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Better the Devil You Know: An Examination of Manufacturer Driven Lethal Injection Drug Shortages

Heather Booth*

ABSTRACT

In 1972, the death penalty, as implemented, was found unconstitutional in Furman v. Georgia. The Supreme Court noted that the death penalty was imposed in such a haphazard manner that the Court considered it to be cruel and unusual punishment. Post-Furman, states reformulated their statutes to comply with the Court’s holding. In a series of cases, beginning with Gregg v. Georgia, the Supreme Court upheld the reformulated statutes, ushering in a new era for executions.

In an attempt to make executions more humane, Oklahoma’s Department of Corrections (“DOC”) consulted a physician to overhaul the state’s execution protocol. This consultation resulted in the implementation of the modern three-drug lethal injection cocktail.

However, recent challenges to lethal injection protocols tell a different story. European-based drug companies, wary of having their products used in executions, have begun refusing to sell drugs to state DOCs. This refusal is mostly with respect to the first drug in the three-drug cocktail, the anesthetic. This refusal has led to drug shortages and improvisation that some doctors say will cause unnecessary pain and suffering during executions. In addition, shortages have increased the cost of these drugs.

One solution to manufacturer-driven shortages is to open a pharmacy in every prison where executions are performed. This pharmacy could compound its own anesthetic. This procedure would ensure DOCs have the most appropriate drugs on hand, making executions both more humane and less costly.

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I. INTRODUCTION

On July 23, 2014, Joseph Wood was put to death by lethal injection.1 His death took two hours.2 He was injected with lethal chemicals 15 times.3 During the execution, Wood “spent an hour of his execution ‘gaspering and snorting’.”4 This scenario has become more common across the country as historic drugs-of-choice have become unavailable, and states have transitioned to unproven alternatives.5 While the death penalty itself has been declared constitutional, the Supreme Court has not specifically weighed in on an appropriate method of administration by which to avoid “cruel and unusual punishment.”6

As of February 2017, 12 states statutorily prohibit the dissemination of information relating to its supplies of lethal injection drugs.7 Shielding the identity of the drug supplier might make it easier for states to obtain the drugs necessary to administer the death penalty, mostly due to the manufacturers’ wish to not be associated with the death penalty.8 However, shielding the identity of the supplier can affect accountability by shielding state policy from judicial review.9 This article argues that if we, as a nation, are going to execute in the name of the state, we should do it

3. Id.; Serwer, supra note 1.
4. Serwer, supra note 1.
9. Id.
correctly—and in the most humane manner possible—every time. In order to achieve that goal, American DOCs either need assistance from both pharmacists and foreign based drug manufacturers, or to proceed in a new direction entirely.

Part II of this article will provide a discussion of the history of lethal injection post-\textit{Furman}. Part III will discuss the reasons behind the shortage of lethal injection drugs. Part IV will examine state responses to those shortages. Part V will consider the lessons for states stemming from the “Death with Dignity” movement and how states can use compounding\textsuperscript{12} to meet the goal of humane executions. Finally, Part VI will address possible actions that states can take to ensure the most effective drugs are available for the administration of lethal injection.

\section{II. LEGAL HISTORY OF LETHAL INJECTION}

\textit{A. Furman and Gregg Reformulate the Death Penalty}

In 1972, the Supreme Court held the death penalty, as then administered, to be unconstitutional.\textsuperscript{13} This ruling came as a result of a consolidated case,\textsuperscript{14} later known as \textit{Furman v. Georgia}.\textsuperscript{15} In \textit{Furman}, three defendants alleged that the punishment of death handed down in their cases constituted cruel and unusual punishment in violation of the Eighth and Fourteenth Amendments.\textsuperscript{16} The Court agreed.\textsuperscript{17} In a \textit{per curiam} opinion, the Court held that the death penalty, as administered by the states of Georgia and Texas, was unconstitutional.\textsuperscript{18} The majority of the Justices opined that the death penalty was being imposed by these states in an arbitrary and capricious manner because it was haphazard.\textsuperscript{19} Justice Stewart specifically stated that this sort of random imposition of the death penalty “[is] cruel and unusual in the same way that being struck by lightning is cruel and unusual.”\textsuperscript{20} Moreover, Justice

