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Quit the Botching, Ohio: Exploring the Flaws in the Ohio Execution Protocol and the Need for Change

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QUIT THE BOTCHING, OHIO: EXPLORING THE FLAWS IN THE OHIO EXECUTION PROTOCOL AND THE NEED FOR CHANGE

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I. INTRODUCTION

At 10:27 a.m. the Warden held a microphone up to Dennis McGuire and asked for his last words.¹ Dennis McGuire mouthed, “I love you” and “I will see you on the

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¹ Trial Pleading at ¶ 54, *In re Dennis R. McGuire v. Mohr*, No. 2:14-CV-00093 (S.D. Ohio filed Jan. 24, 2014), 2014 WL 309071.

other side” to his wife and daughter sitting in the observation room, minutes before he was to be executed.² What normally takes eight minutes,³ took two and a half times as long⁴—a full 20 minutes, as Mr. McGuire began writhing in pain, pushing and arching his back while simultaneously pushing against the gurney.⁵ He was able to get his back and neck off the gurney three to four inches, even though he was strapped down at the waist, feet and hands.⁶ During the twenty-minute execution, members of the execution team had horrified looks on their faces with both wide eyes and shocked expressions.⁷ At 10:53 a.m., the Warden pronounced Mr. McGuire dead and another member of the execution team, who had seen the botched execution unfold mouthed “I’m sorry” to Mr. McGuire’s family in the observation room.⁸

Ohio’s statute for carrying out the death sentence⁹ lacks a critical piece of information—where to purchase drugs used in lethal injections. Before the supply ran out, Ohio used the drug pentobarbital,¹⁰ but switched to a two-drug combination of midazolam and hydromorphone¹¹ for the execution of Mr. McGuire. Previous

² *Id.*

³ See Peter Sergo, *How Does Lethal Injection Work*, SCIENCELINE (Nov. 12, 2007), <http://scienceline.org/2007/11/ask-sergo-deathpenalty> (“According to a 2002 study in the *Journal of Forensic Science*, the average length of time from the first injection to death is 8.4 minutes”).

⁴ See Sergo, *supra* note 3; see also *In re Dennis R. McGuire*, *supra* note 1 at ¶¶ 56, 66.

⁵ See *In re Dennis R. McGuire*, *supra* note 2 at ¶ 55-60, 66.

⁶ *Id.*

⁷ *Id.* at ¶ 62.

⁸ *Id.* at ¶ 67.

⁹ See Ohio Rev. Code Ann. § 2949.22 (West, Westlaw through Files 1 to 140 and Statewide Issue 1 of the 130th GA (2013-2014))

“(A) Except as provided in division (C) of this section, a death sentence shall be executed by causing the application to the person, upon whom the sentence was imposed, of a lethal injection of a drug or combination of drugs of sufficient dosage to quickly and painlessly cause death. The application of the drug or combination of drugs shall be continued until the person is dead. The warden of the correctional institution in which the sentence is to be executed or another person selected by the director of rehabilitation and correction shall ensure that the death sentence is executed.”

¹⁰ *State by State Lethal Injection*, DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org/state-lethal-injection> (referring to Ohio in chart).

¹¹ See *id.*; see also WOLTERS KLUWER, LIPPINCOT, WILLIAMS & WILKINS, *NURSING 2011 DRUG HANDBOOK* 755-56, 778-79 (2011) (Hydromorphone can cause respiratory depression in which the patient should be monitored constantly. See *id.* at 755. It is advised that resuscitation equipment should be available. *Id.* Overdose of hydromorphone can cause “constricted pupils, cold clammy skin . . . respiratory depression . . . cardiac arrest [and] death.” *Id.* at 756. Midazolam is used to “induce sleepiness and amnesia and to relieve apprehension before anesthesia or before or during procedures.” *Id.* at 778); see also Alan Johnson, *Ohio Revises Death Penalty Protocol, Will Delay Executions*, COLUMBUS DISPATCH (Jan. 9, 2015) <http://www.dispatch.com/content/stories/local/2015/01/08/death-penalty-protocol.html>

suppliers from overseas are refusing to sell these drugs to prisons, including prisons in Ohio.¹² As a result, the Ohio Department of Rehabilitation and Corrections (“ODRC”) has turned to compounding pharmacies¹³ for a new source of drugs.¹⁴ However, compounding pharmacies are highly problematic . . . because they are non-FDA regulated which means that regulation is left to the states.¹⁵ Essentially, compounding pharmacies “tend to differ from one state to the next, making it difficult to ensure that compounded drugs are held to consistently high standards of quality, safety and effectiveness.”¹⁶

Ohio’s statute is similar to the death sentence statute in Oklahoma,¹⁷ as both states statutes are silent on where to obtain drugs used in lethal injections. Notably, both states have experienced recent botched executions.¹⁸ In response, Judge Frost from the Southern District of Ohio ordered a stay of all executions in the state until January 15, 2015.¹⁹ The first execution under Ohio’s newly adopted execution protocol²⁰ is scheduled for January 21, 2016.²¹ This note argues that the ODRC should not obtain lethal injection drugs from unregulated compounding pharmacies. Ohio should only

(Recently, the ODRC amended their drug cocktail again: “Ohio will *add thiopental sodium*, a drug used previously, and *drop the two-drug regimen of midazolam and hydromorphone*, which caused problems in the last execution a year ago. But until the Ohio Department of Rehabilitation and Correction can get supplies of pentobarbital, a drug already permitted, or thiopental sodium, executions will be postponed”) (emphasis added).

¹² See Alan Johnson, *Judge Orders Temporary Moratorium on Ohio Executions*, COLUMBUS DISPATCH (May 29, 2014) <http://www.dispatch.com/content/stories/local/2014/05/28/temporary-moratorium-on-lethal-injections.html>.

¹³ See Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEO. L.J. 1331, 1332 (2014) (“[C]omounding pharmacies are non-FDA regulated, small scale pharmacies that make customized drugs on an as-needed basis in response to individual prescriptions”).

¹⁴ Johnson, *supra* note 12.

¹⁵ Denno, *supra* note 13, at 1331.

¹⁶ *Id.* 1332

¹⁷ See 22 OKL. ST. ANN. § 1014 (West 2015).

¹⁸ See generally Michael L. Radelet, *Examples of Post-Furman Botched Executions*, DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org/some-examples-post-furman-botched-executions?scid=8&did=478> (last updated July 24, 2014).

¹⁹ See Order, *In Re Ohio Execution Protocol Litigation*, No. 2:11-cv-01016 (S.D. Ohio Aug. 18, 2014), ECF No. 492; see also Order, *In Re Ohio Execution Protocol Litigation*, No. 2:11-cv-01016 (S.D. Ohio Dec. 23, 2014), ECF No. 503.

²⁰ See ODRC OHIO EXECUTION PROTOCOL, http://drc.ohio.gov/web/drc_policies/documents/01-COM-11.pdf (last updated Jan. 9, 2015) (“If a sufficient quantity of pentobarbital or thiopental sodium is available, then the scheduled execution shall proceed with intravenous administration of either pentobarbital or thiopental sodium, as determined by the Warden, in accordance with the terms of this policy. If a sufficient quantity of pentobarbital or thiopental sodium is not available, or if at any time the available pentobarbital or thiopental sodium is deemed unusable by the Medical Team, then the Warden shall consult with the Director and they shall notify the Governor”).

²¹ See *Execution Schedule*, OHIO DEP’T OF REHABILITATION AND CORRECTION, <http://www.drc.ohio.gov/Public/executionschedule.htm> (last updated Jan. 30, 2015).

purchase drugs from an FDA-registered outsourcing facility. Part II explores the death sentence statute in Ohio and the use of compounding pharmacies. Part III compares Oklahoma's statute in conjunction with Ohio and illustrates the adverse effects by utilizing compounding pharmacies. Part IV proposes recommendations to Ohio's execution protocol. Part V provides a conclusion.

II. BACKGROUND

Ohio's implementation of the death sentence statute²² is minimal in prescribing the precise manner for carrying out the lethal injection protocol. Instead, Ohio's execution protocol, designed and written by the Warden himself, designates the Warden to be in charge, with the assistance of medical personnel, for carrying out all death sentences.²³ Currently, the execution statute simply requires that the:

[D]eath sentence shall be executed by causing the application to the person, upon whom the sentence was imposed, of a lethal injection of a drug or combination of drugs of sufficient dosage to quickly and painlessly cause death. The application of the drug or combination of drugs shall be continued until the person is dead.²⁴

The statute is silent on where to purchase these drugs, which has afforded the ODRC, specifically the Warden, enormous freedom in purchasing these life-ending drugs.²⁵ As a result, Ohio has suffered negative consequences from utilizing compounding pharmacies to purchase these drugs, which were brought to the public light by the unfortunate botched execution of Dennis McGuire.²⁶

²² See OHIO REV. CODE ANN. § 2949.22 (West 2015).

²³ See Ohio Execution Protocol, *supra* note 20 (“The Warden of that facility, or Deputy Warden in the absence of the Warden, is responsible for carrying out the death sentence on the date established by the Ohio Supreme Court. At least three Medical Team Members, two of whom are authorized to administer drugs under Ohio law, shall be used in the conduct of court-ordered executions. Functions required to be performed by medically-qualified persons, as described in this policy, shall be performed by Medical Team Members”).

²⁴ *Id.*

²⁵ See *e.g.*, Alan Johnson, *Ohio Can Use Compounding Pharmacies for Execution Drugs*, COLUMBUS DISPATCH (Oct. 5, 2013), <http://www.dispatch.com/content/stories/local/2013/10/04/new-drugs-added-to-Ohio-execution-policy.html>; see also OHIO REV. CODE ANN. § 2949.22 (West 2015) (“The Warden controls most aspects of the death sentence: “A death sentence shall be executed within the walls of the state correctional institution designated by the director of rehabilitation and correction as the location for executions, within an enclosure to be prepared for that purpose, *under the direction of the warden* of the institution or, in the warden's absence, a deputy warden, and on the day designated by the judge passing sentence or otherwise designated by a court in the course of any appellate or post-conviction proceedings.”) (emphasis added).

²⁶ See *e.g.*, Gary Strauss, *Ohio Killer's Slow Execution Raises Controversy*, USA TODAY (Jan. 16, 2014), <http://www.usatoday.com/story/news/nation/2014/01/16/ohio-killer-executed-with-new-lethal-drug-combo/4512651/>.

