetts caused a fungal meningitis outbreak that killed 48 people. Pentobarbital will kill Yowell in five to eighteen minutes and his consciousness will be diminished almost immediately; therefore, infections like meningitis will not hurt him because they require weeks to incubate.

Texas is not using pentobarbital therapeutically; the scientific aspects of traditional medicine do not apply here. He has no reliable data that compares the risk of contaminants in compounded pentobarbital to pentobarbital from a federally-regulated manufacturer. He relies on decade-old testimony to the Senate about the correct balance of national-state regulation of the medicinal use of compounded drugs. That is a question of governmental structure. Sasich offered no specifics about particular contaminants, harmful levels, pain levels associated with each contaminant, or probability that Georgia or Texas's dose may be highly painful.

¹ Hill v. Owens, *et al.*, No. 2013-CV-233771 (Ga. Superior Ct. July 18, 2013).

3. *Process.*

Conceding that his evidence of cruelty is weak, Yowell blames Texas for having concealed that it planned to execute him with compounded pentobarbital. He says that this prevented him from having access to courts to litigate his claims effectively. In 1977, Texas adopted lethal injection. In 1982, it used it for the first time. Controversy about it has been broad and constant. Yowell has been under this death sentence for 13 years. Since June of 2012, Texas has notified the public on one of its websites that it uses pentobarbital. The only thing that has arisen recently is the source of the ingredients, and that is a potential problem with all procurement.

Parenthetically, since 1998, Yowell has litigated this case with lawyers furnished by the public. This country's courts have been open, and they have properly made sure that he had full use of them.

Texas was ordered to disclose its method of execution within hours of this suit's having been filed. It complied immediately. He has known since June 3, 2013, that he would be executed on October 9, 2013. He also knew that Texas was running out of its traditional source of pentobarbital. If he wanted to know about the drug it planned to use, he could have sued sooner. Texas has not been secretive or recalcitrant.

After the court's hearing on October 4, 2013, Yowell notified the court that the compounding pharmacy was demanding that Texas return the drugs because it was being harassed. Yowell worries that Texas may have to use a different drug to execute him. This is a guess piled on an assumption. Texas is not obliged to return the drugs because the pharmacy was willing to help it secretly but is retreating from helping publicly – a peculiar ethic. A letter from the target of an attack is not the state's responsibility. If it changes drugs and if it does not supply Yowell with the data procedural regularity requires, he may access the court then.

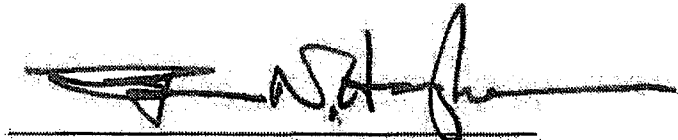
4. *Conclusion.*

Whitaker, Williams, and Yowell have not shown that (a) they are likely to succeed in proving an objectively intolerable risk of harm, (b) they will be injured without an injunction, (c) this potential injury outweighs the harm of not enforcing Texas's judgment, and (d) the requested injunction is consistent with the public's interest. Yowell will, of

course, be executed, but his harm is the probability of the methods having been cruel and not the execution itself.

The motion for a preliminary injunction will be denied. "Though the penalty is great and our responsibility heavy, our duty is clear."² Michael Yowell's execution will not be stayed.

Signed on October 5, 2013, at Houston, Texas.

A handwritten signature in black ink, appearing to read "L. N. Hughes", written over a horizontal line.

Lynn N. Hughes
United States District Judge

² Rosenberg v. United States, 346 U.S. 273, 296 (1953) (Tom Clark).

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

Thomas Whitaker, et al.,

Plaintiffs,

versus

Brad Livingston, et al.,

Defendants.

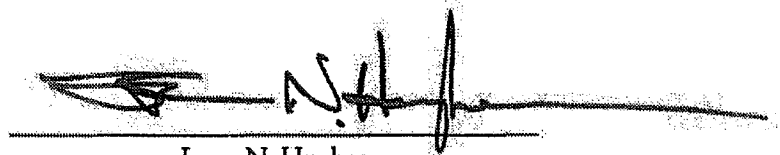
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Civil Action H-13-2901

Order Denying Injunction and Emergency Relief

1. Thomas Whitaker, Perry Williams, and Michael Yowell's motion for a preliminary injunction is denied. (2)
2. Michael Yowell's emergency motion to stay his execution is denied.

Signed on October 5, 2013, at Houston, Texas.



Lynn N. Hughes
United States District Judge

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF TEXAS

Thomas Whitaker, *et al.*,

Plaintiffs,

versus

Brad Livingston, *et al.*,

Defendants.

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Civil Action H-13-2901

Amended Opinion on Preliminary Injunction

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Clause of the United States Constitution requires Texas to punish criminals under the Eighth Amendment by avoiding "cruel and unusual punishments."

To support this extraordinary remedy, they must show: (a) a substantial likelihood of success on the merits, (b) a substantial threat of irreparable injury if the injunction is not issued, (c) a threatened injury if the injunction is denied that outweighs the harm that will result if it is granted, and (d) the requested injunction is consistent with the public's interest.

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Texas was ordered to disclose its method of execution within hours of this suit's having been filed. It complied immediately. He has known since June 3, 2013, that he would be executed on October 9, 2013. He also knew that Texas was running out of its traditional source of pentobarbital. If he wanted to know about the drug it planned to use, he could have sued sooner. Texas has not been secretive or recalcitrant.

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4. *Conclusion.*

Whitaker, Williams, and Yowell have not shown that (a) they are likely to succeed in proving an objectively intolerable risk of harm, (b) they will be injured without an injunction, (c) this potential injury outweighs the harm of not enforcing Texas's judgment, and (d) the requested injunction is consistent with the public's interest. Yowell will, of

course, be executed, but his harm is the probability of the methods having been cruel and not the execution itself.

The motion for a preliminary injunction will be denied. "Though the penalty is great and our responsibility heavy, our duty is clear."² Michael Yowell's execution will not be stayed.

Signed on October 7, 2013, at Houston, Texas.

A handwritten signature in black ink, appearing to read 'L. Hughes', is written over a horizontal line.

Lynn N. Hughes
United States District Judge

² Rosenberg v. United States, 346 U.S. 273, 296 (1953) (Tom Clark).

Certificate Of Analysis

CLIENT: [REDACTED]

LOT #: [REDACTED]

DESCRIPTION: Pentobarbital Sodium 50 mg/mL Solution

DATE RECEIVED: 11/07/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 10 mL syringes w/ 5mL each in brown bags

Analyte / Specifications	Expected Amount	Units	Results	% Of Exp.	Test Method	Date Tested
Pentobarbital Sodium Specifications = 92% - 108%	50	mg/mL	50.490	101.0%	HPLC	11/8/2013

The analyses referenced in this report are for non-cGMP purpose only. The method(s) used for testing are not validated.

[REDACTED] - Chemist

11/08/2013

Date Reported

Results reported above relate only to the sample that was tested.

Page 1 of 1

Zink, et al. v. Lombardi, et al.
No. 2:12-CV-4209 NKL
Respondents' Exhibit 4

108a

Microbiology Report

CLIENT: _____

ARL #: _____

LOT #: _____

DESCRIPTION: Pentobarbital Sodium 50 mg/mL Solution

DATE RECEIVED: 11/07/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 10 mL syringes w/ 5mL each in brown bags

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 7 Days	MBI-144	11/07/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formula: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration / Intrathecal: K is 0.2 EU/kg body weight

Radio pharmaceutical parenteral: K is $175/V$ or Intrathecal radiopharmaceuticals: K is $14/V$, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour \times 1.80 m²/70 Kg.

11/11/2013

Date Reported

Results reported above relate only to the sample that was tested.

Page 2 of 2

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CERTIFICATE OF ANALYSIS

1.5794 gm USED

PRODUCT: PENTOBARBITAL SODIUM USP CII
ITEM NUMBER: [REDACTED]
LOT NUMBER: [REDACTED]
MFG. DATE: 05/20/2011
EXPIRATION: 05/20/2016

CAS: 57-93-0
MW: [REDACTED]
FORMULA: C11H17N2NaO3

TEST	SPECIFICATIONS	RESULTS
Aerobic Plate Count Bact	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Aerobic Plate Count Fung	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Assay	98.0-102.0 %	99.2 %
Bacterial Endotoxins	<0.8 eu/mg max	0.08 eu/mg max
Completeness of solution	pass <i>after 1 minute, the solution is clear and free from undissolved solid.</i>	pass
Description	pass <i>White, crystalline granules or white powder; odorless or has slight characteristic odor; slightly bitter taste; solutions decompose on standing, heat accelerating the decomposition; eq solns are unstable.</i>	pass <i>White powder; odorless</i>
Free Pentobarbital	<=3.5 %	0.4 %
Heavy metals	<= 0.003 % max	0.003 % max
Identification	pass <i>A: UV- Passes test. B: Passes test. C: Passes test for Sodium</i>	pass
Loss on drying	<=3.5 %	0.3 %
OVI	pass <i>meets the requirements.</i>	pass
pH	9.8-11.0	10.3
Related compounds	pass	pass <i>6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: <0.05% 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: <0.05% 6-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: <0.05% UNKNOWN IMPURITIES: <0.05% TOTAL: <0.05%</i> <i>6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: NMT 0.2% 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: NMT 0.1% 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: NMT 0.3% UNKNOWN IMPURITIES: NMT 0.1% TOTAL: NMT 0.6%</i>
Residual Solvents-Ethano	<0.5 % max	0.1002 % max

QC APPROVED
PRINT DATE: 11/14/2013
PAGE: 1 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
This analysis is not to be construed as a warranty, expressed or implied.

CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
ITEM NUMBER: [REDACTED]
LOT NUMBER: [REDACTED]
MFG. DATE: 05/20/2011
EXPIRATION: 05/20/2016

CAS: 57-33-0
MW: [REDACTED]
FORMULA: C11H17N2NaO3

TEST	SPECIFICATIONS	RESULTS
Residual Solvents-Toluen	<0.089 % max	0.0090 % max
Solubility	pass <i>Very soluble in water; freely soluble in alcohol; practically insoluble in ether.</i>	pass
Solution (Water) Color	pass	pass <i>Almost Colorless</i>
Specified Organisms	pass <i>ABSENCE OF E. COLI, SALMONELLA, PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS.</i>	pass

QC APPROVED
PRINT DATE: 11/14/2013
PAGE: 2 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
This analysis is not to be construed as a warranty, expressed or implied.

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CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
ITEM NUMBER: [REDACTED]
LOT NUMBER: [REDACTED]
MFG. DATE: 05/11/2013
EXPIRATION: 05/11/2018

CAS: 57-33-0
NW: [REDACTED]
FORMULA: C11H17N2NaO3

8.9521 gm Used

TEST	SPECIFICATIONS	RESULTS
Aerobic Plate Count Bact	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Aerobic Plate Count Fung	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Assay	98.0-102.0 %	100.1 %
Bacterial Endotoxins	<0.8 eu/mg max	0.0768 eu/mg max
Completeness of solution	pass <i>after 1 minute, the solution is clear and free from undissolved solid.</i>	pass
Description	pass <i>White, crystalline granules or white powder; odorless or has slight characteristic odor; slightly bitter taste; solutions decompose on standing, heat accelerating the decomposition; eq solns are unstable.</i>	pass <i>White powder; odorless</i>
Free Pentobarbital	<=3.5 %	1.0 %
Heavy metals	<= 0.003 % max	0.003 % max
Identification	pass <i>A: UV- Passes test. B: Passes test. C: Passes test for Sodium.</i>	pass
Loss on drying	<=3.5 %	0.5 %
OVI	pass <i>meets the requirements.</i>	pass
pH	9.8-11.0	10.7
Related compounds	pass	pass <i>6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: 0.06% ; 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: <0.05% ; 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: <0.05% ; UNKNOWN IMPURITIES: <0.05% ; TOTAL: 0.08% 6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: NMT 0.2% 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: NMT 0.1% 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: NMT 0.3% UNKNOWN IMPURITIES: NMT 0.1% TOTAL: NMT 0.6%</i>
Residual Solvents-Ethano	<0.5 % max	0.2483 % max

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PRINT DATE: 11/14/2013
PAGE: 1 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
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CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
ITEM NUMBER: [REDACTED]
LOT NUMBER: [REDACTED]
MFG. DATE: 06/11/2013
EXPIRATION: 06/11/2018

CAS: 57-33-0
MW: [REDACTED]
FORMULA: C11H17N2NaO3

TEST	SPECIFICATIONS	RESULTS
Residual Solvents-Toluene	<0.089 % max	0.0090 % max
Solubility	pass <i>Very soluble in water; freely soluble in alcohol, practically insoluble in ether.</i>	pass
Solution (Water) Color	pass	pass
Specified Organisms	pass ABSENCE OF E. COLI, SALMONELLA, PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS.	pass

QC APPROVED
PRINT DATE: 11/14/2013
PAGE: 2 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
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CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
ITEM NUMBER: XXXXXXXXXX
LOT NUMBER: XXXXXXXXXX
MFG. DATE: 05/20/2011
EXPIRATION: 05/20/2016

CAS: 57-33-0
MW: XXXXXXXXXX
FORMULA: C11H17N2NaO3

5.2657 gm
USED

TEST	SPECIFICATIONS	RESULTS
Aerobic Plate Count Bact	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Aerobic Plate Count Fung	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Assay	98.0-102.0 %	99.2 %
Bacterial Endotoxins	<0.8 eu/mg max	0.08 eu/mg max
Completeness of solution	pass <i>after 1 minute, the solution is clear and free from undissolved solid.</i>	pass
Description	pass <i>White, crystalline granules or white powder, odorless or has slight characteristic odor; slightly bitter taste, solutions decompose on standing, heat accelerating the decomposition, aq solns are unstable.</i>	pass <i>White powder, odorless</i>
Free Pentobarbital	<= 3.5 %	0.4 %
Heavy metals	<= 0.003 % max	0.003 % max
Identification	pass <i>A: UV. Passes test. B: Passes test. C: Passes test for Sodium.</i>	pass
Loss on drying	<= 3.5 %	0.3 %
OVI	pass <i>meets the requirements.</i>	pass
pH	9.8-11.0	10.3
Related compounds	pass	pass 6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: <0.05% 5-ETHYL-5-(1-ETHYL-PROPYL)BARBITURIC ACID: <0.05% 5-ETHYL-5-(1,3-DIMETHYLBUTYL)BARBITURIC ACID: <0.05% UNKNOWN IMPURITIES: <0.05% TOTAL: <0.05% 6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: NMT 0.2% 5-ETHYL-5-(1-ETHYL-PROPYL)BARBITURIC ACID: NMT 0.1% 5-ETHYL-5-(1,3-DIMETHYLBUTYL)BARBITURIC ACID: NMT 0.3% UNKNOWN IMPURITIES: NMT 0.1% TOTAL: NMT 0.6%
Residual Solvents-Ethano	<0.5 % max	0.1002 % max

QC APPROVED
PRINT DATE: 12/5/2013
PAGE 1 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
This analysis is not to be construed as a warranty, expressed or implied.

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No. 2:12-CV-4209 NKL

CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
ITEM NUMBER: [REDACTED]
LOT NUMBER: [REDACTED]
MFG. DATE: 05/20/2011
EXPIRATION: 05/20/2016

CAS: 57-33-0
MW: [REDACTED]
FORMULA: C11H17N2NaO3

TEST	SPECIFICATIONS	RESULTS
Residual Solvents-Toluen	<0.089 % max	0.0090 % max
Solubility	pass <i>Very soluble in water; freely soluble in alcohol; practically insoluble in ether.</i>	pass
Solution (Water) Color	pass	pass <i>Almost Colorless</i>
Specified Organisms	pass <i>ABSENCE OF E. COLI, SALMONELLA, PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS.</i>	pass

QC APPROVED
PRINT DATE: 12/5/2013
PAGE 2 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
This analysis is not to be construed as a warranty, expressed or implied.

CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
 ITEM NUMBER: XXXXXXXXXX
 LOT NUMBER: XXXXXXXXXX
 MFG. DATE: 05/11/2013
 EXPIRATION: 05/11/2018

CAS: 57-33-0
 MW: XXXXXXXXXX
 FORMULA: C11H17N2NaO3

10.863 gm
 Used

TEST	SPECIFICATIONS	RESULTS
Aerobic Plate Count Bact	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Aerobic Plate Count Fung	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Assay	98.0-102.0 %	100.1 %
Bacterial Endotoxins	<0.8 eu/mg max	0.0768 eu/mg max
Completeness of solution	pass <i>after 1 minute, the solution is clear and free from undissolved solid.</i>	pass
Description	pass <i>White, crystalline granules or white powder odorless or has slight characteristic odor; slightly bitter taste. solutions decompose on standing, heat accelerating the decomposition, aq solns are unstable.</i>	pass <i>White powder odorless</i>
Free Pentobarbital	<=3.5 %	1.0 %
Heavy metals	<= 0.003 % max	0.003 % max
Identification	pass <i>A: UV- Passes test. B: Passes test. C: Passes test for Sodium.</i>	pass
Loss on drying	<=3.5 %	0.5 %
OVI	pass <i>meets the requirements.</i>	pass
pH	9.8-11.0	10.7
Related compounds	pass	pass <i>6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: 0.08% 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: <0.05% 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: <0.05% UNKNOWN IMPURITIES: <0.05% TOTAL 0.08% 6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: NMT 0.2% 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: NMT 0.1% 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: NMT 0.3% UNKNOWN IMPURITIES: NMT 0.1% TOTAL: NMT 0.5%</i>
Residual Solvents-Ethano	<0.5 % max	0.2483 % max

QC APPROVED
 PRINT DATE: 12/5/2013
 PAGE 1 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
 This analysis is not to be construed as a warranty, expressed or implied.