\begin{footnotesize}
\begin{enumerate}
\item Discussion of the death penalty’s appropriateness as a punishment, and issues regarding its imposition, are outside the scope of this article.
\item \textit{Furman v. Georgia}, 408 U.S. 238, 239 (1972) (per curiam).
\item See, \textit{e.g.}, \textit{Compounding and the FDA: Questions and Answers}, FDA, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm [hereinafter \textit{Compounding and the FDA}] (last updated June 22, 2018) (compounding is “the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient.”).
\item \textit{Gregg}, 408 U.S. at 239–40 (holding that the imposition of the death penalty in Georgia violated the Eighth and Fourteenth Amendments).
\item The cases consolidated under the umbrella of \textit{Furman} also include actions brought by Lucious Jackson against the State of Georgia and Elmer Branch against the State of Texas. Furman, Jackson, and Branch were all sentenced to death after their convictions; however, Furman was the only one of the defendants whose crime included the murder of his victim. Branch and Jackson were convicted of rape. \textit{Id.} at 252–53; Jackson v. State, 171 S.E.2d 501, 503 (Ga. 1969); Branch v. State, 447 S.W.2d 932, 933 (Tex. Crim. App. 1969).
\item \textit{Furman}, 408 U.S. at 238.
\item \textit{Id.} at 239.
\item \textit{Id.} at 239–40.
\item \textit{Id.} at 239 (none of the Justices in the majority joined in the opinion of any other Justice. Justices Brennan and Marshall believed the death penalty to be cruel and unusual punishment and not comporting with the standards of evolving decency. All four dissenting Justices joined in one opinion).
\item \textit{Id.} at 310 (Stewart, J., concurring) (finding the death penalty to have been “wantonly and freakishly imposed”); see also William Cody Newsome, Note & Comment, \textit{A Promise Unfulfilled: Challenges to Georgia’s Death Penalty Statute Post-Furman}, 33 GA. ST. U. L. REV. 839, 839 (2017).
\item \textit{Furman}, 408 U.S. at 310 (Stewart, J., concurring).
\end{enumerate}
\end{footnotesize}
White determined that, given how infrequently the death penalty was actually carried out, it could not satisfy any rationale for punishment.21

This ruling, in addition to reversing the three death sentences at the center of this case, “invalidat[ed] death penalty statutes in approximately 40 states and over-turn[ed] 600 death penalty sentences.”22 The main issue in all capital jurisdictions was unbridled jury discretion in the imposition of the death penalty.23 Prior to the Court’s decision in Furman, every capital jurisdiction in the country determined a death sentence solely in a unitary trial format.24 This was problematic for many reasons, most notably because of the lack of mitigating evidence presented at such trials.25 Defendants in capital cases were reluctant to introduce such evidence during trial “for fear that a jury might regard such evidence as an indirect admission of guilt.”26 Additionally, juries were “death qualified,” meaning any jurors who refused to consider death for a guilty defendant would have been excluded.27

American support for the death penalty began to decline in the late 1960s.28 In 1966, fewer Americans supported the death penalty than opposed it.29 Once Furman abrogated the death penalty in all jurisdictions, some were of the opinion that new laws would not be written and the death penalty would die out.30 Even the Justices themselves believed the death penalty had seen its last day. Justice Stewart reportedly informed his clerks that “the death penalty in America was finished.”31 Justice Burger, who had dissented in Furman, believed that America had seen its last execution.32 However, this was not the case.