A. Ohio's Death Sentence Statute: A Historical Approach

Ohio has employed three different methods of capital punishment: public hangings, electrocution, and the current method of lethal injection.²⁷ When Ohio was first recognized as a state in 1803, executions were performed by public hangings, before Ohio switched to the electric chair.²⁸ In 1993, inmates on death row could choose between the electric chair and lethal injection.²⁹ A few years later in 2001, Ohio Governor Bob Taft signed a bill that eliminated the electric chair completely, leaving lethal injection as the only option.³⁰

Before a death sentence is imposed on a defendant, there are numerous steps throughout the judicial process that must be satisfied. First and foremost, Ohio courts that seek the death penalty, or a life sentence, must comply with the Ohio Revised Code ("ORC") section 2929.04,³¹ which specifies a number of aggravating and mitigating factors to be evaluated by either a trial judge, jury, or three judge panel.³² To date, Ohio has executed 393 convicted murderers by a combination of the three methods.³³

1. A Glimpse into Ohio's Death Penalty Process

In Ohio, in order for the prosecutor to seek the death penalty, certain aggravating factors must be specified on the indictment and proven beyond a reasonable doubt.³⁴ For example, one aggravating factor purports that:

²⁷ See generally *Capital Punishment in Ohio*, OHIO DEPARTMENT OF REHABILITATION AND CORRECTION, <http://www.drc.ohio.gov/public/capital.htm> (last updated Sept. 14, 2014) ("On November 15, 2001, Governor Bob Taft signed House Bill 362 eliminating the electric chair as a form of execution." *Id.* "The only method of execution in Ohio is lethal injection." *Id.* "On February 26, 2002, Ohio's electric chair, nicknamed "Old Sparky," was decommissioned and disconnected from service." *Id.* "The original electric chair was donated to the Ohio Historical Society on December 18, 2002, and a replica electric chair was donated to the Mansfield Reformatory Preservation Society." *Id.*)

²⁸ *Id.* ("Capital punishment has been a part of Ohio's justice system since early in the state's history. From 1803, when Ohio became a state, until 1885, executions were carried out by public hanging in the county where the crime was committed. In 1885, the legislature enacted a law that required executions to be carried out at the Ohio Penitentiary in Columbus.").

²⁹ *Id.* ("In 1993, a bill granting prisoners the option to choose between death by electrocution or lethal injection was passed and signed into law by former Governor George V. Voinovich. The Death Row inmate would be asked to choose between the two methods seven days before the scheduled execution. The law stipulated that if the prisoner did not choose, the default method of execution would be death by electrocution.").

³⁰ *Id.* ("On November 15, 2001, Governor Bob Taft signed House Bill 362 eliminating the electric chair as a form of execution. The only method of execution in Ohio is lethal injection.").

³¹ See OHIO REV. CODE ANN. § 2929.04 (West 2015).

³² See OHIO REV. CODE ANN. § 2929.03(C)(1)(2)(a)(iii)(b)(i)(West, 2014)); see also OHIO REV. CODE ANN. § 2929.03(C)(1)(2)(a)(iii)(b)(ii) (West 2105).

³³ See *Capital Punishment in Ohio*, *supra* note 27.

³⁴ See generally OHIO REV. CODE ANN. § 2929.04(A) (West 2014) (Some aggravating factors include but are not limited to: the assassination of the President of the United States, or

The offense was committed while the offender was committing, attempting to commit, or fleeing immediately after committing or attempting to commit kidnapping, rape, aggravated arson, aggravated robbery, or aggravated burglary, and either the offender was the principal offender in the commission of the aggravated murder or, if not the principal offender, committed the aggravated murder with prior calculation and design.³⁵

In addition to weighing the aggravating factors, the trier of fact must also consider numerous mitigating factors, which include the “nature and circumstances of the offense, history, character, and background of the offender.”³⁶ The trier of fact must also evaluate whether the offender was under duress or provocation, and consider the lack of an offender’s prior criminal history.³⁷ Lastly, the trier of fact must decide whether the aggravating factors outweigh the mitigating factors in issuing a death or life sentence.

There are currently 393 men and one woman sitting on death row in Ohio.³⁸ In order for a criminal defendant to be subject to capital punishment there are three main requirements: he or she must be at least 18 years old when the offense was committed, the indictment must charge the defendant with aggravated murder plus an aggravating circumstance specification,³⁹ and he or she must not be mentally retarded.⁴⁰ In capital

person in line for succession of the presidency, the offense was committed for hire or purpose of escaping detection or trial, the victim was a law enforcement officer.) *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *See id.*

³⁸ *See Death Row Inmates*, OHIO DEPARTMENT OF REHABILITATION AND CORRECTION, <http://www.drc.ohio.gov/public/deathrow.htm> (last updated Dec. 4, 2014).

³⁹ *See supra* note 34; *see also infra* note 36, at 5-6 (“The following are Aggravating Circumstances in Ohio: 1. Assassination of President, Vice President, Governor or Lieutenant Governor; 2. Committed for hire; Committed for the purpose of escaping detection, apprehension, trial or punishment of another crime; 4. While in detention or at large from breaking detention; 5. Prior to the current offense, the offender was convicted of a purposeful killing or attempt to kill, or the offense was part of a course of conduct involving the purposeful killing or attempt to kill two or more persons; 6. The victim was a law enforcement officer, whom the offender knew or had reasonable cause to know was a law enforcement officer. The law enforcement officer was either engaged in work duties or the offender’s specific purpose was to kill a law enforcement officer; 7. The offense was committed, while the offender was committing, attempting to commit, or fleeing after committing or attempting to commit, kidnapping, rape, aggravated arson, aggravated robbery, or aggravated burglary and the offender was the principal offender in the aggravated murder, or if not the principal offender, the aggravated murder was committed by prior calculation and design; 8. Killing of a potential witness in a criminal case to prevent their testimony; 9. Killing of a person less than 13 years of age with prior calculation or design; or 10. The offense was committed while the offender was committing, attempting to commit, or fleeing immediately after committing, or attempting to commit terrorism”).

⁴⁰ *See Capital Crimes Annual Report*, OHIO ATTORNEY GENERAL’S OFFICE (Apr. 1, 2014), <http://www.ohioattorneygeneral.gov/getattachment/f8e455c3-b5b1-4ab5-bc24-4af0ffe41273/2013-Capital-Crimes-Annual-Report.aspx> (Aggravated murder is defined in ORC § 2903.01 and the aggravating circumstances are defined in ORC § 2929.04(A)(1) – (A)(10)). *Id.* at 4-6. Furthermore, “Whenever an indictment charges the defendant with capital murder, the clerk of

punishment cases, trials are split into two phases—“the guilty phase and the sentencing or mitigation phase.”⁴¹ A criminal defendant has a right to a trial by jury during both phases of the trial.⁴² However, the defendant has an option to waive his right to a jury trial such that a three-judge panel will decide whether the defendant is guilty and impose a sentence.⁴³ Before a criminal defendant can be sentenced, the prosecutor must prove beyond a reasonable doubt the defendant committed aggravated murder, in conjunction with an aggravating circumstance.⁴⁴ Furthermore, the aggravating circumstance(s) must outweigh any mitigating circumstances.⁴⁵

A criminal defendant also has the option to file a petition for a writ a habeas corpus.⁴⁶ A writ of habeas corpus orders the custodian of an individual in custody to produce the individual before a court either to inquire about the individual’s detention, to testify, or to appear for prosecution.⁴⁷ Typically, an inmate files a petition for a writ of habeas corpus to contest: the way the sentence is being carried out, if that person is in custody because of something other than a judgment of conviction, or the person is alleging they are being illegally detained in immigration custody.⁴⁸

Once a criminal defendant exhausts all possible appeals,⁴⁹ the defendant typically sits on death row for several years,⁵⁰ before he or she is put to death. The Warden is responsible for carrying out the death sentence and must abide to the procedures prescribed in the Ohio execution protocol in addition to any statutory requirements.⁵¹ A medical team of three people assists the Warden and at least two members must be authorized to administer drugs under Ohio law.⁵² All executions in Ohio take place at the Southern Ohio Correctional Facility, located in Lucasville, Ohio.⁵³

the court in which the indictment is filed must provide notification to the Ohio Supreme Court. Notice must be filed within 15 days of the filing of the indictment and shall contain the following information: the name of the person; the docket number; the name of the court in which the case will be heard, and the date the indictment was filed.” *Id.* at 6.; *see also State v. Lott*, 97 Ohio St.3d 303 (2002) (establishing Ohio’s procedure for determining mental retardation).

⁴¹ *Id.* at 6.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.* at 7.

⁴⁵ *Id.*

⁴⁶ *See* U.S. Const. art I, § 9, cl. 2; *see also* Petition for a Writ of Habeas Corpus Form, U.S. COURTS, available at <http://www.uscourts.gov/uscourts/FormsAndFees/Forms/AO242.pdf>.

⁴⁷ *See Service of Process, Writ of Habeas Corpus*, U.S. MARSHALS SERVICE, <http://www.usmarshals.gov/process/habeas.htm> (last visited Mar. 15, 2015).

⁴⁸ *See Petition for a Writ of Habeas Corpus Form*, *supra* note 46.

⁴⁹ *See Capital Crimes Annual Report*, *supra* note 40, at 8.

⁵⁰ *Id.* at 24 (“The average numbers of years on death row in Ohio is 15.68 years”).

⁵¹ *See OHIO EXECUTION PROTOCOL*, *supra* note 20.

⁵² *Id.* at 3.

⁵³ *Id.* at 4.

2. Dennis McGuire: Ohio's Most Recent Execution

Dennis McGuire experienced horrific complications during his execution in January 2014.⁵⁴ Keeping in mind the end result of this execution, it is critical to understand Mr. McGuire's case, and how he ended up on death row. Mr. McGuire was indicted on December 22, 1993, and was sentenced to death on December 23, 1994.⁵⁵ After numerous unsuccessful appeals, Mr. McGuire was the "[o]nly person in Ohio to have been put to death using the combination of midazolam and hydromorphone."⁵⁶

In the case of Dennis McGuire, the victim, Joy Stewart, approached Mr. McGuire because she wanted to purchase marijuana from him.⁵⁷ The following day, Joy's body was found in the woods.⁵⁸ This homicide was investigated by the Preble County Prosecutor's Office, but to no immediate avail.⁵⁹ However, Mr. McGuire, while incarcerated on an unrelated offense, informed law enforcement that he had inside knowledge pertaining to Joy's death.⁶⁰ Mr. McGuire explained that his brother-in-law, Jerry Richardson, forced Joy to have sex with him and that he "[s]tabbed her 'in the shoulder bone' and 'cut her throat'."⁶¹ The autopsy report revealed that Joy had been stabbed twice and the coroner had found an abundant amount of sperm.⁶² However, while in prison, Mr. McGuire spoke to different people about Joy's murder, implicating himself by stating he was going to blame it all on his brother-in-law, Jerry Richardson.⁶³ After DNA and blood testing of Mr. McGuire, his brother-in-law Jerry Richardson, and the victim, "McGuire was indicted on one count of aggravated murder, with one felony-murder specification for rape."⁶⁴ Mr. McGuire was also indicted on two counts of rape (vaginal and anal) and one count of kidnapping.⁶⁵ The indictment included a death penalty specification, which alleged that McGuire was the principal offender in an aggravated murder, which occurred while he was committing,

⁵⁴ See Johnson, *supra* note 11 ("During his Jan. 16, 2014, execution, McGuire choked and coughed for about 20 minutes before succumbing to the drug mixture. His son and daughter, who witnessed the execution, sued the state, alleging his death was cruel and unusual punishment.").

⁵⁵ See *Capital Crimes Annual Report*, *supra* note 40 at *235.

⁵⁶ See Johnson, *supra* note 11.

⁵⁷ See *State v. McGuire*, 686 N.E.2d 1112, 1115 (Ohio 1997).

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*; see also *id.* (After describing in explicit detail how his brother-in-law, Jerry Richardson, murdered the Ms. Stewart, McGuire led investigators to a hayloft in a barn where the murder weapon, a knife was stored).