CERTIFICATE OF ANALYSIS**PRODUCT:** PENTOBARBITAL SODIUM USP CII**ITEM NUMBER:** [REDACTED]**CAS:** 57-33-0**LOT NUMBER:** [REDACTED]**MW:** [REDACTED]**MFG. DATE:** 05/11/2013**FORMULA:** C₁₁H₁₇N₂NaO₃**EXPIRATION:** 05/11/2018

TEST	SPECIFICATIONS	RESULTS
Residual Solvents-Toluen	<0.089 % max	0.0090 % max
Solubility	pass <i>Very soluble in water; freely soluble in alcohol; practically insoluble in ether</i>	pass
Solution (Water) Color	pass	pass
Specified Organisms	pass ABSENCE OF E. COLI, SALMONELLA, PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS	pass

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PRINT DATE: 12/5/2013
PAGE: 2 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
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CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
ITEM NUMBER: XXXXXXXXXX
LOT NUMBER: XXXXXXXXXX
MFG. DATE: 05/11/2013
EXPIRATION: 05/11/2018

CAS: 57-33-0
MW: XXXXXXXXXX
FORMULA: C11H17N2NaO3

0.432 gm
Used

TEST	SPECIFICATIONS	RESULTS
Aerobic Plate Count Bact	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Aerobic Plate Count Fung	<300 cfu/g max <i>Alert at 100 CFU/g</i>	50 cfu/g max
Assay	98.0-102.0 %	100.1 %
Bacterial Endotoxins	<0.8 eu/mg max	0.0768 eu/mg max
Completeness of solution	pass <i>after 1 minute, the solution is clear and free from undissolved solid</i>	pass
Description	pass <i>White, crystalline granules or white powder; odorless or has slight characteristic odor, slightly bitter taste, solutions decompose on standing, heat accelerating the decomposition, aq solns are unstable.</i>	pass <i>White powder; odorless</i>
Free Pentobarbital	<=3.5 %	1.0 %
Heavy metals	<= 0.003 % max	0.003 % max
Identification	pass <i>A. UV. Passes test. B. Passes test. C. Passes test for Sodium.</i>	pass
Loss on drying	<=3.5 %	0.5 %
OVI	pass <i>meets the requirements.</i>	pass
pH	9.8-11.0	10.5
Related compounds	pass	pass 6-IMINO-ETHYL-5-(1-METHYL-BUTYL)BARBITURIC ACID: 0.08% ; 5-ETHYL-5-(1-ETHYL-PROPYL) BARBITURIC ACID: < 0.05% ; 5-ETHYL-5-(1,3-DIMETHYLBUTYL) BARBITURIC ACID: < 0.05% ; UNKNOWN IMPURITIES: < 0.05% ; TOTAL: 0.08
Residual Solvents-Ethano	<0.5 % max	0.2483 % max

QC APPROVED
PRINT DATE 12/5/2013
PAGE: 1 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
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CERTIFICATE OF ANALYSIS

PRODUCT: PENTOBARBITAL SODIUM USP CII
 ITEM NUMBER: [REDACTED]
 LOT NUMBER: [REDACTED]
 MFG. DATE: 05/11/2013
 EXPIRATION: 05/11/2018

CAS: 57-33-0
 MW: [REDACTED]
 FORMULA: C11H17N2NaO3

TEST	SPECIFICATIONS	RESULTS
Residual Solvents-Toluen	<0.089 % max	0.0090 % max
Solubility	pass <i>Very soluble in water, freely soluble in alcohol, practically insoluble in ether</i>	pass
Solution (Water) Color	pass	pass
Specified Organisms	pass <i>ABSENCE OF E. COLI, SALMONELLA, PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS.</i>	pass

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 PAGE: 2 of 2

The above test results have been obtained by our supplier or in our quality control laboratory.
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Microbiology Report

CLIENT:

ARL #:

LOT #:

DESCRIPTION: S-Pentobarbital Sodium 50mg/mL Inj Sol

DATE RECEIVED: 11/27/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 20 mL syringes with 15 mL each in a brown bag

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	MBI-144	11/29/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

12/02/2013

Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)

Radiopharmaceutical parenteral: K is $175/V$ or Intrathecal radiopharmaceuticals: K is $14/V$, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour × 1.80 m²)/70 Kg.

Results reported above relate only to the sample that was tested.

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Page 1 of 1

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

DAVID ZINK, et al.,)	
)	
Plaintiffs,)	
)	
v.)	No. 2:12-CV-4209-NKL
)	
GEORGE A. LOMBARDI, et al.,)	
)	
Defendants.)	

PROTECTIVE ORDER

In this action, Plaintiffs are prisoners of the Missouri Department of Corrections (Department) challenging the constitutionality of the specific means its Director has specified for use in executing them. Plaintiffs seek the identities of the execution team members.

The disclosure of this information would be contrary to safety, security, and anonymity interests of the Department and its execution personnel, contrary to Missouri state law, and covered by the federal common law privilege protecting state secrets. The disclosure of the identity of the pharmacy, where any pharmacist has compounded pentobarbital for use in Missouri executions, of any pharmacist who has or may compound pentobarbital for use in Missouri Executions, and or the laboratory the Department uses to test the purity, potency, and sterility of the execution chemical would be a direct violation of §546.720.2, Cum. Supp. 2012, because

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No. 2:12-CV-4209 NKL

it would be disclosing a record knowing it could, and likely would, identify a person as being a member of the execution team. Additionally, disclosure of the aforementioned information would be contrary to the State's interest in ensuring the purity, potency, and sterility of the execution chemical, and a violation of the federal common law privilege protecting state secrets.

The Federal Rules of Civil Procedure empower the court to enter, for "good cause shown" and when "justice [so] requires," protective orders designed to prevent "a party or person from annoyance, embarrassment, oppression, or undue burden or expense." Fed.R.Civ.P. 26(c).

In order to permit Plaintiffs to discover information relevant to this case without further delay, and pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, it is hereby ORDERED:

1. This Order shall govern any interrogatory responses, documents, or other materials produced during discovery as well as all testimony at any deposition, pretrial hearing, trial, or other proceeding in this action, whether in response to any discovery request or subpoena made pursuant to the Federal Rules of Civil Procedure or otherwise, and any copies, abstracts, excerpts, analyses, summaries, or other materials (whether in written, electronic, or other form) which contain, reflect or disclose information from such documents, testimony, or other materials. The testimony, documents,

and materials referred to in this paragraph collectively shall constitute "Discovery Materials."

2. Notwithstanding any provisions of this Order to the contrary, the names, addresses, dates and places of birth, professional licensing numbers, Social Security Numbers, and any other information that could be used to locate or identify any officers, employees, agents, and/or contractors involved as execution team members, as defined by the Missouri execution protocol, shall not be revealed to anyone, including counsel for the Plaintiffs. Similarly, the identity of the pharmacy, where any pharmacist has compounded pentobarbital for use in Missouri executions, of any pharmacist who has compounded pentobarbital for use in Missouri Executions, and or the laboratory the Department uses to test the purity, potency, and sterility of the execution chemical, shall not be revealed to anyone including counsel for the Plaintiffs. Counsel for Defendants shall provide counsel for Plaintiffs with a "John Doe" designation for each individual member of the execution team. Should the Department add any individual or individuals to its execution team during the course of this litigation, counsel for Defendants shall promptly disclose the existence of each such added individual and assign to each new execution team member a John Doe designation. Additionally, counsel for Defendants will provide a generic identification of each person's credentials or title as relates to his or her execution duties, for example

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“Nurse” or “Emergency Medical Technician,” as well as his or her role(s) within the execution team, for instance “Team Leader” or “Syringe Pusher.”

3. Outside of discovery authorized by the Federal Rules of Civil Procedure, counsel for Plaintiffs may not conduct investigations of those persons counsel for Plaintiffs believe to be involved in past executions, nor of those expected to be involved in future executions. For example, neither counsel, nor anyone acting on their behalf, may contact schools, former employers or credentialing agencies in an effort to determine the identity of, or gain background information on, the aforementioned persons because to do so would pose an unacceptable risk that their participation and identities would be made public. During the course of this litigation, only John Doe or a John Roe designation or other generic identifier (such as “the Emergency Medical Technician” or “the Team Leader,” as suits the convenience and needs of the parties), shall be used to denote any member of the execution team. Nothing in this Order shall be construed to prevent Plaintiff’s counsel from inquiring during a deposition or other discovery process into the education, professional background, board certification, licensing or credentialing of members of the execution team, except that members’ names, identifying numbers on licenses and other credentials, and any other uniquely personal identifiers solely as set out in paragraph 2, shall be governed by the terms of paragraph 2. Nothing in this paragraph shall be

construed to expand or otherwise alter the protections set forth in paragraph 2 of this Order.