Although public sentiment went against the death penalty, the confluence of several factors ensured its resurgence. First, Furman only held state statutes unconstitutional by a slim majority.33 Not only was the case decided by a 5-4 margin, not one of the Justices in the majority joined in an opinion with any of the others.34 Second, because there were six separate opinions (the five in the majority plus the dissent), there was no clear singular holding.35 Because only Justices Brennan and Marshall held the death penalty unconstitutional on its face, the door was left open for states to attempt to meet the requirements espoused in Furman—namely, to

21. Id. at 311–12 (White, J., concurring).
24. Id.
25. Id. at 44–45.
26. Id. (mitigating evidence is, by definition, culpability reducing. To introduce such evidence during trial would be akin to stating, “I did it, but I should not be put to death because I am not as culpable as the evidence makes me out to be.”).
27. Id. at 45.
29. Id. (according to polling, 47% of Americans were against the death penalty while 42% were in favor).
32. Id.
33. Id.
34. Id.
35. STEIKER & STEIKER, supra note 23, at 60.
check the jury’s unbridled discretion and to make the imposition of death less arbitrary and capricious.36

Third, in addition to the confusion caused by the various opinions in *Furman*, public officials opposed the holding. President Nixon, in 1973, openly called for a return of the death penalty for federal crimes.37 Georgia Governor Lester Maddox publicly stated that the Court’s decision in *Furman* was a “license for anarchy, rape, and murder.”38 This was enough to turn the tide of American sentiment, and beginning in 1972, there was a fresh surge of support for the death penalty.39

In response to *Furman* and public anti-abolitionist sentiment, death penalty states, including Georgia, overhauled their statutes and reenacted legislation in order to resume imposing death sentences.40 Just six months after the Court’s decision in *Furman*, Florida became the first of many states to reinstate the death penalty.41 Thirty-five states in total enacted new laws to comply with the Court’s directives.42 Seven states enacted laws that held a mandatory death sentence for any murder conviction.43 While the remaining states still retained some jury discretion, that discretion was limited by statutory guidance.44

In 1962, the American Legal Institute recommended the Model Penal Code (“MPC”).45 The Council, after some hesitation, included § 210.6, “Sentence of Death for Murder; Further Proceedings to Determine Sentence.”46 Although this section has since been withdrawn,47 it was the blueprint many states used when reformulating their capital punishment statutes.48 The MPC provided that capital punishment was only available for first-degree murder in which the fact-finder

36. *Furman*, 408 U.S. at 290, 369 Justice Brennan wrote that the death penalty was inconsistent with the concept of human dignity. “Death is truly an awesome punishment. The calculated killing of a human being by the State involves, by its very nature, a denial of the executed person’s humanity.” Justice Marshall opined that, if the public possessed all of the available information regarding the death penalty, they would “find it shocking to his conscience and sense of justice.”


39. Jones, supra note 28 (stating that, in 1972, 57% of Americans supported the death penalty).

40. Stein, supra note 22, at 12.

41. *Florida Becomes First to Reinstate the Death Penalty*, N.Y. TIMES (Dec. 9, 1972), http://www.nytimes.com/1972/12/09/archives/florida-becomes-first-to-reinstate-the-death-penalty.html. Florida’s statute bifurcated the trial into a guilt phase and a sentencing phase. During the guilt phase, a jury decided liability and would then recommend either death or life in prison. The trial judge then had complete discretion to determine the fate of defendant, even if it meant overruling the jury’s recommendation.

42. STEIKER & STEIKER, supra note 23, at 62.


44. STEIKER & STEIKER, supra note 23, at 62.


46. MODEL PENAL CODE § 210.6 (A.L.I., withdrawn 2009); ALI REPORT, supra note 45, at 2.

47. See ALI REPORT, supra note 45.

found at least one aggravating circumstance, and that aggravating circumstance outweighed any mitigating circumstances. Additionally, the MPC espoused a bifurcated trial with a guilt phase followed by a sentencing phase. Proceeding in this manner would allow defendants to submit evidence of mitigating factors to the jury without worry of implicit acknowledgement of guilt.

The Court had the opportunity to review the new slate of state statutes in Gregg v. Georgia. Troy Gregg was charged with robbery and murder by the state of Georgia and sentenced to death. Georgia’s new capital punishment system, reformulated post-Furman, required a bifurcated trial. The liability or guilt phase remained the same as in any other trial; the change arose in the sentencing phase. The new sentencing scheme allowed “substantial latitude as to the types of evidence that [the defendant could] introduce.” Moreover, prior to a jury handing down a death sentence, they “must find beyond a reasonable doubt one of the ten aggravating circumstances specified in the statute,” and they must then specify that factor when they impose sentence. Further, the jury’s recommended sentence was binding on the judge. Ultimately, any death sentence handed down in a trial court was automatically appealed to the Georgia Supreme Court.