⁶² *Id.*

⁶³ *Id.* at 1116.

⁶⁴ *Id.*

⁶⁵ *Id.*

attempting to commit, or fleeing immediately after committing a rape.⁶⁶ Mr. McGuire pleaded not guilty to all counts,⁶⁷ but the jury returned a verdict of guilty including the death sentence specification, which the trial judge imposed.⁶⁸ The Ohio Court of Appeals for Preble County affirmed the death sentence of Mr. McGuire.⁶⁹

On appeal, the Supreme Court of Ohio affirmed Mr. McGuire's convictions and the death sentence.⁷⁰ The Supreme Court reasoned that McGuire's statements tended to show guilt,⁷¹ which combined with the DNA evidence, was consistent with McGuire's guilt.⁷² The Supreme Court reasoned that the mitigating factors of his turbulent childhood, lack of education, mental abuse and marijuana use did not outweigh the aggravating factors that he was the principal offender who "committed rape in conjunction with murder."⁷³

B. A Rocky Road with Lethal Injection

"People who are detained or imprisoned do not cease to be human beings, no matter how serious the crime of which they have been accused or convicted."⁷⁴ "The court . . . which dealt with their case decreed that they should be deprived of their liberty, not that they should forfeit their humanity."⁷⁵ Our society adheres to a series of procedures to protect the individual—from the time a person is arrested⁷⁶ through a person's last appeal to the high court.⁷⁷ The design of our judicial system in conjunction with the Eighth Amendment prohibition of cruel and unusual punishment⁷⁸ illustrates why every person, no matter the crime committed, should be treated with dignity and entitled to humane treatment. The safeguards should continue until a person, specifically on death row, takes their last breath. We as a society should treat all persons on death row with respect—physical and mentally, which includes the actual execution process. Therefore, before the execution process even begins,

⁶⁶ *State v. McGuire*, No. CA95-01-001, 1996 WL 174609, at *1 (Ohio Ct. App. Apr. 15, 1996); *see infra* text accompanying notes 31.

⁶⁷ *See McGuire*, 1996 WL 174609, at *1.

⁶⁸ *See Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* at 1124.

⁷¹ *Id.* at 1118.

⁷² *Id.*

⁷³ *Id.* at 1123.

⁷⁴ *See Andrew Coyle, A Human Rights Approach to Prison Management* 31 (2009), available at http://www.prisonstudies.org/sites/prisonstudies.org/files/resources/downloads/handbook_2nd_ed_eng_8.pdf.

⁷⁵ *Id.*

⁷⁶ *See generally Miranda v. Arizona*, 384 U.S. 436 (1966).

⁷⁷ *See The Appeals Process*, UNITED STATES COURTS, <http://www.uscourts.gov/FederalCourts/UnderstandingtheFederalCourts/HowCourtsWork/TheAppealsProcess.aspx> (last visited Mar. 15, 2015).

⁷⁸ *See* U.S. CONST. amend. VIII.

Ohio should be very cautious of where the lethal injection drugs are purchased. The ODRC should only purchase drugs for lethal injection from FDA-regulated outsourcing facilities to decrease the likelihood of another botched execution.

1. Ohio: One Too Many People Have Suffered as a Result of Ohio's Lethal Injection Procedures

Ohio is no stranger to mishaps occurring with its lethal injection procedures.⁷⁹ In addition to Dennis McGuire, Ohio has also botched three other executions: Joseph Clark, Christopher Newton, and Romell Broom.⁸⁰

The ODRC continues to amend the execution protocol, namely in the drugs utilized.⁸¹ In previous years, the ODRC repeatedly experienced execution complications by failing to adequately locate a suitable vein to commence the executions.⁸² After the execution of Mr. McGuire, it seems as if those troubles have been swept under the rug by the ODRC. Presently, the main source of controversy focuses on where the drugs are purchased. After the execution of Mr. McGuire, the ODRC should note that the seller of these drugs might be the root of the resulting complications.

Joseph Clark was sentenced to death on November 28, 1984,⁸³ but the 2006 execution was not seamless. The execution team took 22 minutes to find a suitable vein for the IV-injection of drugs.⁸⁴ The overall execution took almost 90 minutes to complete,⁸⁵ when the average time from injection of drugs until death lingers around eight minutes.⁸⁶ Mr. Clark was able to lift himself off the gurney while stating; "it's not working," during the execution.⁸⁷ A year later in 2007, the ODRC followed a

⁷⁹ See *Ohio Famous Cases*, DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org/ohio-1#sent> ("Richard Cooley challenged Ohio's lethal injection protocol, saying that it would cause a severely painful death. The U.S. Court of Appeals for the Sixth Circuit rejected his claim, and Cooley was executed on October 14, 2008.").

⁸⁰ *Id.* ("Joseph Clark (May 2006), Christopher Newton (May 2007) and Romell Broom (September 2009)").

⁸¹ See OHIO EXECUTION PROTOCOL, *supra* note 20 (On June 9, 2015 the ODRC amended the Execution Protocol to supersede the April 28, 2014 Execution Protocol).

⁸² See *infra* text accompanying notes 83-87.

⁸³ See *Capital Crimes*, *supra* note 40 at 81 ("Clark murdered 22-year-old night clerk David Manning at a service station in Toledo. Clark demanded money and when Mr. Manning informed Clark that there was no money, Clark shot Mr. Manning once in the chest. After being arrested for robbing a bank, Clark admitted to the robbery-murder of Mr. Manning.").

⁸⁴ See Adam Liptak, *Trouble Finding Inmate's Vein Slows Lethal Injection in Ohio*, N.Y. TIMES (May 3, 2006), http://www.nytimes.com/2006/05/03/us/03inmate.html?_r=0.

⁸⁵ *Id.*

⁸⁶ See *Sergo*, *supra* note 3.

⁸⁷ See Liptak, *supra* note 84.

parallel procedure that caused Christopher Newton to suffer during his execution.⁸⁸ Similar to the execution of Mr. Clark, the ODRC had difficulties finding a suitable vein for Mr. Newton.⁸⁹ The execution team struggled for over an hour during this execution.⁹⁰

Unlike Mr. Clark or Mr. Newton, Romell Broom, is the “country’s only survivor of a botched lethal injection.”⁹¹ Mr. Broom suffered even longer during the execution process; two hours of pain while the execution team, again, tried to find a suitable vein.⁹² Not learning from prior mistakes, the ODRC stuck Mr. Broom 18 times with needles in fruitless attempt to commence the execution.⁹³ Mr. Broom has appealed his case, and remains on death row until he is assigned a new execution date.⁹⁴

2. Ohio: Recent Issues with Lethal Injection

Previously, Ohio used the drug pentobarbital in a one-drug cocktail to carry out the death sentence.⁹⁵ However, in 2013, the supply of pentobarbital began to run dry and prisons all over the country, including Ohio, were in dire need of drugs to continue executing inmates on schedule.⁹⁶ The suppliers, typically European manufacturers, either stopped producing these drugs or refused to sell these drugs to U.S.

⁸⁸ See Jim Leckrone, *Ohio Executes Man Who Killed Prison Cellmate*, REUTERS (May 24, 2007), <http://www.reuters.com/article/2007/05/24/us-execution-ohio-idUSN2437135120070524>.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ See *Ohio Supreme Court to Rule on Second Execution of Romell Broom*, ASSOCIATED PRESS (June 3, 2014) <http://www.theguardian.com/world/2014/jun/03/ohio-supreme-court-romell-broom-botched-execution>.

⁹² *Id.* (“An hour into the execution, the Department of Rehabilitation and Correction recruited a part-time prison doctor with no experience or training with executions to try – again, unsuccessfully – to find a vein.”).

⁹³ *Id.* (“Broom has said he was stuck with needles at least 18 times, with pain so intense that he cried and screamed.”)

⁹⁴ *Id.* (Mr. Broom’s attorneys are prepared to argue on his behalf that attempting to execute him again would “punish him twice for the same offense.” *Id.* “The State of Ohio argues that Broom never underwent the execution process since the procedure was called off before the drugs could be introduced into his veins.” *Id.*).

⁹⁵ See *State by State Lethal Injection*, *supra* note 10.

⁹⁶ See *Id.*; see generally *Johnson*, *supra* note 12.

distributors.⁹⁷ As a result, Ohio turned to compounding pharmacies to obtain drugs.⁹⁸ Ohio used a new two-drug cocktail of midazolam and hydromorphone, for the first time, on Mr. McGuire on January 14, 2014.⁹⁹ However, after the execution of Mr. McGuire, the ODRC amended the execution protocol,¹⁰⁰ replacing midazolam and hydromorphone with either pentobarbital or thiopental sodium.¹⁰¹ In Ohio's recently updated execution protocol, the ODRC does not specify where to obtain the lethal injection drugs, but rather includes a host of potential suppliers including a manufacturer, distributor or compounding pharmacy.¹⁰² Compounding pharmacies pose a plethora of dangers because they "do not face the same approval process for their products that large manufacturers face, leading to concerns about the safety and efficacy of their products."¹⁰³

⁹⁷ See *Johnson*, *supra* note 12; see *id.* Cf. *Denno*, *supra* note 13, at ¶ 28 ("... pentobarbital was manufactured in Denmark by Lundbeck, Inc. Lundbeck announced a prohibition against use of the drug for executions, and Ohio's supply was subsequently exhausted. As a result, in October of 2013, Ohio adopted an "alternate" clinically untested drug mixture containing midazolam and hydromorphone"). See also COUNCIL OF EUROPE PUBL'G & RENATE WOHLWEND LIECHTENSTEIN DELEGATION TO THE PARLIAMENTARY ASSEMBLY OF THE COUNCIL OF EUROPE, THE DEATH PENALTY ABOLITION IN EUROPE 55 (1999) ("Europe has become de facto a death-penalty free zone, with all of the Council of Europe's forty-one member states either having abolished the death penalty, or having instituted a moratorium on executions").

⁹⁸ See *Johnson*, *supra* note 12.

⁹⁹ See *State by State Lethal Injection*, *supra* note 10; see also Ohio Execution Protocol, *supra* note 20 (For the execution of Dennis McGuire, in January 2014, Ohio used the combination of midazolam and hydromorphone: "If a sufficient quantity of pentobarbital is not available, or if at any time the available pentobarbital is deemed unusable by the Medical Team, then the scheduled execution shall proceed with intravenous administration of midazolam and hydromorphone, in accordance with the terms of this policy").

¹⁰⁰ See Ohio Execution Protocol, *supra* note 20 (Replacing the combination of hydromorphone and midazolam, Ohio switched, on January 9, 2015, to pentobarbital or sodium thiopental:

If a sufficient quantity of pentobarbital or thiopental sodium is available, then the scheduled execution shall proceed with intravenous administration of either pentobarbital or thiopental sodium, as determined by the Warden, in accordance with the terms of this policy. If a sufficient quantity of pentobarbital or thiopental sodium is not available, or if at any time the available pentobarbital or thiopental sodium is deemed unusable by the Medical Team, then the Warden shall consult with the Director and they shall notify the Governor.

¹⁰¹ See *State by State Lethal Injection*, *supra* note 10.