4. This Order is without prejudice to the rights of any party to seek from the Court the modification of this Order.

December 9, 2013
Date

/s/ NANETTE LAUGHREY
Nanette Laughrey,
District Judge

Missouri Revised Statutes

Chapter 546 Trials, Judgments and Executions in Criminal Cases Section 546.720

August 28, 2013

Death penalty--manner of execution--execution team to be selected, members, confidentiality.

546.720. 1. The manner of inflicting the punishment of death shall be by the administration of lethal gas or by means of the administration of lethal injection. And for such purpose the director of the department of corrections is hereby authorized and directed to provide a suitable and efficient room or place, enclosed from public view, within the walls of a correctional facility of the department of corrections, and the necessary appliances for carrying into execution the death penalty by means of the administration of lethal gas or by means of the administration of lethal injection.

2. The director of the department of corrections shall select an execution team which shall consist of those persons who administer lethal gas or lethal chemicals and those persons, such as medical personnel, who provide direct support for the administration of lethal gas or lethal chemicals. The identities of members of the execution team, as defined in the execution protocol of the department of corrections, shall be kept confidential. Notwithstanding any provision of law to the contrary, any portion of a record that could identify a person as being a current or former member of an execution team shall be privileged and shall not be subject to discovery, subpoena, or other means of legal compulsion for disclosure to any person or entity, the remainder of such record shall not be privileged or closed unless protected from disclosure by law. The section of an execution protocol that directly relates to the administration of lethal gas or lethal chemicals is an open record, the remainder of any execution protocol of the department of corrections is a closed record.

3. A person may not, without the approval of the director of the department of corrections, knowingly disclose the identity of a current or former member of an execution team or disclose a record knowing that it could identify a person as being a current or former member of an execution team. Any person whose identity is disclosed in violation of this section shall:

(1) Have a civil cause of action against a person who violates this section;

(2) Be entitled to recover from any such person:

(a) Actual damages; and

(b) Punitive damages on a showing of a willful violation of this section.

4. Notwithstanding any provision of law to the contrary, if a member of the execution team is licensed by a board or department, the licensing board or department shall not censure, reprimand, suspend, revoke, or take any other disciplinary action against the person's license because of his or her participation in a lawful execution. All members of the execution team are entitled to coverage under the state legal expense fund established by section 105.711 for conduct of such execution team member arising out of and performed in connection with his or her official duties on behalf of the state or any agency of the state, provided that moneys in this fund shall not be available for payment of claims under chapter 287.

(RSMo 1939 § 4112, A.L. 1988 H.B. 1340 & 1348, A.L. 1990 H.B. 974, A.L. 2007 H.B. 820)

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No. 2:12-CV-4209 NKL

Respondents' Exhibit 7

Case 2:12-cv-04209-NKL Document 189-1 Filed 12/06/13 Page 61 of 62

<http://www.moga.mo.gov/statutes/c500-599/5460000720.htm>

12/6/2013

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Missouri General Assembly

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Weather: Overcast, 22°F

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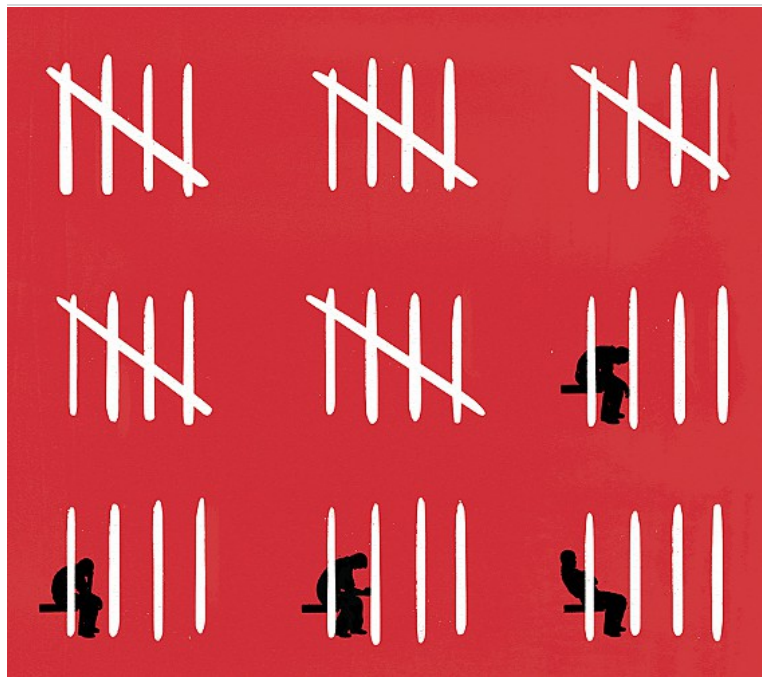
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Share

As questions linger about Missouri's shadowy lethal-injection protocol, the state is days away from killing another inmate

by Steve Vockrodt

click to enlarge



Chris Gash

At 10:52 p.m. December 11, the Missouri Department of Corrections executed Allen Nicklasson with a single, lethal drug dripped into the convicted murderer's veins.

Just before the dose was administered, Missouri Attorney General Chris Koster issued a statement to the media saying that "the highest court in the nation has removed the last restriction to carrying out the lawfully imposed punishment of Allen Nicklasson."

Except, for the second time last year, that wasn't quite the case.

click to flip through (4)



TRACI TAMURA

Joseph Paul Franklin



"Missouri put Nicklasson to death before the federal courts had a final say on whether doing so violated the federal constitution," said Judge Kermit Bye, of the 8th U.S. Circuit Court of Appeals, in a December 20 opinion.

Bye, a federal appellate-court judge since 1999, said the 11 judges on the 8th Circuit had not yet voted on Nicklasson's request for a stay of his execution.

Missouri put Nicklasson to death before his due process had been fully resolved.

A death-row inmate's gauntlet of appeals often takes years, and Nicklasson's run through the courts was no exception. He was sentenced to death in 1996. Death-penalty proponents say the appeals process is expensive and drags out the suffering of victims' families. But that process is designed to safeguard against the possibility of an innocent person suffering an irreversible fate — and to ensure that the death penalty is administered properly.

There was no question of innocence in Nicklasson's case. He had admitted to shooting Excelsior Springs businessman Richard Drummond in the middle of a 1994 crime spree, after Drummond offered to help Nicklasson and Dennis Skillicorn with their broken-down car. Rather, Nicklasson's attorneys were trying to figure out where Missouri would obtain the drug it intended to use on him. Is that drug, they wanted to know, suitable to kill a prisoner with a right to avoid a painful death? Nicklasson died before he got those answers.

So did serial killer Joseph Franklin. When Franklin was executed November 20, he, too, was still awaiting a final ruling from a judge on whether his attorneys could learn more about Missouri's death-penalty protocol.

"I think that because they didn't let the courts do what they were supposed to do, it undermines the authority of the court," says Rita Linhardt, board chairwoman for Missourians for Alternatives to the Death Penalty. "It's setting Missouri above the law that the court isn't allowed to do what it's allowed to do."

Bye's opinion has attracted newfound skepticism of Missouri's whack-a-mole execution methods.

State Rep. Jay Barnes, a Republican from Jefferson City, called for a hearing before the Missouri House committee on Government Oversight and Accountability over whether the state is affording condemned prisoners their due process before their executions. "Regardless of what anyone thinks of the death penalty, everyone should agree that it must be carried out according to the requirements of the Constitution and the laws of our state," he said in a January 13 statement.

That hearing was canceled when George Lombardi, director of the Missouri Department of Corrections, declined to testify.

Rep. John Rizzo, a House Democrat from Kansas City, has called for a one-year moratorium on Missouri's death penalty while the Legislature studies the Department of Corrections' actions.

But that scrutiny hasn't slowed the Department of Corrections. Herbert Smulls is the next death-row prisoner set to die. His execution is scheduled for January 29.

"The trend nationwide is away from executions, and Missouri is jumping into this full force," Linhardt says.

Missouri officials are staying quiet publicly. The Department of Corrections, Koster's office and Gov. Jay Nixon's office have all either declined or ignored *The Pitch's* requests for comment on Bye's decision and other questions about Missouri's death-penalty practices.

Ahead of Smulls' execution, though, a lawsuit is under way in the U.S. District Court in Kansas City, as well as in the 8th Circuit in St. Louis.

Attorneys for several condemned prisoners are asking those courts to cast light on Missouri's shadowy death-penalty methods.

So far, lawyers suing the state believe that Missouri has purchased its lethal-injection drug from a compounding pharmacy in Oklahoma that is not licensed to do business in Missouri.

The state of Missouri, responding to an open-records request, disclosed a heavily redacted copy of a license from the pharmacy from which it obtained pentobarbital. Two things not redacted were the date upon which the license was issued (November 16, 2012) and the fee paid for the license (\$255).

The Pitch obtained from the Oklahoma Board of Pharmacy a list of licenses processed on that date.