In a plurality opinion, the Gregg Court held that the newly-reenacted statutory scheme did not violate either the Eighth or the Fourteenth Amendment, clearing the way for death sentences to be carried out across the country. The same could not be said of the states with mandatory death sentences for murder convictions. While the Court did not explicitly strike down mandatory death sentences in Gregg, the Court strongly implied that individualized determinations were required. The Court later explicitly struck down statutes requiring mandatory death sentences.

49. MODEL PENAL CODE § 210.6 (listing eight aggravating circumstances and eight mitigating circumstances).
50. Id.
51. See STEIKER & STEIKER, supra note 23, at 44–45.
53. Id. at 158.
54. Id. at 163 (retaining capital punishment for murder, rape, armed robbery, aircraft hijacking, treason, and kidnapping for ransom or resulting in harm to the victim).
55. Id. at 163–66.
56. Id. at 164.
57. Id. at 164–65. The jury is not required to find the presence of an aggravating factor in cases of airline hijacking.
58. Id. at 166.
59. Id. at 198.
60. Id. at 207. Later cases restricted capital punishment to specific crimes and prohibited for certain types of defendants. See Coker v. Georgia, 433 U.S. 584, 599 (1977) (requiring death of the victim in addition to aggravating circumstances in order to inflict capital punishment on defendant); Ford v. Wainwright, 477 U.S. 399, 408 (1986) (holding the Eighth Amendment insulates the insane from capital punishment); Atkins v. Virginia, 536 U.S. 304, 321 (2002) (holding that the mentally handicapped cannot be sentenced to death); Roper v. Simmons, 543 U.S. 551, 575 (2005) (prohibiting the death penalty for juveniles).
61. See Gregg, 428 U.S. at 180–81.
62. Id. at 206.
B. Post-Gregg Lethal Injection

After Gregg affirmed the constitutionality of the death penalty, states resumed executions.64 In 1977, a medical examiner from Oklahoma proposed the modern, three-drug cocktail for lethal injection: a barbiturate to anesthetize the inmate; a paralytic agent to immobilize him; and potassium to stop the heart.65 Oklahoma’s legislature adopted this as the official method of executions.66 Texas followed suit just one day later.67 On December 7, 1982, Texas became the first state to execute an inmate by lethal injection.68 Currently, 33 states have statutes approving lethal injection as the primary method of execution.69 Eight states have carried out lethal injections using a single dose of anesthetic.70 Since 1976, there have been 1,473 executions—1,298 by lethal injection.71

While the method of execution is consistent across those 33 states, the protocol varies from state to state.72 Deviation from the original three-drug cocktail of sodium thiopental (“thiopental”), pancuronium bromide (“pancuronium”), and potassium chloride has become more common as the availability of these chemicals has decreased.73 This decrease is due in large part to European based drug manufacturers’ refusal to provide these pharmaceuticals to departments of corrections.

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67. TEX. CODE CRIM. PROC. ANN. art. 43.14 (West 2015).


69. Methods of Execution, DEATH PENALTY INFO. CTR., https://deathpenaltyinfo.org/methods-execution (last visited Nov. 21, 2018) [hereinafter Methods]. Several states have alternate methods of execution available by statute in case lethal injection chemicals are not available or lethal injection be declared unconstitutional. See, e.g., OKLA. STAT. ANN. tit. 22, § 1014 (West 2017) (providing that, should lethal injection be deemed unconstitutional, execution shall be administered via gas chamber, electrocution, or firing squad).

70. State by State, supra note 7 (indicating that the states that have executed using only a single drug have either used pentobarbital or sodium thiopental).