¹⁰² See Ohio Execution Protocol, *supra* note 20, at 8. (References pentobarbital or thiopental sodium, however lists suppliers of this drug vary which are still "in accordance with this policy").

¹⁰³ See *Compounding Pharmacies and Lethal Injection*, DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org/compounding-pharmacies> (last visited August 13, 2015).

C. Compounding Pharmacies: A Way for Prisons to Bypass Regulation

Compounding pharmacies are different from commercial pharmacies because they combine, mix, or alter drugs, which are used to meet the specific needs of an individual patient in response to a prescription.¹⁰⁴ Even though a licensed pharmacist prepares compounded drugs, compounding pharmacies, as a whole, are not governed under the strict requirements of the Food and Drug Administration (“FDA”).¹⁰⁵ This leaves the requirements and standards of the pharmacists to be regulated by state pharmacy boards, which vary from state to state.¹⁰⁶ Compounding pharmacies may elect to become accredited by the Pharmacy Compounding Accreditation Board, however it is not a mandatory requirement.¹⁰⁷

Due to the lack of uniformity among the states to regulate compounding pharmacies, there was concern that some pharmacies were straying from the scope of traditional compounding practices.¹⁰⁸ The FDA issued two reports revealing compounded drugs that failed safety and efficacy tests, as well as exposing serious illnesses and deaths that had occurred in association with compounded drugs.¹⁰⁹ These reports failed to fix the problems compounding pharmacies posed and as a result in October 2012, the New England Compounding Center (“NECC”) was the root of a fungal meningitis outbreak in the United States.¹¹⁰ The drugs from this compounding pharmacy harmed over 700 people in 20 states, and left over 60 people dead.¹¹¹

Congress responded in November 2013 by passing the Drug and Quality Security Act.¹¹² Encompassed within this Act is the Compounding Quality Act, which makes “a distinction between traditional compounders who work at the neighborhood

¹⁰⁴ *Id.* See also Denno, *supra* note 13, at 1367 (“Traditionally, all compounded drugs were custom-made in small batches for individual patients pursuant to a medical prescription. Physicians usually prescribe compounded medications when commercial drugs are unavailable or the use of existing commercial alternatives is inhibited by allergies”).

¹⁰⁵ See Denno, *supra* note 13, at 1367.

¹⁰⁶ *Id.* at 1367-68. See also *State Regulation of Compounding Pharmacies*, NAT’L CONFERENCE OF STATE LEGISLATURES (Oct. 1, 2014), <http://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx> (“Every state has laws and regulations guiding pharmacy standards and requirements, addressing issues such as required licenses for each facility and for the credentialed pharmacists and other employees who work there”).

¹⁰⁷ See *Compounding Pharmacies and Lethal Injection*, *supra* note 103.

¹⁰⁸ See Denno, *supra* note 13, at 1370.

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 1371.

¹¹¹ See *Compounding Pharmacies and Lethal Injection*, *supra* note 103; see also T.R. Goldman, *Regulating Compounding Pharmacies*, HEALTH AFFAIRS (May 1, 2014), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=114 (“An FDA investigation later revealed that one-quarter of the steroid vials in an NECC bin contained a greenish black foreign matter. Hit with a raft of lawsuits, NECC declared bankruptcy, and in late 2013 the company’s owners and its insurers reportedly reached an agreement in principle for a compensation fund of more than \$100 million”).

¹¹² See Denno, *supra* note 13, at 1374; see also Drug Quality and Security Act, 21 U.S.C. § 503(b) (2013).

pharmacy and companies producing large quantities of compounded drugs without the need for a prescription.”¹¹³ This Act leaves regulation over traditional small-scale compounding pharmacies in the hands of the states.¹¹⁴ On the other hand, compounding pharmacies that mass-produce drugs may register with the FDA as outsourcing facilities.¹¹⁵ Under the Compounding Quality Act, outsourcing facilities are subject to rules on quality control and oversight.¹¹⁶ The loophole that puts prisons at an advantage is that large-scale compounding pharmacies are not mandated to register with the FDA.¹¹⁷ As a result, small-scale compounding pharmacies and large-scale compounding pharmacies that opt out of FDA registration provide available means for prisons to purchase drugs for lethal injections.

There are allegations that Ohio took advantage of this loophole by purchasing drugs from compounding pharmacies to carry out executions.¹¹⁸ Moreover, it is alleged that the ODRC purchased hydromorphone and midazolam from Hospira, Inc., a compounding pharmacy and distributor, which was utilized in the botched execution of Dennis McGuire.¹¹⁹ These matters are still pending in court, however, Ohio’s execution protocol allows the ODRC to obtain drugs from compounding pharmacies.¹²⁰ As a result of the mishap by the ODRC concerning Dennis McGuire, and “[i]n light of the continuing need for discovery and necessary preparations related to the adoption and implementation of the new execution protocol,”¹²¹ all executions have been halted in Ohio until January 2016.¹²²

III. ARGUMENT: OHIO SHOULD PURCHASE DRUGS ONLY FROM FDA-REGISTERED OUTSOURCING FACILITIES

The ODRC is following in the dark footsteps of Oklahoma. Ohio and Oklahoma have remarkably similar track records regarding lethal injection.¹²³ Both states have

¹¹³ See Goldman, *supra* note 111.

¹¹⁴ See Denno, *supra* note 13, at 1374.

¹¹⁵ Sabrina Tavernise, *Bill on Drug Compounding Clears Congress a Year After a Meningitis Outbreak*, N.Y. TIMES (Nov. 18, 2013), <http://www.nytimes.com/2013/11/19/us/bill-on-regulating-drug-compounding-clears-senate.html?module=Search&mabReward=relbias%3Aw>.

¹¹⁶ *Id.*

¹¹⁷ See generally Denno, *supra* note 13, at 1374 (“The Act refers to these large scale compounding manufacturers as outsourcing facilities and provides voluntary federal registration for outsourcing facilities, set to begin in fiscal year 2015”).

¹¹⁸ See *In re Dennis R. McGuire*, *supra* note 1, at ¶¶ 82-83.

¹¹⁹ See *id.* at ¶ 73. It is also alleged “Hospira products have been used in at least five executions in the state of Ohio since at least November 2012.” *Id.* at ¶ 83.

¹²⁰ See Ohio Execution Protocol, *supra* note 20 at 8.

¹²¹ See Execution Schedule, *supra* note 21.

¹²² See *id.* The first scheduled execution is Ronald Phillips on January 21, 2016. *Id.*

¹²³ See generally Amanda Sakuma, *Oklahoma Executes First Inmate Since Botched Lethal Injection*, MSNBC (Jan. 15, 2015), <http://www.msnbc.com/msnbc/first-lethal-injection-oklahoma-botched-inmates-execution>.

used a similar combination of drugs that resulted in botched executions.¹²⁴ While Oklahoma hides behind its secrecy statute¹²⁵ to protect the identities of the suppliers, Oklahoma has not tried to hide the fact that the Department of Corrections is open to using compounding pharmacies.¹²⁶ Keeping in line with Oklahoma's actions, Ohio, too, recently enacted a secrecy statute known as House Bill 663 ("HB 663").¹²⁷ HB 663 protects the ODRC from what it has already done, provide immunity and confidentiality to all persons involved in the lethal injection process, including compounding pharmacies.¹²⁸

¹²⁴ See generally *Radelet*, *supra* note 18.

¹²⁵ See 22 Okla. Stat. Ann. tit. 22, § 1015(B) (West, Westlaw current with chapters of the Second Regular Session of the 54th Legislature (2014) effective September 1, 2014) ("The identity of all persons who participate in or administer the execution process and persons who supply the drugs, medical supplies or medical equipment for the execution shall be confidential and shall not be subject to discovery in any civil or criminal proceedings. The purchase of drugs, medical supplies or medical equipment necessary to carry out the execution shall not be subject to the provisions of the Oklahoma Central Purchasing Act").

¹²⁶ See Erik Eckholm, *One Execution Botched, Oklahoma Delays the Next*, N.Y. TIMES (Apr. 29, 2014), http://www.nytimes.com/2014/04/30/us/oklahoma-executions.html?_r=0 ("Faced with shortages, Oklahoma and other states have turned to compounding pharmacies — lightly regulated laboratories that mix up drugs to order. Opponents have raised questions about quality control, especially after the widely reported dying gasps of a convict in Ohio for more than 10 minutes, and an Oklahoma inmate's utterance, "I feel my whole body burning," after being injected with compounded drugs").

¹²⁷ See *Death Penalty Legislation HB 663 Death Penalty Legislation*, ACLU OF OHIO, <http://www.acluohio.org/legislation/2013-2014-hb-663> (last visited Jan. 15, 2015) ("HB 663 excludes from the definition of "public record" any information and records that relate in any manner to the execution of a death sentence. These records are made confidential, and not subject to any form of disclosure under the Public Records Law, as well as for the media and defense counsel during any legal cases. This includes determining the manufacturing origin of any drugs used during the lethal injection process or the combination of drugs that may be administered"); see also H.B. 663, 130th Gen. Assemb., Reg. Sess. (Oh. 2014) ("To amend section 149.43 and to enact sections 2949.221 and 2949.222 of the Revised Code to provide confidentiality and license protection for persons and entities involved in executing a sentence of capital punishment by lethal injection and to void as against public policy any agreement that prevents the supplying of any drug or drugs to be used in executing a sentence of capital punishment by lethal injection, and to amend the version of section 149.43 of the Revised Code that is scheduled to take effect on March 20, 2015, to continue the provisions of this act on and after that date").

¹²⁸ See *Strauss*, *supra* note 26; see also Ohio Execution Protocol, *supra* note 20, at 11 ("If the Warden determines that a sufficient quantity of pentobarbital is available and has been selected to be used, then a Drug Administrator shall prepare the execution drugs as follows:")

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 50mg/mL solution, shall be withdrawn and divided into two syringes labeled "1" and "2".

Syringes 3 and 4: Five (5) additional grams of pentobarbital (under whatever name it may be available from a manufacturer, distributor or compounding pharmacy), 100 ml of a 50mg/mL solution, shall be obtained and kept available in the Equipment Room, but need not be withdrawn into syringes unless the primary dose of five grams proves

A. Ohio and Oklahoma Have Used the Same Drug That Resulted in Botched Executions

Ohio has used many different drugs to carry out lethal injections over the past few years.¹²⁹ In 2009, Ohio used sodium thiopental,¹³⁰ but switched to pentobarbital in 2011.¹³¹ After the pentobarbital supply dried up, Ohio turned to a new two-drug combination of midazolam and hydromorphone.¹³² This two-drug combination was used for the execution of Dennis McGuire.¹³³ Midazolam is used because it “is an anesthetic used sometimes in surgery, and hydromorphone is a narcotic pain killer.”¹³⁴ The midazolam is thought to render the inmate unconscious for the execution . . . and hydromorphone causes death by shutting down breathing and stopping the heart from beating.¹³⁵ In response to Dennis McGuire, beginning in 2015, Ohio’s amended drug cocktail for lethal injection includes either pentobarbital, or a dose of thiopental sodium.¹³⁶

After the botched execution of Dennis McGuire, the administrators of his estate filed a complaint as a result of the misguided decisions of the ODRC.¹³⁷ The complaint alleges that the ODRC adopted this compounded two-drug protocol without any prior clinical testing.¹³⁸ Despite medical testimony and warnings, the ODRC went

to be insufficient for the procedure. These two additional syringes labeled “3” and “4” shall be kept available for contingent use. (emphasis added).