Three Oklahoma pharmacies on that day received the type of license and the specific combination of permits shown on the redacted license released by Missouri, and made the \$255 payments. One was Pharmcare in Hydro; another was Economy Pharmacy in Muskogee; the third was the Apothecary Shoppe in Tulsa.

The Pitch called pharmacy technicians at all three businesses and asked if they performed sterile injectable compounding, a method through which compounding pharmacies make drugs suitable for injections. Technicians at Pharmcare and at Economy Pharmacy said they did not; a pharmacy clerk at Apothecary Shoppe said the company did.

The Pitch reached Apothecary Shoppe CEO Deril Lees on January 20. When asked if the pharmacy ever had ever supplied Missouri with pentobarbital or had a contract with Missouri, Lees said no.

"There are serious questions about the integrity of the pharmacy," says Tony Rothert, legal director of the American Civil Liberties Union of Missouri. "If you wanted to buy a drug from an [unlicensed] out-of-state pharmacy for a controlled substance, you'd be put in jail."

Compounding pharmacies, unlike conventional drug makers, exist outside the reach of the stringent federal regulatory framework. They operate in the murky "gray market" of the pharmaceutical industry — theirs is not an illegal black market but one in which a product's origins are untraceable and beyond the watch of the U.S. Food and Drug Administration. It's often difficult to determine in advance the potency of a compounding pharmacy's product or whether it's contaminated or impure.

In 2011, the Missouri Board of Pharmacy tested 158 compounded drugs from various pharmacies. It found that 17 percent failed its potency test.

Why does anyone care where the Department of Corrections gets its drugs? The primary concern is whether condemned inmates suffer painful and unconstitutional deaths by lethal injection — something that has almost surely happened in Missouri.

Missouri's first lethal-injection machine was designed by a Nazi sympathizer.

Fred Leuchter was the only bidder in 1990, after Missouri resumed the death penalty in 1989 and needed a device to administer fatal drugs. He had no formal training in medicine or engineering, but that didn't stop him from advertising his invention as an effective means of capital punishment at a time when previous methods were falling out of favor.

The Constitution protects Americans from cruel and unusual punishment, and by the 1970s and 1980s, electrocuting or gassing inmates to death was widely considered problematic. In 1928, photojournalist Tom Howard sneaked a camera into New York's Sing Sing Prison and snapped a photo of Ruth Snyder at the moment she received a fatal jolt of electricity. Howard's grotesque document of Snyder — hooded and strapped to the electric chair

— ran on the front page of the next day's *New York Daily News* and gave the world a glimpse of state-sanctioned death.

After that came consistent reports of inmates screaming as currents ran through their bodies and of the odor of burning flesh. Florida dispensed with its electric chair after the 1999 execution of Allen Lee Davis, who witnesses said convulsed and bled while being electrocuted. The Florida Supreme Court later released troubling photos of Davis that showed what was under his hood when prison officials lifted it: a bloodied face mashed against the leather strap meant to keep his head still.

The gas chamber didn't make a suitable replacement; inhaling cyanide gas proved to be a painful way for some inmates to die.

Lethal injection, first used by Texas in 1982, was proposed as humane and painless. An inmate would receive a drug and drift off into a medically induced slumber, as though waiting to have a molar pulled. Some death-penalty critics opposed lethal injection because they didn't want Americans to have the illusion that state-sanctioned death was a clean procedure.

The lethal-injection machine that Missouri bought from Leuchter was designed to pump three drugs into an inmate: one to knock him out, another to paralyze him, and the last to end his life.

Everybody but the Missouri Department of Corrections had written off Leuchter, whose credibility was shredded when he offered his testimony in support of anti-Semite Ernst Zündel in 1988. Zündel was on trial that year in Canada, where it is illegal to antagonize ethnic and racial groups with bogus information. He had published Richard Verrall's pamphlet "Did Six Million Really Die?" that questioned whether Jews were exterminated by Nazi Germany before and during World War II.

Leuchter was one of the chief experts testifying on Zündel's behalf, presenting so-called evidence denying the Holocaust. The minimal scientific veneer of his testimony was undercut when his phony engineering credentials were exposed, and Leuchter was charged in Massachusetts in 1990 for running an unlicensed engineering practice. A *New York Times* article about Leuchter's legal troubles reported that an anesthesiologist in Illinois had testified that Leuchter's lethal-injection protocol would "paralyze inmates and cause them intense pain before they died."

Missouri ultimately canceled its contract with Leuchter but pushed on with a similar three-drug protocol, despite experts' misgivings about whether a method that presented itself as antiseptic and painless was actually an excruciating way to die.

The first drug to enter an inmate's veins was sodium thiopental, a fast-acting anesthetic commonly used in outpatient surgeries to induce unconsciousness. It's not as strong as general anesthesia, though, and is prone to wearing off. The next drug was Pavulon, which paralyzes muscles. Finally, potassium chloride was used to stop the inmate's heart.

But questions persisted about inmates receiving enough of the sodium thiopental. Without an adequate dose, death would be painful, and expression of that pain would be impossible because of the paralyzing Pavulon.

Carol Weihrer, a Virginia resident, became the spokeswoman for what is now called anesthetic awareness when the sodium thiopental she was given for an eye surgery in 1998 wore off before her doctors completed the procedure. She sent written testimony to the Pennsylvania House of Representatives in 2005 that described her experience.

"I remember the intense pulling on my eye, the spine-chilling instructions of the surgeon to the resident to 'cut deeper here, pull harder, no pull harder, you really have to pull.' I remember fighting with every ounce of energy and thought process I had to let the surgical team know I was awake," she recalled.

Sean O'Brien, a University of Missouri–Kansas City School of Law professor and frequent legal counsel to death–penalty inmates, says he first became interested in the potentially painful effects of lethal injection when Missouri executed Emmitt Foster in 1995.

In those days, Department of Corrections personnel involved in the execution would shout "foxfire one" when the first drug began its flow to the inmate, "foxfire two" when the next drug was pushed, and "foxfire three" when the fatal drug began its course. "Checkmate" was the word when the inmate was pronounced dead.

O'Brien says when the first drug reached Foster, the inmate started coughing and twitching. Something seemed amiss. Prison officials closed the curtain to the window that allowed witnesses to observe the execution.

A prison official realized that a strap was restricting the flow of drugs to the rest of Foster's body. The band was removed, and Foster took 30 minutes to die.

The April 16, 2005, edition of the weekly medical journal *The Lancet* analyzed autopsy and toxicology reports of 49 executed inmates. It found that 43 of them had received doses of sodium thiopental lower than the standard for surgery, and that 21 had received such a low dose that they could have been aware of what was happening to them.

"That is: those being executed may have been awake," the report's abstract reads. "Of course, because they were paralyzed, no one could tell. It would be a cruel way to die: awake, paralyzed, unable to move, to breathe, while potassium burned through your veins."

The same report pointed out that the American Veterinary Medical Association and 19 states ban the use of drugs such as sodium thiopental in the killing of animals. In other words, the drugs that can be used in a state–sanctioned execution of a human are in some places deemed unsuitable to put down a dog with an untreatable case of heartworm.

The *Lancet* article came out a month ahead of Vernon Brown's scheduled execution in Missouri. His lawyers used the journal's findings as the basis to ask the state how much sodium thiopental it planned to use in Brown's execution. But Missouri fought Brown's attorneys in court, ultimately killing Brown without having to tell him how much of a drug they were going to give him.

The concern was well–founded. The following year, it was discovered that a doctor who had assisted in 54 Missouri executions was dyslexic and, according to his testimony, had improvised the dosages.

Missouri corrections officials couldn't keep the doctor from testifying in front of a federal judge, but they succeeded in obscuring his name from the public record.

A federal judge in Kansas City was furious about the doctor's testimony and lamented that Missouri lacked a written protocol for its lethal injections. He ruled that the state needed to come up with a better lethal–injection method and to stop using the doctor in question.

Despite the state's secrecy, reporters with the *St. Louis Post–Dispatch* figured out that the dyslexic doctor was Alan Doerhoff, a physician who had been reprimanded by the Missouri Board of Registration for the Healing Arts for trying to hide the fact that he had been sued for malpractice.

Missouri's embarrassment over the Doerhoff affair slowed the state's death–penalty pipeline. The state didn't execute another prisoner until Dennis Skillicorn, in 2009.

Missouri's capital–punishment methods returned to the international limelight in 2013, when the state prepared to execute Joseph Franklin. He was an admitted mass murderer, but his case attracted attention from someone he didn't kill.

Larry Flynt, the pornography magnate who doubles as a free-speech proponent and anti-death-penalty activist, has been in a wheelchair since 1978. That was when Franklin, a white supremacist who took exception to Flynt's *Hustler* magazine showing photo spreads of interracial sex, shot Flynt and a lawyer in Georgia. Flynt and the American Civil Liberties Union sued to find out which medical personnel were participating in executing Missouri's condemned.