71. Methods, supra note 69. These numbers include executions up to and including April 19, 2018.

72. See State by State, supra note 7.

In response to the decreased availability of thiopental, many states switched to using pentobarbital as the barbiturate of choice. However, drug manufacturers, mostly based in Europe, have placed distribution controls on drugs that are commonly used in executions. This has left states scrambling to find new—and untested—drugs to use for lethal injection protocols. For example, Florida executed Mark Asay using a combination of etomidate to anesthetize, rocuronium bromide to paralyze, and potassium acetate to stop the heart. This execution protocol is particularly concerning because etomidate was never before used in an execution, and potassium acetate was only used before on accident.

Due to the shortage of pentobarbital, many states have moved to administering midazolam as the first drug in the three-drug cocktail. Midazolam differs from the traditionally used anesthetic pharmaceuticals in that it is a sedative used for short term procedures, which results in the patient having little to no memory of the procedure. However, it does not produce a deep anesthesia such as traditional anesthetic agents do. Although controversial, the Court held that the use of midazolam in executions does not violate the Eighth Amendment’s prohibition of cruel and unusual punishment because “the prisoners failed to establish that Oklahoma’s use of a massive dose of midazolam in its execution protocol entails a substantial risk of severe pain.”

Critics of these new lethal injection protocols have argued that these new combinations of drugs are untested and unproven. Additionally, some have called the use of these untested protocols akin to human experimentation—an assertion which,
if true, implicates a whole spate of other regulatory issues.85 One Florida Supreme Court Justice went so far as to call Assay, the inmate executed by injection of etomidate, “the proverbial guinea pig of [Florida’s] newest lethal injection protocol.”86 Moreover, some physicians have stated the current three-drug protocol is so inhumane, due in large part to the paralytic component, that it has been deemed inappropriate even in animal euthanasia.87

The Court’s decisions in Furman,88 Gregg,89 Glossip,90 and Baze91 caused states to reformulate death penalty statutes to follow the Court’s directives. Currently, state statutes overwhelmingly prefer lethal injection;92 however, those statutes are becoming increasingly difficult to implement given the shortage of lethal injection pharmaceuticals.

III. THE SHORTAGE OF LETHAL INJECTION PHARMACEUTICALS

A. Sodium Thiopental

Until 2011, the anesthetic of choice for lethal injections was thiopental.93 However, this changed as the supply of thiopental dwindled.94 Hospira, the only American manufacturer of thiopental, ceased production in 2009 after citing quality control issues.95 While Hospira planned to resume production at a plant in Italy, those plans became unworkable as Hospira was “unwilling to take on the liability risk after government officials in Italy demanded the company ‘control the product all the way to the ultimate end user to prevent use in capital punishment.’”96 Hospira decided not to risk it and exited the thiopental market altogether.97

88. 408 U.S. 238 (1972) (per curiam).
92. See Methods, supra note 69.
93. See State by State, supra note 7; Horne, supra note 73.
94. Horne, supra note 73 (detailing the need to change drug protocols due to drug shortages that occurred with Hospira ceased manufacturing sodium thiopental in the United States).
96. Jaspen, supra note 95.
97. Id.
Thiopental’s use in the United States predated the implementation of the Food, Drug, and Cosmetic Act (“FDCA”) of 1938 and, therefore, has never been approved by the Food and Drug Administration (“FDA”) for importation.98 It is “unlawful to introduce into interstate commerce a misbranded drug, or an unapproved new drug” under the terms of the FDCA.99 Drugs are considered misbranded if they are imported by a manufacturer not currently registered with the FDA.100

All new drugs101 must pass a rigorous FDA application process, or, in the alternative, must satisfy two requirements.102 The first requirement is that the drug must have been shown to be “generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested” on the label.103 Second, even supposing that the drug has been shown to be “[generally recognized as safe and effective] as a ‘result of investigations to determine its safety and effectiveness for use under such conditions,’” it is still considered a new drug unless it has been in use in conditions other than the investigative process “to a material extent or for a material time under such conditions.”104 These regulations have been implemented to ensure that drugs entering the United States from foreign wholesalers and distributors meet a certain safety standard.105

So long as Hospira continued to manufacture thiopental in the United States, these statutes were not implicated.106 However, in 2011, when Hospira ceased production, there were no remaining manufacturers located in the United States.107 As the supply of thiopental disappeared in the United States, some states attempted to import the drug from less than reputable sources.