A similar procedure is to be followed if the ODRC uses thiopental sodium. *Id.*

¹²⁹ See *State by State Lethal Injection*, *supra* note 10 (Ohio used pentobarbital in 2011 and switched to midazolam and hydromorphone in 2014. *Id.* Recently, the ODRC announced plans to utilize sodium thiopental or pentobarbital. *Id.*).

¹³⁰ See Julie Carr Symth and Andrew Welsh-Huggins, *Ohio Clears Specialty Drug-Makers in Executions*, ASSOCIATED PRESS (Oct. 4, 2013), <http://bigstory.ap.org/article/ohio-announces-alternative-lethal-injection-drug>.

¹³¹ *Id.*

¹³² Compare *State by State Lethal Injection*, *supra* note 10, with *In re Dennis R. McGuire*, *supra* note 1, at ¶ 28 (“As described in greater detail herein, pentobarbital was manufactured in Denmark by Lundbeck, Inc. Lundbeck announced a prohibition against use of the drug for executions, and Ohio’s supply was subsequently exhausted. As a result, in October of 2013, Ohio adopted an “alternate” clinically untested drug mixture containing midazolam and hydromorphone”).

¹³³ *Id.*

¹³⁴ Ben Brumfield, *Arizona Execution Raises Questions Over Novel Lethal Injections*, CNN (July 25, 2014), <http://www.cnn.com/2014/07/24/justice/lethal-injection-controversy/>.

¹³⁵ *Id.*

¹³⁶ See Andrew Welsh-Huggins, *Ohio Drops 2-Drug Lethal Injection Method, Delays Execution*, ABCNEWS (Jan. 8, 2015), <http://abcnews.go.com/US/wireStory/apnewsbreak-ohio-execution-drug-supply-expires-april-28082090>.

¹³⁷ See generally *In re Dennis R. McGuire*, *supra* note 1.

¹³⁸ See *id.* at ¶ 39. (Prior to the execution, Dr. David Waisel “testified that midazolam can induce sedation, however a person can still consciously experience one’s surroundings and feel pain and horrific stimuli, including air hunger, while under sedation.” *Id.* at ¶ 52. Furthermore,

forward with the two-drug plan of hydromorphone and midazolam, which caused Mr. McGuire to experience intolerable pain and suffering.¹³⁹

Similarly enough, Oklahoma used midazolam as part of a three-drug combination in the botched execution for Clayton Lockett.¹⁴⁰ After challenging Oklahoma's secrecy statute, the Oklahoma Supreme Court denied to stay the execution of Clayton Lockett.¹⁴¹ Oklahoma then proceeded to use "midazolam, which causes unconsciousness; vecuronium bromide, which stops respiration; and potassium chloride, which stops the heart."¹⁴² Similar to Ohio, which used an untested combination that included midazolam, the first time Oklahoma used midazolam was for the execution of Clayton Lockett.¹⁴³ As a result, according to the Oklahoma Department of Corrections, Clayton Lockett later suffered a heart attack and died.¹⁴⁴ Midazolam contributed to both botched executions, as it was an ingredient in both drug cocktails for Mr. McGuire and Mr. Lockett.

B. Compounding Pharmacies and Secrecy Statutes Do Not Provide Any Solutions

Compounding pharmacies provide a convenient pathway for prisons to obtain drugs for lethal injections. Ohio's death sentence statute¹⁴⁵ provides no guidance on where to purchase these drug cocktails, but the recently updated¹⁴⁶ execution protocol explicitly permits the ODRC to utilize compounding pharmacies.¹⁴⁷ The protocol specifically designates the Warden to be in charge "and responsible for carrying out

Dr. Waisel testified, "hydromorphone is not generally administered to induce amnesia." *Id.* at ¶ 54).

¹³⁹ See *id.* at ¶ 63 ("Decedent repeated cycles of snorting, gurgling and arching his back, appearing to writhe in pain. It looked and sounded as though he was suffocating. His stomach was rising and falling quickly, as he took quick, shallow breaths. This continued for nearly 19 minutes. The noises he made were audible the entire time, though they gradually quieted as he was dying. Decedent was conscious during the majority of this time").

¹⁴⁰ See Matt Pearce, Molly Hennessey-Fiske, Paresh Dave, *Oklahoma Halts Double Execution After One is Botched*, L.A. TIMES (Apr. 29, 2014), <http://www.latimes.com/nation/nationnow/la-na-nn-oklahoma-execution-20140429-story.html#page=1>.

¹⁴¹ Lockett v. Evans, 330 P.3d 488, 491 (Okla. 2014)

¹⁴² See Pearce, *supra* note 140.

¹⁴³ OKLA. DEP'T. OF PUB. SAFETY, THE EXECUTION OF CLAYTON D. LOCKETT, available at <http://www.dps.state.ok.us/Investigation/14-0189SI%20Summary.pdf> ("The new three drug protocol utilized in this execution included the administration of midazolam, vecuronium bromide and potassium chloride. It was determined vecuronium bromide and potassium chloride had both been used in previous executions as the second and third drugs to be administered. **This was the first Oklahoma execution where midazolam was used. On April 14, midazolam was the newest drug added to the protocol after it was determined pentobarbital was not available**") (emphasis added).

¹⁴⁴ See Pearce, *supra* note 140.

¹⁴⁵ See Ohio Rev. Code Ann. § 2949.22 (West 2015)

¹⁴⁶ See Ohio Execution Protocol, *supra* note 20, at 1 (Ohio's protocol was updated April 14, 2014 and again on January 9, 2015).

¹⁴⁷ See *id.* at 8.

the death sentence on the date established by the Ohio Supreme Court.”¹⁴⁸ Absent any statutory requirements, the execution protocol places the power in the Warden’s hands to determine what drugs to utilize, how much of each quantity shall be ordered and most important, where to purchase these drugs.¹⁴⁹ In promulgating this new protocol, the ODRC included a host of potential suppliers, which gives a false appearance, to the public, of using a reputable and safe supplier. The protocol allows the Warden to “order execution drugs from a licensed pharmacist at the Central Pharmacy at the Department on Mental Health,¹⁵⁰ or any other licensed pharmacist.”¹⁵¹ However, a few pages later in the protocol, the ODRC expands the potential supplier list to include any manufacturer, distributor or compounding pharmacy.¹⁵² Ohio’s execution protocol does not address the real issue of the dangers posed by compounding pharmacies and includes all possible suppliers to maintain flexibility in times of disarray. The newly updated execution protocol is expansive in providing options for the ODRC, but leaves prisoners with limited options. Based on Ohio’s newly enacted secrecy statute, the enormous power of the Warden, and lack of adequate protections in the execution protocol, death row inmates can be subject to untested drugs from an unregulated compounding pharmacy.

1. Ohio

The administrators of Mr. McGuire’s estate named the ODRC’s Warden, Donald Morgan,¹⁵³ as one of many defendants in the complaint filed on his behalf. The complaint alleges that the Warden purchased hydromorphone and midazolam from Hospira, a compounding pharmacy and distributor.¹⁵⁴ The plaintiffs have a good faith factual basis for this claim because in 2011 Hospira had manufactured and sold sodium

¹⁴⁸ *Id.* at 3.

¹⁴⁹ *See id.* at 5-6.

¹⁵⁰ Compare Ohio’s Pharmacy Service Center, <http://mha.ohio.gov/Default.aspx?tabid=370> (“The Ohio Pharmacy Service Center (OPSC) provides pharmaceuticals to governmental and qualifying entities in Ohio. Over-the-counter drugs, medical and laboratory supplies, personal care products and forms are also stocked”), with Ohio’s Central Pharmacy Inpatient, <http://mha.ohio.gov/Default.aspx?tabid=367> (“Central Pharmacy Inpatient (CPI) has been providing comprehensive, centralized pharmaceutical services for more than 30 years. CPI focuses on best practices for patient care within state, county, or governmental inpatient settings. CPI offers competitively priced medications through consolidated purchasing, formulary management, medication monitoring, and coordinated care to ensure that health care dollars are spent wisely”), and Ohio’s Central Pharmacy Outpatient, <http://mha.ohio.gov/Default.aspx?tabid=368> (“CPO assists Community Mental Health Boards with the economic purchase and dispensing of psychotropic medications to needy clients meeting specific clinical and income eligibility criteria”).

¹⁵¹ *See* Ohio Execution Protocol, *supra* note 20, at 5.

¹⁵² *See* Ohio Execution Protocol, *supra* note 20, at 8.

¹⁵³ *See In re Dennis R. McGuire*, *supra* note 1, at ¶ 10 (“Defendant Donald Morgan is the Warden at Southern Ohio Correctional Facility (“herein SOCF”). He is responsible for overseeing all operations at SOCF, including executions. He was present during Decedent’s execution. He was acting in his official and individual capacity as such”).

¹⁵⁴ *Id.* at ¶¶ 108-109.

thiopental to the ODRC to use in the executions for that year.¹⁵⁵ Because Hospira previously sold compounded drugs,¹⁵⁶ in conjunction with the present allegations, the ODRC is adhering to the new execution protocol that allows compounding pharmacies to provide the Warden's choice of drugs.

2. Oklahoma

Oklahoma's execution protocol differs from Ohio's execution protocol regarding the suppliers of drugs.¹⁵⁷ Oklahoma has passed not only a secrecy statute,¹⁵⁸ to protect the identity of suppliers, but also incorporated the secrecy requirement in their execution protocol.¹⁵⁹ Ohio too, passed a secrecy bill, mainly to shield the identity of

¹⁵⁵ See generally Letter from Keës Gioenhout, Vice President, Clinical Research and Development, Hospira, Inc., to Ohio Department of Rehabilitation and Correction (Mar. 31, 2010) (available at <http://www.deathpenaltyinfo.org/documents/HospiraMarch2010Statement.pdf>)

¹⁵⁶ See *id.*

¹⁵⁷ Compare *Ohio Execution Protocol*, *supra* note 20, at 8 (the ODRC is permitted to obtain drugs from a manufacturer, compounding pharmacy or distributor), with *Oklahoma Execution Protocol*, *infra* note 159, at 4 (the Oklahoma Department of Corrections is not permitted to disclose where the execution drugs are purchased, as disclosure is prohibited by their secrecy statute).