Doctors are supposed to save lives and are thus prohibited by virtually all professional codes of conduct from helping with an execution.

Flynt's lawsuit didn't stop Franklin's execution. But it was the European Union that temporarily stalled Missouri's death penalty.

Missouri had dispensed with the old three-drug method and was planning to kill Franklin with a drug called propofol.

Propofol, used as a relaxant and an anesthetic, is coveted by hospitals and doctors in the United States. It's manufactured mostly in Germany, where capital punishment is illegal. When the Germans caught wind of Missouri's plans to use propofol, the European Union threatened to stop exporting the drug to the United States.

Several medical associations expressed annoyance at the prospect of a propofol shortage if the state pressed on with the drug for Franklin's execution. That got Missouri Gov. Jay Nixon's attention. He delayed the execution until the state could figure out another way to kill Nicklasson.

Some states' use of federally approved drugs against the wishes of their manufacturers has resulted in something of a shortage of drugs that have other legitimate medical functions.

Joel Zivot, a medical director and an anesthesiologist at Emory University School of Medicine in Atlanta, wrote in a December 16 editorial published in Ohio's *Lancaster Eagle-Gazette* that drug maker Hospira stopped producing sodium thiopental in protest of states using the drug in executions. This left him without access to the medicine: "States may choose to execute their citizens, but when they employ lethal injection, they are not practicing medicine. They are usurping the tools and arts of the medical trade and propagating a fiction."

With propofol out of the picture, the Missouri Department of Corrections changed its execution protocol several times in the weeks leading up to Franklin's execution, a move that frustrated attorneys representing Franklin and other inmates.

On October 18, the state proposed using pentobarbital. On November 15, it changed the execution recipe again, five days before Franklin was scheduled to die. That left little time for lawyers to investigate what the drug was and where Missouri was getting it. Franklin's attorneys made a motion before the U.S. District Court in Kansas City to stay his execution, but he died November 20, before a judge could get to that motion.

The shell game that preceded Franklin's execution, coupled with Missouri's secrecy over how it plans to carry out future executions, is the subject of intense litigation in the U.S. District Court in Kansas City — just days before Herbert Smulls is scheduled to die.

Modern capital-punishment laws have typically kept the identity of the executioner secret. The stigma attached to ending someone else's life, even in a state-sanctioned execution, has enabled governments to justify obscuring an executioner's name from public view.

Until 2010, Utah used a firing squad for some of its executions. The custom called for five rifle shooters to aim at the prisoner. One of the five guns was loaded with the rough equivalent of a blank cartridge to ease each shooter's conscience; each man could doubt whether he had fired one of the lethal shots.

Missouri laws also keep secret the names of members of the state's execution team, which includes not only the person who administers the fatal dose but also those who assist that person. Missouri officials have tried to expand that cloak to include the pharmacy that makes the execution drug and the pharmacist who writes a prescription for the fatal dose. Attempts by attorneys for death-row prisoners to learn the whereabouts of the state's drug supplier were met throughout 2013 by resistance from the Missouri Attorney General's Office and the Department of Corrections, which insisted that Missouri law allowed corrections officials to keep the drug supplier secret as part of the execution team.

Toward the end of 2013, state officials deployed the "state secret" privilege to convince federal judges to affirm the shield around the death team. It's a legal concept normally used in matters of national security, intelligence gathering, and budgets for federal organizations such as the National Security Agency and the Central Intelligence Agency.

That led to a December 12 teleconference among U.S. District Judge Nanette Laughery and attorneys for both prisoners and Missouri officials. Joseph Luby, a lawyer with Kansas City's Death Penalty Litigation Clinic, reminded Laughery of his legal team's Catch-22.

"The only scientific expert that is present in this case says that we actually do have a need to know who it is that is supplying these drugs, who has compounded them, so that we have an idea of what it is that the state is administering and seeking to administer in the future," Luby said, according to a transcript of the conversation. "Otherwise, we don't know where the active pharmaceutical ingredient comes from, how it was manufactured, the circumstances under which it was compounded, what impurities might exist and what hazards are involved in administering it."

The scientific expert whom Luby referenced was Larry Sasich, chairman of the pharmacy practice at the Lake Erie College of Osteopathic Medicine in Pennsylvania and adviser to the Food and Drug Administration commissioner. Sasich offered a lengthy affidavit outlining the potential hazards of compounded drugs: "The potential harm associated with the use of such contaminated or sub-potent drugs is extremely high. Consumers who use compounded drugs do so at their own risk."

Andrew Bailey, a lawyer representing the Missouri Department of Corrections, reiterated the need for secrecy to protect the safety of those involved with an execution. He cited the slaying of a former Missouri Department of Corrections official a year ago.

He didn't name the victim, but he was likely talking about Tom Clements, the longtime Department of Corrections director who took the same position in Colorado in 2011. He was killed at his home in March 2013 by a man who investigators believe was a white supremacist and may have been carrying out an assassination.

But Clements' identity and responsibilities were widely known. The issue of secrecy wasn't a factor in his death.

Bailey pressed on, saying that disclosing the identity of the drug supplier would have no effect on whether the state could carry out an appropriate execution.

"The director [Lombardi] has stated that he will not use chemicals that aren't pure, potent and sterile and the director's administered two successful executions at this point," Bailey said.

Laughery didn't find the state's position persuasive. She rejected both the state-secrets argument and the notion that Missouri law required that the pharmacy remain secret.

"The balance clearly weighs in favor of revealing the information to the plaintiffs [prisoners] because it's impossible for the plaintiffs to meet the burden of proof established by the courts in the absence of those elements," Laughery said. She ordered the Missouri Department of Corrections to hand

over information about its drug supplier, the pharmacist writing the prescription, and the lab reports about the drug to Luby and to Cheryl Pilate, a Kansas City lawyer who is part of the death-row-inmate legal team.

The information was supposed to go to Luby and Pilate and no one else.

Missouri officials tried to get Laughery to change her mind on December 16, but she didn't and instead reiterated that Missouri must release its drug-supplier records.

Pilate on December 16 sent several e-mails to Department of Corrections lawyers, asking for the information she was expecting. She sat before her computer until midnight, waiting for information that never came.

Attorneys for Missouri kept resisting disclosure while trying to get the 8th Circuit to reverse Laughery's decision.

In an odd twist, Missouri officials did send their information to Laughery's office. And in an odder twist, Laughery sent the information to Pilate and Luby on December 28, not knowing that, the day before, the 8th Circuit had said to hold off.

Once Laughery realized that a higher court had intervened, she told Pilate and Luby to sit tight with any knowledge they had gleaned from her disclosure. On December 30, she held another teleconference with all of the lawyers involved. She told Pilate and Luby not to act on anything they had learned from the Department of Corrections' file and to scrub any record of it from their files and computers.

That left attorneys representing condemned prisoners with knowledge of a key piece of information — the identity of a pharmacy they fought in court for more than a year to discover — but unable to investigate it further.

Laughery recused herself from the case on December 30.

"We have a pharmacy in Oklahoma that is manufacturing chemicals and importing them into Missouri in violation of Missouri and federal law and possibly in violation of the intellectual rights of pentobarbital's manufacturer," says UMKC's O'Brien.

Meanwhile, the tortured legal proceedings over whether prisoners are allowed to know where Missouri's death-penalty drugs comes from is in limbo while a new judge, former Kansas City U.S. Attorney Beth Phillips, gets up to speed. A trial is scheduled for June 16.

That leaves unresolved the fate of Herbert Smulls. Will his attorneys persuade the state or federal judges to delay his January 29 execution while the peculiarities surrounding Missouri's death penalty get sorted out? Will Missouri give federal judges enough time to figure it out?

At least one appellate judge may stand in Missouri's way.

Judge Kermit Bye wrote in a biting December 20 opinion: "Missouri's ... current practice of using shadow pharmacies hidden behind the hangman's hood, copycat pharmaceuticals, numerous last-minute changes to its execution protocol and finally, its act of proceeding with an execution before the federal courts had completed their review of an active request for a stay has committed this judge to subjecting the state's future implementation of the penalty of death to intense judicial scrutiny, for the sake of death-row inmates involved as well as adversaries and advocates for capital punishment alike."

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Criminal Justice

State has explored illegally obtaining drug for upcoming execution

By Della Hasselle, Contributor 6 HOURS AGO

2 Comments



This specialty prescription lab in Tulsa, Oklahoma, has been in touch with the Louisiana prison system about producing a special-order batch of the lethal-injection drug pentobarbital.

Louisiana prison officials have looked into illegally obtaining a lethal-injection drug from an Oklahoma pharmacy for the Feb. 5 execution of convicted child killer Christopher Sepulvado, according to just-released state documents.

The Tulsa-based compounding lab (<http://thelensnola.org/2014/01/15/with-lethal-injection-drugs-hard-to-get-states-turning-to-custom-pharmacies/>), called The Apothecary Shoppe, is not listed in the state pharmacy board's online database of suppliers licensed to provide drugs to any pharmacy in Louisiana. That would make the sale of pentobarbital (<http://thelensnola.org/2013/02/05/state-says-it-will-use-a-new-single-drug-for-upcoming-execution/>) from that business to the Louisiana State Penitentiary Pharmacy an illegal transaction under state law.

A September email (<https://www.documentcloud.org/documents/1009376-mx-m550n-20140124-212405.html>) shows that The Apothecary Shoppe asked the state to complete a non-disclosure agreement. The document spells out the confidentiality agreement between the pharmacy and the signatory.

Although the Department of Corrections said Friday that the state didn't have any pentobarbital, it was in the "process of procuring" it, department attorney James Hilburn wrote in a court document.

No other recent purchase records were made available, nor any other records that show written communication with any other pharmacy regarding pentobarbital, according to state documents given to Sepulvado's lawyers and records obtained by The Lens.

The Apothecary Shoppe is one of three pharmacies suspected of supplying pentobarbital for the recent Oklahoma execution of Michael Lee Williams, (<http://nation.time.com/2014/01/10/oklahoma-convict-who-felt-body-burning-executed-with-controversial-drug/>) who reportedly said "I feel my whole body burning" as he was killed in early January, said Sophie Cull, the director of the Louisiana Coalition for Alternatives to the Death Penalty.

That same pharmacy is suspected of being the source of Missouri's pentobarbital, according to Cull, and it is not licensed to sell drugs in that state, either.

An investigation by St. Louis Public Radio and the St. Louis Beacon (<http://news.stlpublicradio.org/post/investigation-missouris-execution-drug-source-raises-legal-ethical-questions>) found that Missouri's pentobarbital was supplied by one of three compounding pharmacies in Oklahoma not licensed to sell drugs in the state. A follow-up by The Pitch found that of the three possible pharmacies, only The Apothecary Shoppe performed sterile injectable compounding, (<http://www.pitch.com/kansascity/herbert-smulls-allen-nicklasson-death-penalty-missouri-department-of-corrections/Content?oid=4094006&storyPage=2>) or made drugs suitable for injections.

Questions regarding the type and mix of lethal injection drugs have arisen since Dennis McGuire "appeared to gasp several times and took more than 15 minutes to die" (<http://www.foxnews.com/politics/2014/01/20/shortage-lethal-drugs-ugly-ohio-execution-re-ignites-death-penalty-debate/>) when he was executed Jan. 16 with a mix of sedative midazolam and the painkiller hydromorphone.

The state on Friday gave Sepulvado's lawyers the email with The Apothecary Shoppe's confidentiality agreement. The document was attached to a Sept. 5, 2013 email from Deril J. Lees, pharmacy manager of The Apothecary Shoppe, to Seth Smith, deputy warden of the Elayn Hunt Correctional Center.

"Please find the attached NDA [non-disclosure agreement] and return it," Lees told Smith in the letter.

The agreement is blank in some parts, but filled out with the name "Georgia Department of Corrections" in others.

The confidentiality agreement was first received by The Lens from the state Wednesday in a heavily redacted format, in response to a public-records request for any correspondence regarding the procurement of pentobarbital.

Sepulvado's lawyers received a non-redacted copy of the document late Friday.

The document was given to lawyers filing a lawsuit on behalf of Sepulvado and death row inmate Jessie Hoffman. Hoffman filed the lawsuit in December 2012, and Sepulvado intervened January 2013, after the state refused to disclose how they would execute him. In February 2013, the state announced a change from a three-drug mixture of lethal injection drugs to the single drug.

Sepulvado and Hoffman's lawsuit contends that condemned inmates have a right to know how they'll be executed.

Sepulvado, who has had several executions come and go in the past year, received another death warrant in January (<http://thelensnola.org/2014/01/07/killer-gets-new-execution-date-but-state-might-not-have-lethal-injection-drug-then/>) after the U.S. Fifth Circuit of Appeals in December (<http://thelensnola.org/2014/01/07/killer-gets-new-execution-date-but-state-might-not-have-lethal-injection-drug-then/>) upheld a decision that the state's lethal injection secrecy did not violate his due-process right. (<http://thelensnola.org/2013/08/30/appeals-court-lets-execution-move-forward/>)

But in January, U.S. Magistrate Judge Stephen Riedlinger in Baton Rouge ruled that the state needed to release additional information about the execution process, including where it would be obtaining its lethal injection drug and if the protocol would be changing.

Getting that information from the state has been tricky, said Michael Rubenstein, a lawyer for Hoffman.

"We had to push hard," Rubenstein said. "They've had a total lack of transparency."

Rubenstein said Friday afternoon that his team had to travel to Baton Rouge to pick up the documents that death-row lawyers demanded as part of discovery for the federal lawsuit. The state blamed the cold weather for not being able to deliver them on the date demanded by Riedlinger, Rubenstein said.

Even then, however, the state gave an "incomplete" version of the documents, Rubenstein said. Among the items missing were where the state planned to find the drug.

"DOC is in the process of procuring at least 15 grams of pentobarbital," the initial state document read. "Defendants will supplement this answer as necessary."

The agreement naming The Apothecary Shoppe was found in a second delivery of records, obtained by death penalty lawyers late Friday night, among more than a thousand other documents, the lawyers said.

Cull agreed that the state lacks transparency.

"The procurement of pentobarbital by the Louisiana Department of Corrections continues to be shrouded in secrecy, insulating the State from public or legal scrutiny," Cull said in an email to The Lens.

"The State's failure to guarantee the efficacy of compounded drugs results in the unacceptable risk that an execution may be slow and tortuous, in violation of the U.S. Constitution's ban on cruel and unusual punishment."

Calls and emails to the Louisiana Department of Corrections, The Apothecary Shoppe and the head of the Louisiana Board of Pharmacy were not immediately returned.

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Jeffrey Cody

From: SETH SMITH <SETHSMITH@corrections.state.la.us>
Sent: Wednesday, January 22, 2014 2:17 PM
To: Jeffrey Cody
Subject: Fw: NDA
Attachments: NDA.pdf

Importance: High

See below chain.

Seth Smith
Deputy Warden / Programs
Elayn Hunt Correctional Center
(225) 319-4507

----- Forwarded by SETH SMITH/EHCC/CORRECTIONS on 01/22/2014 02:16 PM -----

SETH SMITH/EHCC/CORRECTIONS

To WILLIAM KLINE/CORRECTIONS

cc

09/06/2013 09:37 AM

Subject Fw: NDA

Attached

Seth Smith
Deputy Warden / Programs
Elayn Hunt Correctional Center
(225) 319-4507

----- Forwarded by SETH SMITH/EHCC/CORRECTIONS on 09/06/2013 09:37 AM -----

DJ Lees <djlees@apothecarytulsa.com>

To "kaseylees@aol.com" <kaseylees@aol.com>

cc "sethsmith@corrections.state.la.us" <sethsmith@corrections.state.la.us>

09/05/2013 04:04 PM

Subject RE: NDA

Seth,

Please find the attached NDA and return it.

Thanks,

D.J.

From: DJ Lees
Sent: Thursday, September 05, 2013 12:53 PM
To: kaseylees@aol.com
Cc: 'sethsmith@corrections.state.la.us'
Subject: NDA

139a

Kasey,

Please send the NDA to: Seth Smith who has been cc'd to this email. Let me know if you need anything else.

Thanks,

D.J. LEES Pharm.D.
The Apothecary Shoppe
918-665-2003 office ext 229
918-665-8283 office fax
918-857-1221 cell



CONFIDENTIALITY AND NONDISCLOSURE AGREEMENT

This Confidentiality and Nondisclosure Agreement (this "Agreement") is made and entered into as of July __, 2013, by and between The Apothecary Shoppe, Inc., an Oklahoma corporation ("Company"), and _____ ("Recipient").

WHEREAS, Recipient the Georgia Department of Corrections;

WHEREAS, in connection with such Recipient's relationship with the Company, the Company will need to provide certain Confidential Information (as defined below) to Recipient in order for Recipient to perform certain aspects of Recipient's employment with Georgia Department of Corrections (the "Purpose");

WHEREAS, Company will disclose the Confidential Information to Recipient for such Purpose only, and the parties believe that this Agreement is necessary to adequately protect the Confidential Information; and

WHEREAS, without such protections, the Company would be unable to provide such Confidential Information to Recipient.

NOW, THEREFORE, in consideration of Company's disclosure of the Confidential Information and the other agreements, covenants and conditions set forth herein, Company and Recipient hereby agree as follows:

1. Confidential Information. As used herein, "Confidential Information" shall mean all information, data or products, whether disclosed by Company to Recipient at any time orally, in writing, or in electronic format, and whether or not marked as "confidential" or "proprietary," in any way related to the business affairs of Company that is not generally available to other employees of the Company (excluding any Company employee who is also a Company stockholder), including without limitation any records, drafts, and financial or other information or data of or relating to Company or any information related to a potential transaction involving the Company and its stockholders. The term "Confidential Information" shall not include information that (i) is or becomes public knowledge through no act or omission of Recipient; or (ii) is received by, or otherwise made available to, Recipient from a third party who does not owe a duty of confidentiality to Company in connection with the Confidential Information disclosed.