¹⁵⁸ See 22 Okla. Stat. Ann. tit. 22, § 1015 (Westlaw 2014) ("The identity of all persons who participate in or administer the execution process and persons who supply the drugs, medical supplies or medical equipment for the execution shall be confidential and shall not be subject to discovery in any civil or criminal proceedings. The purchase of drugs, medical supplies or medical equipment necessary to carry out the execution shall not be subject to the provisions of the Oklahoma Central Purchasing Act"); see also Adam Lozeau, *Obscuring the Machinery of Death: Assessing the Constitutionality of Georgia's Lethal Injection Secrecy Law*, 32 LAW & INEQ. 451, 467 (2014) (Oklahoma is not the only state with a secrecy statute and "in early 2013, Arkansas, South Dakota, and Tennessee amended their states' public records laws to shield the identities of the suppliers of lethal injection drugs from disclosure under their public records acts.") *Id.* "A law enacted in March 2013 in Georgia went even further." *Id.* "The law, known as the "Lethal Injection Secrecy Act," states:

The identifying information of any person or entity who participates in or administers the execution of a death sentence and the identifying information of any person or entity that manufactures, supplies, compounds, or prescribes the drugs, medical supplies, or medical equipment utilized in the execution of a death sentence shall be confidential and shall not be subject to disclosure under Article 4 of Chapter 18 of Title 50 or under judicial process. Such information shall be classified as a confidential state secret. *Id.*

After Georgia's secrecy statute was passed, an inmate filed for a stay of execution. See *id.* at 468. "The presiding judge delayed the execution, and just three days later, found the law unconstitutional under the Eighth Amendment of the federal Constitution and under the Separation of Powers Clause of the Georgia State Constitution." *Id.* "The stay of execution is in effect until the Georgia Supreme Court rules on the constitutionality of the law." *Id.*

¹⁵⁹ See Oklahoma Execution Protocol, OKLAHOMA DEPARTMENT OF CORRECTIONS, <http://www.ok.gov/doc/documents/op040301.pdf> (last updated Sept. 30, 2014) ("Maintaining confidentiality of identifying information regarding any person who participates in or performs any function of an execution. As defined in Oklahoma State Statute Title 22, Section 1015, "The identity of all persons who participate in or administer the execution process and persons who

the suppliers,¹⁶⁰ but did not include the secrecy component in the updated execution protocol that took effect on January 9, 2015. The Oklahoma Supreme Court held the secrecy statute constitutional,¹⁶¹ which poses a significant problem as it shields the company responsible for providing the drugs used in botched executions. The media has alleged that Oklahoma resorted to compounding pharmacies as a result of drug shortages.¹⁶² Despite these allegations, people not directly involved in executions will never truthfully know where the Oklahoma Department of Corrections obtains drugs.

3. Secrecy Statutes Provide No Cure to Botched Executions

Ohio is similar to Oklahoma in that both Departments of Corrections seem to have a false sense of security. For Oklahoma, the secrecy statute did not provide a solution to the botched execution of Clayton Lockett. Looking at Oklahoma, Ohio should note that the neither a secrecy statute nor including a vague host of suppliers solves the problems that resulted from the botched execution of Dennis McGuire, or provides a solution for upcoming executions. Both states have the appearance of hiding behind a cloak of invisibility¹⁶³ instead of addressing the root of the problem—where these drugs are purchased. Instead of covering up the identities of suppliers,¹⁶⁴ Ohio should be forthcoming on where they obtain drugs for lethal injection for the bodily health and respect of the inmate. The ODRC seems to be covering their tracks leading up to the executions, knowing that the statute will protect and cover up suspicious behavior by persons involved with lethal injection. Ohio's enactment of HB 663 was conveniently passed after Oklahoma's mishaps with Clayton Lockett, the enactment of Oklahoma's secrecy bill and the ODRC's botched execution of Dennis McGuire. In reality, Ohio's enactment of HB 663 is a band-aid on open wound that needs stitches to heal properly.

Ohio should exclude the use of small-scale state regulated compounding pharmacies and large-scale compounders that do not elect to register with the FDA as an outsourcing facility. Ohio should only purchase drugs for lethal injections from an FDA-registered outsourcing facility. Ohio would be taking a small, albeit proactive step, to ensure that the drugs are coming from a pharmacy with FDA oversight.

supply the drugs, medical supplies or medical equipment for the execution shall be confidential and shall not be subject to discovery in any civil or criminal proceedings. The purchase of drugs, medical supplies or medical equipment necessary to carry out the execution shall not be subject to the provision of the Oklahoma Central Purchasing Act”).

¹⁶⁰ See *Death Penalty Legislation*, *supra* note 127.

¹⁶¹ See *Lockett v. Evans*, 330 P.3d 488, 491 (Okla. 2014) (holding that the “secrecy provision of death sentence statute did not violate inmates' constitutional right of access to the courts”).

¹⁶² See Eckholm, *supra* note 126 (“Faced with shortages, Oklahoma and other states have turned to compounding pharmacies — lightly regulated laboratories that mix up drugs to order”).

¹⁶³ See generally Louis E. Wolcher, Keynote Address, 17 J. L. BUS. & ETH. 9, 13 (2011) (Referencing Plato and the “ancient fable of the Ring of Gyes. This magical ring allowed its wearer to become invisible at will, and I wonder, as Plato did more than two millennia ago, whether someone who could put it on would behave the same way if she knew that she never had to fear the personal consequences of her actions”); see also Plato, REPUBLIC: BOOK II.

¹⁶⁴ See *Death Penalty Legislation*, *supra* note 127.

C. Solutions

1. Outsourcing Facilities Versus State-Regulated Compounding Pharmacies

a. Outsourcing Facilities: More Regulations Required by the FDA

Purchasing drugs from outsourcing facilities would assist the ODRC in narrowing down the current supplier list in the execution protocol to a more reliable provider. Compounding pharmacies that elect to register with the FDA as an outsourcing facility¹⁶⁵ must comply with CGMP¹⁶⁶ [current good manufacturing practices] requirements, be inspected by FDA, report adverse events and, provide the FDA with certain information about the products they compound.¹⁶⁷

The FDA promulgated a guide to illustrate the their position on current good manufacturing practices¹⁶⁸ pertaining to Compounding Quality Act, specifically section 503(B) within the Food, Drug and Cosmetic Act.¹⁶⁹ This draft contains detailed explanations regarding: “facilities designs, procedures for maintaining suitable facilities, environmental and personnel monitoring, equipment and container

¹⁶⁵ See *Information Concerning Outsourcing Facilities Registration*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm> (last updated Mar. 14, 2014) (for more information on how to register as an outsourcing facility see submission #1); see also

Registration for Human Drug Compounding Facilities Under Section 503B of the Federal Food, Drug and Cosmetic Act, Draft Guidance, U.S. FOOD AND DRUG ADMINISTRATION (Dec. 2013), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377051.pdf>.

¹⁶⁶ *Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm> (last updated Sept. 12, 2014) (“FDA ensures the quality of drug products by carefully monitoring drug manufacturers’ compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have”).

¹⁶⁷ *Protecting the Public Health: Examining FDA’s Initiatives and Priorities: Before the S. Comm. on Health, Education, Labor and Pensions*, 113th Cong. 22 (2014) (statement of Margaret A. Hamburg, M.D., Comm’r of Food and Drugs, Food and Drug Administration), available at <http://www.hsdl.org/?view&did=754891>.

¹⁶⁸ See *Guidance for Industry Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act, Draft Guidance*, U.S. DEP’T OF HEALTH AND HUMAN SERVICES, U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) (July 2014), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf>.

¹⁶⁹ *Id.* at 1 (“This interim guidance describes FDA’s expectations regarding compliance with current good manufacturing practice (CGMP) requirements for facilities that compound human drugs and register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)”).

guidelines, production, testing, and packaging and quality assurance.”¹⁷⁰ This guide includes a section that is likely related to the New England Compounding Pharmacy fiasco,¹⁷¹ which reads: “[c]ertain elements of facility design are considered critical to ensuring the quality of compounded sterile drug products.”¹⁷² “For example, all processing and controlled areas must be clean and free of visible signs of filth, dirt, mold or mildew, insects, and inappropriate items or debris.”¹⁷³

Furthermore, outsourcing facilities must comply with written procedures for production and process controls to ensure that the consistent production of a drug meets the applicable standards of identity, strength, quality, and purity.¹⁷⁴ One benefit of electing to use outsourcing facilities is that the FDA requires testing before a compounded drug is released for distribution.¹⁷⁵ Prior testing will assist the ODRC because outsourcing facilities are required to warrant that the finished product contains the proper identity and strength of the active ingredient.¹⁷⁶ Moreover, by purchasing drugs from outsourcing facilities, the ODRC will know that the drugs comply with proper packaging requirements,¹⁷⁷ be of proper quality, and remain sterile through the labeled expiration date.¹⁷⁸ These regulations allow the ODRC to know that the drugs will produce the intended effects and work properly up until expiration.

Most notable are the strict regulations regarding the equipment utilized in the compounding process, as well as actual testing before the drug is distributed.¹⁷⁹ Before a product can even hit the marketplace, outsourcing facilities must have scientifically proven data to support their reasons for using certain containers or enclosures for the compounded drugs.¹⁸⁰ After selecting appropriate containers or enclosures, these products must be tested to determine whether they can “maintain the quality of the finished drug product and sterility over the expiry period.”¹⁸¹

¹⁷⁰ See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 168 (see table of contents).

¹⁷¹ See text accompanying notes 110-111.

¹⁷² See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 168, at 3.

¹⁷³ See *id.*

¹⁷⁴ *Id.* at 11; see generally 21 C.F.R. § 211.100 (West 2014).

¹⁷⁵ See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 168, at 14; see also 21 C.F.R. § 211.165 (West, Westlaw current through Oct. 30, 2014), see also 21 C.F.R. § 211.167 (West 2014).

¹⁷⁶ See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 168, at 14; see also 21 C.F.R. § 211.160(b) (West 2014).

¹⁷⁷ See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 168, at 19; see also 21 C.F.R. § 211.122 (West 2014).

¹⁷⁸ See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 168, at 18; see also 21 C.F.R. § 211.166 (West 2014).

¹⁷⁹ See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 144, at 7; see also 21 C.F.R. § 211.160(b) (West, Westlaw current through Feb. 5, 2015); 21 C.F.R. § 211.84(d)(3) (West, Westlaw current through Feb. 5, 2015); 21 C.F.R. § 211.184 (West 2015).

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

After selecting containers, outsourcing facilities must engage in pre-releasing testing.¹⁸² Facilities must compare the projected output and the actual output of the drug to fix any inconsistencies.¹⁸³ Any differences between the projected and actual outcome of compounded drugs are considered indicators of potential problems with production and must further be investigated and re-tested.¹⁸⁴ The mandate of pre-release testing guarantees drugs meet the “final product specifications before their release for distribution.”¹⁸⁵ Outsourcing facilities are required to establish quality control units which are responsible for ensuring that the finished drug product is not released until this testing is conducted and the results confirm that the finished drug product meets certain specifications.¹⁸⁶ As an added layer of protection, drugs that are stored for long periods must be retested to verify the proper identity, strength, quality, and purity, or after any exposure to natural elements such as air or heat.¹⁸⁷ Pre-release testing will benefit prisons because the compounded drugs will not only be sterile, but will have also gone through prior testing such that the drugs will produce the intended results. By leaving the testing requirements to the outsourcing facility, prisons will not have to experiment with these drugs on inmates in carrying out a death sentence. All of the requirements imposed on outsourcing facilities act as additional precautionary measures, which will curb the likelihood of another botched execution.

When a compounding pharmacy registers as an outsourcing facility the company is taking a proactive step that illustrates transparency regarding the compounding processes. “Once an outsourcing facility is registered, the FDA will inspect it within two months of registration.”¹⁸⁸ After the initial inspection, subsequent inspections will be based on multiple factors including:

the compliance history of the outsourcing facility; the record, history, and nature of recalls linked to the outsourcing facility; the inherent risk of the drugs compounded at the outsourcing facility; the inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected within the last 4 years; and whether the outsourcing facility has registered as an entity that intends to compound drugs in shortage.¹⁸⁹

¹⁸² See *Guidance for Industry Current Good Manufacturing Practice*, *supra* note 168, at 14; see also 21 C.F.R. § 211.165 (West 2014); see also 21 C.F.R. § 211.167 (West 2014).

¹⁸³ *Id.* at 11.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* at 14.

¹⁸⁶ *Id.*; see also 21 C.F.R. § 211.22 (West 2014).

¹⁸⁷ *Id.* at 10.

¹⁸⁸ See *Information Concerning Outsourcing Facilities Registration*, *supra* note 165.

¹⁸⁹ See *Information Concerning Outsourcing Facilities Registration*, *supra* note 165 (“It is important to note that “registration means *only* that FDA has received the information required to register the facility. It does *not* mean that the facility is making FDA-approved drugs and it does not mean it is in compliance with current good manufacturing practice requirements...””) (emphasis added).

There are some drawbacks when a pharmacy registers as an outsourcing facility. Most importantly, drugs compounded at an outsourcing facility are not FDA approved;¹⁹⁰ however purchasers, such as the ODRC, will know that the facility is complying with good manufacturing practices.¹⁹¹ Additionally, when a pharmacy registers as an outsourcing facility, an annual establishment fee will be imposed upon the company.¹⁹²

There are drawbacks associated when registering as an outsourcing facility, but the benefits of subjecting the compounding process to FDA oversight provide a better safeguard for prisons. By choosing to comply with FDA regulations, “compounders will have an incentive to register as outsourcing facilities in order to enjoy a market advance, because their products may be perceived to be safer than those produced by other compounders.”¹⁹³ Even more beneficial is that the ODRC has several options for choosing an outsourcing facility because as of February 28, 2014, 30 companies had registered as outsourcing facilities.¹⁹⁴ One outsourcing facility is located in Poland, Ohio,¹⁹⁵ which is approximately five hours¹⁹⁶ from Lucasville, Ohio, where inmates are executed at the Southern Ohio Correctional Facility.¹⁹⁷

b. Small-Scale State Regulated Compounding Pharmacies Are Inadequate

Unlike outsourcing facilities, small-scale compounding pharmacies are regulated by state pharmacy boards.¹⁹⁸ State pharmacy boards can be as large as 20 members,

¹⁹⁰ See *id.* (“Drugs made by compounders, including those made at human drug compounding outsourcing facilities, are NOT FDA-approved. This means that they have not undergone the same premarket review as approved drugs. They lack an FDA review of safety and efficacy and of manufacturing quality”).

¹⁹¹ See *id.* (“Although the drugs will not be FDA approved, purchasers of drugs compounded at a registered outsourcing facility that has had a recent satisfactory FDA inspection will have some assurance that the conditions at that facility met applicable current good manufacturing practice standards at the time of the inspection, and the compounded drugs are labeled with the required information”).

¹⁹² See Drug Quality and Security Act Boost Regulation of Compounders, Clarifies FDA Oversight Authority, FDA Enforcement Manual Newsletter (Food and Drug Administration), Jan. 2014, at 2 (“In addition, outsourcing facilities will be subject to an annual establishment fee of \$15,000, adjusted for inflation. A reduced fee for small businesses -- one-third of the full fee amount -- will apply to compounders with annual gross sales of \$1 million or less. A fee in the same amount will be charged for each re-inspection of an outsourcing facility”).

¹⁹³ *Id.* (“In addition, outsourcing facilities -- unlike other compounders -- will be able to compound a drug without having a patient-specific prescription”).

¹⁹⁴ See Fed. Drug Adm’r., Registered Outsourcing Facilities, U.S. FOOD AND DRUG ADMINISTRATION, (Aug. 7, 2015) <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm>.

¹⁹⁵ See *id.*

¹⁹⁶ See MapQuest directions from Lucasville, Ohio to Poland, Ohio, <http://www.mapquest.com/#f9c3783bd47f9f6509621695>.

¹⁹⁷ See *Capital Punishment in Ohio*, *supra* note 27 (“The “Death House” remains at the Southern Ohio Correctional Facility”).

¹⁹⁸ See Denno, *supra* note 13, at 1367-68.

or as small as five members, all who are appointed by the Governor.¹⁹⁹ State pharmacy boards are responsible for all pharmacy practices that occur in the state.²⁰⁰ Inspections of pharmacies occur in different fashions: a scheduled in-person inspection, a surprise inspection, or a self-inspection.²⁰¹ Self-inspections are troublesome because pharmacies submit responses to questionnaires essentially declaring the pharmacy is in compliance with state law.²⁰² Self-inspections may lead pharmacies to exceed the scope of traditional pharmaceutical practices, without any oversight or punishment from a state pharmacy board.

A congressional report highlighted the states overall inability to regulate compounding pharmacies.²⁰³ State pharmacy boards have trouble overseeing pharmacies physically located in the state and therefore can not oversee compounding pharmacies in other states who sell and ship compounded drugs across state lines.²⁰⁴ Further complicating the regulatory scheme is the focus of enforcement efforts. State pharmacy boards focus their efforts on licensing issues, billing violations, failing to register with the state, failing to have a licensed pharmacist on site, and violations related to the use and distribution of drugs.²⁰⁵ Pharmacy boards do not place enough attention on the safety or scope of compounding practices.²⁰⁶

The role state pharmacy boards play in the enforcement of pharmaceutical practices appears to be very low. This congressional report found that states do not have the proper resources, as evidenced by finding number one:

state boards of pharmacy generally do not know which pharmacies engage in compounding, do not know whether pharmacies ship compounded drugs across state lines, and do not know which pharmacies manufacture large quantities of compounded drugs. In many cases, states are incapable of even providing accurate information regarding the numbers of registered pharmacies in their states.²⁰⁷

It is easy to see why many state pharmacy boards do not play an active role in the oversight of compounding pharmacies—a majority of states do not even require a compounding license or permit.²⁰⁸ Even more troublesome is that only 13 state

¹⁹⁹ See Edward J. Markey et al., *State of Disarray, How State's Inability to Oversee Compounding Pharmacies Puts Public Health at Risk*, Homeland Security Digital Library (Apr. 15, 2013), <http://www.hsdl.org/?%20view&did=735130> (Written by Congressman Ed Markey (D-MA), Henry Waxman (D-CA), John Dingell (D-MI), Frank Pallone (D-NJ) and Diana Degette (D-CO)) at 10.

²⁰⁰ *See id.* at 2.

²⁰¹ *Id.* at 10.

²⁰² *See id.*

²⁰³ *See id.*

²⁰⁴ *Id.* at 12.

²⁰⁵ *Id.* at 12-13.

²⁰⁶ *Id.* at 13.

²⁰⁷ *Id.* at 15.

²⁰⁸ *Id.* (Mississippi and Missouri are the only states that require a specific permit or license to track certain compounding practices. *Id.*)

pharmacy boards know which pharmacies are compounding sterile drugs, and Ohio's pharmacy board is not included.²⁰⁹

Another drawback of state regulation is the lack of records kept during inspections. Without records, states cannot evaluate which pharmacies perform reputable and lawful compounding practices, or pharmaceutical practices in general. In fact, over 20 states do not keep any type of historical records of inspection, nor track problems related to compounding.²¹⁰ This means that states have limited knowledge of issues regarding contamination, cleanliness, drug potency, drug safety and bulk manufacturing, just to name a few.²¹¹ Even with a lack of inspection records, states have reported over 2,000 disciplinary actions instituted against compounding pharmacies. Disciplinary actions have stemmed from:

issues of unsafe storage, compounding copies of commercially available drugs, compounding without a prescription, issues with potency, problems with sterility, use of improper ingredients, and manufacturing large quantities of drugs outside the scope of a pharmacy license.²¹²

As most states do not keep any type of inspection records, one can expect that most states do not memorialize the disciplinary process with great detail.²¹³ Therefore, the public is left in the dark as to what pharmaceutical practices were violated, and what, if any, disciplinary actions were taken against a compounding pharmacy.²¹⁴ Even though a few states publish enforcement actions taken against compounding pharmacies on state websites, the public is still left in the dark.²¹⁵ Most websites do not provide enough information for the public to understand the nature of the violation, making it virtually impossible to know what prior compounding issues a facility underwent.²¹⁶ The lack of adequate record keeping highlights the ineffectiveness of state pharmacy boards to regulate compounding pharmacies.

State pharmacy boards are also faced with financial restraints and lack of manpower.²¹⁷ Generally, state pharmacy boards are composed of few representatives who must operate with a very limited budget allocated by the state.²¹⁸ Because budgets vary from state to state, compounding pharmacies in different states must succumb to

²⁰⁹ *Id.* at 17; *see also id.* at 14. (Only thirteen state boards of pharmacy know which pharmacies are providing sterile compounding services and only five of these states have inspectors that are trained to identify problems with sterile compounding. The thirteen state pharmacy boards include: Alabama, California, Connecticut, Delaware, Iowa, Idaho, Massachusetts, New Jersey, New York, Oklahoma, Texas, Virginia and Washington).

²¹⁰ *Id.* at 20.

²¹¹ *See id.*

²¹² *Id.* at 20.

²¹³ *Id.*

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ *Id.* at 25.

²¹⁸ *Id.*

varying standards and frequencies of inspections.²¹⁹ For example, “Nevada currently has a pharmacy board operating budget that provides for approximately \$3,260 per pharmacy, for which the board is responsible for inspecting, while Indiana’s board of pharmacy has an operating budget that provides for approximately \$173 per pharmacy.”²²⁰ The lack of financial resources poses the question of whether state pharmacy boards can provide adequate oversight of the compounding process to ensure the safety of the drugs and protect the public health in general.²²¹ Limited monetary resources go hand in hand with fewer inspectors employed by state pharmacy boards. For example, Ohio employs 22 inspectors, which is a significant number compared to its counterpart states, Vermont, Hawaii and Wyoming, all of which employ fewer than two pharmacy inspectors.²²² Even if state pharmacy boards desired to provide and keep adequate inspection and disciplinary records, it would be virtually impossible due to insufficient capital.

These findings provide only a slight glimpse into the inadequacy of state pharmacy boards to safely and properly regulate compounding pharmacies. The FDA mandates more requirements for outsourcing facilities, which assure prisons that the compounded drugs are suitable for the intended uses.

2. Compounding Pharmacies Have Been Linked to Pain and Suffering

a. Ohio

At 10:31 a.m. after the first syringe was injected²²³ into Dennis McGuire, he took a deep breath and clenched his hands into fists.²²⁴ “He then made a very loud snorting sound which could be heard in the witness room without any sound amplification.”²²⁵ Mr. McGuire then proceeded to “make extremely loud noises like he was grunting and fighting for air at the very same time.”²²⁶ This was one of Ohio’s longest executions since Ohio reinstated capital punishment in 1999.²²⁷

Among the many allegations against the Warden and the ODRC, the family of Dennis McGuire believes that the execution caused Mr. McGuire to suffer serious physical harm, serious psychological harm and a lingering, undignified death in which he endured needless pain and suffering during his execution.²²⁸ Purchasing drugs from compounding pharmacies attributed to the pain and suffering that ultimately led to the botched execution of Dennis McGuire. Furthermore, utilizing compounding

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.*

²²² *Id.* at 26.