2. Nondisclosure of Confidential Information. Recipient acknowledges and agrees that the Confidential Information is of great value to Company and that the restrictions and agreements contained in this Agreement are reasonably necessary to protect the Confidential Information and the goodwill of Company. Accordingly, Recipient shall not, directly or indirectly, disclose to any other person or entity the Confidential Information or the fact that discussions between Company and Recipient are taking place regarding such Confidential Information, or use the Confidential Information for any purpose other than the Purpose. If Recipient is required to disclose Confidential Information pursuant to any applicable law or judicial or governmental order, she may do so to the extent so required after promptly notifying Company thereof and furnishing to Company any associated subpoena, demand, or similar

documents and a summary of the circumstances related thereto. Recipient shall, at Company's election, return to Company or destroy any Confidential Information immediately after a request by Company.

3. Remedies. Recipient acknowledges and agrees that due to the unique nature of the Confidential Information, there may not be adequate remedy at law for any breach of Recipient's obligations under this Agreement and, therefore, that upon any such breach or any threat thereof, Company shall be entitled to appropriate equitable relief in addition to whatever remedies it might have at law, including, without limitation, attorneys' fees, in connection with any breach or enforcement of Recipient's obligations hereunder or the unauthorized use or release of any such Confidential Information. Recipient shall notify Company in writing immediately upon the occurrence of any such unauthorized release or other breach of which she is aware. Further, Company reserves the right to take any employment action that it deems appropriate upon any breach of this Agreement by Recipient.

4. Miscellaneous. The rights and obligations of the parties under this Agreement shall inure to the benefit of and be binding upon their permitted successors and assigns. The parties agree that this Agreement shall be governed by, interpreted and construed in accordance with the laws of the State of Oklahoma. Sections 1, 2, 3 and 4 hereof shall survive any termination of this Agreement. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any third party with which or into which Company may be merged or which may succeed to Company's assets or business; provided, however, that Recipient may not assign any of her rights or delegate any of her duties under this Agreement. This Agreement contains the entire understanding of the parties hereto with regard to the subject matter contained herein, and supersedes all prior agreements, understandings or intents between the parties hereto. This Agreement may be amended, modified or supplemented only by a writing signed by the parties hereto. No waiver or any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach. This Agreement may be executed in one or more counterparts, each of which shall be considered an original instrument, but all of which shall be considered one and the same agreement.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the day and year first above written.

COMPANY:

RECIPIENT:

The Apothecary Shoppe, Inc.

By: _____
Deril J. Lees, Jr., Pharmacy Manager

Microbiology Report

CLIENT: _____

ARL #: _____

LOT #: _____

DESCRIPTION: Pentobarbital Sodium 50 mg/mL Solution

DATE RECEIVED: 11/07/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 10 mL syringes w/ 5mL each in brown bags

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 7 Days	MBI-144	11/07/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formula: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg or Maximum dose/g

Parenteral: K is 5 EU/kg for any route of administration (Intrathecal: K is 0.2 EU/kg body weight)

Radio pharmaceutical parenteral: K is 175/Y or Intrathecal radio pharmaceuticals: K is 14/Y, where Y is the maximum recommended dose in mL.

Dermal Applications: K/M , where K = 5 EU/kg and M is the (maximum dose/24 hour = 1.86 mg/70 Kg).

11/11/2013

Date Reported

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Results reported above relate only to the sample that was tested

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Microbiology Report

CLIENT:

ARL #:

LOT #:

DESCRIPTION: S-Pentobarbital Sodium 50mg/mL Inj Sol

DATE RECEIVED: 11/27/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 20 mL syringes with 15 mL each in a brown bag

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	MBI-144	11/29/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

12/02/2013

Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)

Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour × 1.80 m²)/70 Kg.

Results reported above relate only to the sample that was tested.

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Microbiology Report

CLIENT: _____

ARL #: _____

LOT #: _____

DESCRIPTION: Pentobarbital Sodium 50 mg/mL Solution

DATE RECEIVED: 11/07/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 10 mL syringes w/ 5mL each in brown bags

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility ("Preliminary")	Sterile / Not Sterile	No Growth at 7 Days	MBI-144	11/07/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formula: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dosage

Parenteral: K is 5 EU/kg for any route of administration / Intrathecal: K is 0.3 EU/kg body weight

Radio pharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.

Dermal Applications: K/M , where K = 5 EU/kg and M is the (maximum dose/hour \times 1.80 m²/70 Kg.

11/11/2013

Date Reported

Results reported above relate only to the sample that was tested.

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Microbiology Report

CLIENT:

ARL #:

LOT #:

DESCRIPTION: S-Pentobarbital Sodium 50mg/mL Inj Sol

DATE RECEIVED: 11/27/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 20 mL syringes with 15 mL each in a brown bag

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	MBI-144	11/29/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

12/02/2013

Date Reported

Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)

Radlpharmaceutical parenteral: K is $175/V$ or Intrathecal radlpharmaceuticals: K is $14/V$, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour × 1.80 m²)/70 Kg.

Results reported above relate only to the sample that was tested.

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Microbiology Report

CLIENT:

ARL #:

LOT #:

DESCRIPTION: S-Pentobarbital Sodium 50mg/mL Inj Sol

DATE RECEIVED: 11/27/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 20 mL syringes with 15 mL each in a brown bag

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility ("Preliminary")	Sterile / Not Sterile	No Growth at 7 Days	MBI-144	11/29/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.7 EU/kg body weight)

Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour \times 1.60 m²/70 Kg.

12/02/2013

Date Reported

Results reported above relate only to the sample that was tested.

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Certificate Of Analysis

CLIENT:

ARL #:

LOT #:

DESCRIPTION: S-Pentobarbital Sodium 50mg/mL Inj Sol

DATE RECEIVED: 11/27/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 20 mL syringes with 15 mL each in a brown bag

Test	Test Method	Limits	Results	Date Tested
Identification (HPLC-Retention time)	USP 36	Conforms to USP Specifications	Conforms	12/10/2013
Assay (HPLC)	USP 36	92.0% - 108.0%	98.1%	12/10/2013

12/10/2013

Date Reported

Results reported above relate only to the sample that was tested

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Microbiology Report

CLIENT: _____

ARL #: _____

LOT #: _____

DESCRIPTION: Pentobarbital Sodium 50 mg/mL Solution

DATE RECEIVED: 11/07/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 10 mL syringes w/ 5mL each in brown bags

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility ("Preliminary")	Sterile / Not Sterile	No Growth at 7 Days	MBI-144	11/07/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Forced - This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formula: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dosage

Parenteral: K is 5 EU/kg for any route of administration / *Intrathecal*: K is 0.2 EU/kg body weight

As the pharmaceutical parenteral: K is 175/V or *Intrathecal radiopharmaceuticals*: K is 14/V, where V is the maximum recommended dose in mL.

Dermal Applications: K/M , where K = 5 EU/kg and M is the (maximum dose/hour = 1.00 mL/70 Kg.

11/11/2013

Date Reported

Results reported above relate only to the sample that was tested.

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Case 2:12-cv-04209-BP Document 290-5 Filed 01/23/14 Page 1 of 6

Exhibit 4

Suggestions in opposition
Exhibit 2

Microbiology Report

CLIENT:

ARL #:

LOT #:

DESCRIPTION: S-Pentobarbital Sodium 50mg/mL Inj Sol

DATE RECEIVED: 11/27/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 20 mL syringes with 15 mL each in a brown bag

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 7 Days	MBI-144	11/29/2013

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Sterility - This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Fungal - This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endotoxin - To calculate the endotoxin limit use the following formulae: $EL = K/M$ where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.7 EU/kg body weight)

Radiopharmaceutical parenteral: K is $175/V$ or Intrathecal radiopharmaceuticals: K is $14/V$, where V is the maximum recommended dose in mL.

Dermal Application: K/M , where K = 5 EU/kg and M is the (maximum dose/m²/hour = 1.50 m²/70 Kg.

12/02/2013

Date Reported

Results reported above relate only to the sample that was tested.

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Certificate Of Analysis

CLIENT:

ARL #:

LOT #:

DESCRIPTION: S-Pentobarbital Sodium 50mg/mL Inj Sol

DATE RECEIVED: 11/27/2013

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: Two 20 mL syringes with 15 mL each in a brown bag

Test	Test Method	Limits	Results	Date Tested
Identification (HPLC-Retention time)	USP 36	Conforms to USP Specifications	Conforms	12/10/2013
Assay (HPLC)	USP 36	92.0% - 108.0%	98.1%	12/10/2013

12/10/2013

Date Reported

Results reported above relate only to the sample that was tested

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