²²³ See *In re Dennis R. McGuire*, *supra* note 1, at ¶ 56.

²²⁴ *Id.* at ¶ 59.

²²⁵ *Id.*

²²⁶ *Id.* at ¶ 61.

²²⁷ See Gary Strauss, *Ohio Killer's Slow Execution Raises Controversy*, USA TODAY (Jan. 16, 2014), <http://www.usatoday.com/story/news/nation/2014/01/16/ohio-killer-executed-with-new-lethal-drug-combo/4512651/>.

²²⁸ See *In re Dennis R. McGuire*, *supra* note 1, at ¶ 100.

pharmacies is in direction contradiction with the Ohio death sentence statute,²²⁹ which requires “lethal injection to quickly and painlessly cause death.”²³⁰ Further complicating the execution process is that the terms quick and painless are not defined statutorily.²³¹ This gives prisons unfettered discretion in determining what constitutes quick and painless—as the execution is underway. Only after the death of an inmate, can a court determine whether the execution procedures complied with the ambiguous statutory requirements—but the damage has already been done. That death row inmate has already suffered for a period of time based on the standards and procedures employed by the prison.

b. Oklahoma

Clayton Lockett was executed under Oklahoma’s protocol on April 29, 2014.²³² Similar to Dennis McGuire, Mr. Lockett also experienced horrific complications namely with the IV used.²³³ Once Mr. Lockett’s execution was stopped, he later died in the execution chamber.²³⁴ As a result, the Governor of Oklahoma ordered an independent review to look into the procedures employed prior to and during Mr. Lockett’s execution.²³⁵ This report revealed that the IV had been infiltrated that lead to blood and a clear liquid appearing on Mr. Lockett’s skin.²³⁶ Further, the physician in the execution chamber noticed significant swelling on Mr. Lockett’s body.²³⁷ As a result, the execution was halted just as Mr. Lockett was being injected with potassium chloride.²³⁸ The toxicology report indicated that Mr. Lockett’s blood contained a small amount of the lethal injection drugs.²³⁹ Arguably, the execution was halted for a variety of reasons including the faulty IV, which was injecting drugs which may have been purchased from a compounding pharmacy. The Oklahoma protocol and secrecy

²²⁹ See Ohio. Rev. Code § 2949.22.

²³⁰ *Id.*, see also *In re Dennis R. McGuire*, *supra* note 1, at ¶¶ 55, 66 (highlighting the execution began at 10:27 a.m. and he was pronounced dead at 10:53 a.m., it took over 20 minutes to die); see also Sergo, *supra* note 3 (“According to a 2002 study in the *Journal of Forensic Science*, the average length of time from the first injection to death is 8.4 minutes”).

²³¹ See Ohio. Rev. Code § 2949.22.

²³² See The Execution of Clayton D. Lockett, OKLA. DEP’T OF PUBLIC SAFETY, <http://www.dps.state.ok.us/Investigation/14-0189SI%20Summary.pdf> (last visited Nov. 3, 2014).

²³³ *Id.* at 1.

²³⁴ *Id.*

²³⁵ *Id.* at 2 (On “April 30, Governor Fallin issued Executive Order 2014-11, which appointed Secretary of Safety and Security and Department of Public Safety (DPS) Commissioner Michael Thompson to conduct an independent review of the events leading up to and during Lockett’s execution”).

²³⁶ *Id.* at 18.

²³⁷ *Id.*

²³⁸ *Id.*

²³⁹ *Id.* at 18 (“On May 14 and May 19, OCME [Oklahoma County Medical Examiner] documented the toxicology results they received from NMS Labs on an aliquot of the femoral blood sample they obtained from Lockett’s body on April 30. The results indicated a midazolam concentration of 0.57 mcg/mL and a vecuronium concentration of 320 ng/mL”).

statute did not provide for a seamless execution, as it was eventually halted in the middle of the execution.²⁴⁰ Both of the botched executions in Ohio and Oklahoma illustrate the need to change both execution procedures, which can start with the pharmacies supplying these drugs.

IV. RECOMMENDATIONS TO THE OHIO DEPARTMENT OF REHABILITATION AND CORRECTION

Below is a list of recommendations for the Ohio Department of Rehabilitation and Correction's current execution protocol pertaining to lethal injection. These recommendations may assist in curtailing another botched execution and will provide more transparent information to officials involved in the execution process. The ODRC should consider the following regarding the current lethal injection protocol:

- A. Update the execution protocol sections titled: 'EXECUTION PREPARATION—APPROXIMATELY 14 DAYS PRIOR TO THE EXECUTION'²⁴¹ AND 'EXECUTION PREPARATION—APPROXIMATELY 30 DAYS PRIOR TO THE EXECUTION'²⁴² to explicitly direct the Warden to purchase drugs only from an FDA-registered outsourcing facility.
- B. Update the execution protocol sections titled: EXECUTION PREPARATION—APPROXIMATELY 14 DAYS PRIOR TO THE EXECUTION'²⁴³ AND 'EXECUTION PREPARATION—APPROXIMATELY 30 DAYS PRIOR TO THE EXECUTION'²⁴⁴ to explicitly prohibit the Warden from purchasing drugs from small-scale state regulated compounding pharmacies *and* large-scale compounding pharmacies that do not elect to register with the FDA as an outsourcing facility.
- C. Modify the execution protocol section titled: DRUG PREPARATION'²⁴⁵ to only permit the Warden to use drugs from outsourcing facilities and prohibit the use of drugs purchased from small-scale state regulated compounding pharmacies *and* large-scale compounding pharmacies that do not elect to register with the FDA as an outsourcing facility.
- D. Include a list of potential outsourcing facilities in the execution protocol section titled: DRUG PREPARATION'²⁴⁶—to provide another option of purchasing drugs for lethal injection.

The above-mentioned suggestions are not a complete solution to the various issues related to the execution process. However, these recommendations may help curtail the likelihood of another botched execution from occurring in Ohio. Using outsourcing facilities provides transparency of the drug compounding process, even in light of Ohio's recently enacted secrecy statute.²⁴⁷ Purchasing drugs for lethal injection from an outsourcing facility removes the experimentation factor of whether

²⁴⁰ *See id.* at 1.

²⁴¹ *Id.* at 7.

²⁴² *Id.* at 5.

²⁴³ *Id.* at 7.

²⁴⁴ *Id.* at 5.

²⁴⁵ *Id.* at 11.

²⁴⁶ *Id.*

²⁴⁷ *See generally* *Death Penalty Legislation*, *supra* note 127.

the drugs will properly perform because of the strict FDA requirements. The FDA requirements provide extremely detailed safety, testing and packaging mandates that ensure compounded drugs will produce the intended effect.²⁴⁸ Even in light of Ohio's recently enacted secrecy statute,²⁴⁹ the ODRC can still adjust the execution protocol to list outsourcing facilities as a potential provider of lethal injection drugs.²⁵⁰ If the general option of purchasing from an outsourcing facility is added to the execution protocol, the ODRC could still comply with the secrecy statute²⁵¹ by omitting specific names of outsourcing facilities. These recommendations will provide more concrete regulation to the execution protocol and assist in lowering the chances of another botched execution from occurring.

V. CONCLUSION

The ODRC is not immune to unplanned events occurring during the execution process. In response to the recent botched execution of Mr. McGuire, and the previous botched executions of three other inmates, the ODRC should implement several changes to the current execution protocol. The ODRC continues to amend the drugs used for lethal injection, when the real source of botched executions may not be the actual drugs utilized, but may be where the drugs are purchased.

Previously, Ohio turned to compounding pharmacies to purchase these drugs—facilities that have limited regulation and oversight.²⁵² Compounding pharmacies are traditionally regulated by state pharmacy boards, which typically cannot provide enough oversight to regulate the compounding process.²⁵³ However, compounding pharmacies may elect to register with the FDA as outsourcing facilities.²⁵⁴ Outsourcing facilities are required to follow strict FDA guidelines when compounding drugs to ensure the drugs produce the intended results.²⁵⁵ The FDA is better equipped to regulate the compounding process, as outsourcing facilities must begin the compounding process by testing containers or enclosures that are appropriate for certain compounded drugs.²⁵⁶ Furthermore, outsourcing facilities must go through pre-releasing testing of compounded drugs to ensure the proper identity, strength, quality, and purity.²⁵⁷ When a compounding pharmacy voluntarily elects to register as an outsourcing facility, the compounding process must abide by more stringent safeguards, which in turn assists prisons when purchasing drugs for lethal injection.

²⁴⁸ See generally text accompanying note 170.

²⁴⁹ *Id.*

²⁵⁰ See text accompanying note 245.

²⁵¹ See generally *Death Penalty Legislation*, supra note 127.

²⁵² See Denno, supra note 13.

²⁵³ See Markey, supra note 200.

²⁵⁴ See *Information Concerning Outsourcing Facilities Registration*, supra note 165.

²⁵⁵ See *Protecting the Public Health*, supra note 167.

²⁵⁶ See text accompanying note 180.

²⁵⁷ See text accompanying note 174.

Unlike FDA regulated outsourcing facilities, state pharmacy boards regulate small-scale compounding pharmacies.²⁵⁸ However, state pharmacy boards do not have the financial resources or human capital to adequately oversee the compounding process.²⁵⁹ State pharmacy boards do not focus their efforts to oversee the compounding process, unlike the FDA. Even more problematic is that most state pharmacy boards do not keep any type of adequate records pertaining to inspection or disciplinary actions.²⁶⁰ Without records, the public, people who use drugs purchased from state regulated compounding pharmacies, including prisons, are unaware of the compounding practices. Due to the lack of transparency and ineffective management of state regulation, state pharmacy boards cannot ensure adequate oversight. The FDA provides more reliable and rigorous requirements for the compounding process and has the ability to oversee the entire compounding process—down to the very container used to house the compounded drug.

The main priority for the ODRC should be to change the current practice of utilizing unregulated and state-regulated compounding pharmacies. Instead, the ODRC should be more forthcoming when purchasing these drugs to ensure that the drugs are purchased from a safe supplier with adequate FDA oversight. Ohio should note that the prior mistakes during executions could have been the result of where the ODRC obtained these drugs, and not the actual drug utilized. To start, the ODRC must be more specific in the lethal injection protocol instead of including a long list of potential suppliers. Ohio has the option to amend the execution protocol to add outsourcing facilities as a choice for purchasing drugs. Further, the ODRC can choose to eliminate purchasing drugs from unregulated compounding pharmacies for all upcoming executions.

Outsourcing facilities abide to more stringent safety requirements that can assist in preventing another botched execution from occurring. While outsourcing facilities cannot guarantee a seamless execution, the compounding process is more regulated at the FDA level, as opposed to its counterpart—state pharmacy boards. The ODRC should only purchase drugs for lethal injections from compounding pharmacies that voluntarily choose to register with the FDA as an outsourcing facility.

²⁵⁸ See Denno, *supra* note 13, at 1374.

²⁵⁹ See generally Markey, *supra* note 200.

²⁶⁰ See text accompanying note 210.