Several states ordered a supply of the drug from a British based distributor known as Dream Pharma.108 Dream Pharma obtained the finished thiopental it sold to American DOCs from Archimedes Pharma UK, Ltd., who obtained unfinished

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98. See Matthew Gunther, Sodium Thiopental, CHEMISTRY WORLD (Mar. 11, 2015), https://www.chemistryworld.com/podcasts/sodium-thiopental/8360.article. Sodium Thiopental was first discovered in the late 1930s and was first used as an anesthetic on humans in 1934. Cook, 733 F.3d at 4.
99. 21 U.S.C. § 331(a) (2018); Cook, 733 F.3d at 3.
100. Id. § 352(o) (2018).
101. Id. § 355(a) (2018). Any drug introduced into interstate commerce without having first been approved by the FDA is considered an unapproved new drug.
102. See id. § 355(b).
103. Id. § 321(p)(1) (2016).
104. Id. § 321(p)(2) (2009); E-mail from Todd W. Cato, FDA Dir., Sw. Imp. Dist. Office, at 11 (Apr. 20, 2017), https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM555237.pdf (internal quotations and citations omitted) [Hereinafter Cato Letter]; U.S. v. Premo Pharm. Labs., Inc., 511 F. Supp. 958, 976 (D.N.J. 1981) (stating that the decision as to whether a drug has been used to a material extent or for a material time is subject to determination by the FDA).
thiopental from Sandoz.109 None of these parties were registered with the FDA or authorized to distribute thiopental to any purchaser in the United States.110

In *Cook v. Food and Drug Administration*, the United States Court of Appeals for the District of Columbia Circuit decided whether the FDA had discretion to ignore statutory requirements to seize and test any drug shipments from unregistered distributors entering the United States.111 Several death row prisoners brought suit against the FDA after the FDA publicly stated that it would not be reviewing shipments of thiopental sent to states’ DOCs.112 The FDA further stated it would be deferring to the determinations of local law enforcement agencies.113

The plaintiffs alleged that the FDA’s statement violated the Administrative Procedure Act (“APA”) in that the FDA’s decision was not in accordance with the FDCA.114 The FDA argued that it had discretion whether to review imported shipments of thiopental, while the plaintiffs argued that the FDA was bound by the FDCA to refuse admission to any drug shipment that did not meet statutory requirements.115 The district court entered summary judgment on behalf of the plaintiffs in this case, and, in a separate order, “permanently enjoined the FDA from permitting the entry of, or releasing any future shipments of, foreign manufactured thiopental that appears to be misbranded or an unapproved new drug.”116 Further, the district court required the state’s DOC to return the thiopental in its possession as “the use of such [foreign manufactured thiopental] is prohibited by law.”117

The relevant statutory language provides that if imported drugs are from an establishment not registered with the FDA, samples of the drugs must be sent to the Secretary of Health and Human Services for review.118 Additionally, “[i]f it appears from the examination of such samples or otherwise that . . . such article is adulterated, misbranded, or [an unapproved new drug] . . . then such article shall be refused admission.”119

This statutory language clearly and unambiguously imposes a mandatory requirement for the FDA to seize any and all shipments of drugs from non-registered facilities and detain them if it finds that they do not meet the requirements of the FDCA. The FDA argued its decisions were not justiciable and “the court should defer to its interpretation of the statute.”120 Moreover, even if, *arguendo*, the FDA’s decision was justiciable, “the court should defer to the FDA’s interpretation of the statute.”121

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109. *Cook v. FDA*, 733 F.3d 1, 4 (D.C. Cir. 2013). Sandoz is a German company which was producing sodium thiopental in its plant in Austria.
111. *Cook*, 733 F.3d at 1.
112. *Id.* at 4.
113. *Id.* at 4.
114. *Id.* at 3.
115. *Id.* at 4–5.
116. *Id.* at 5 (internal quotation marks omitted).
117. *Id.*
119. *Id.*
120. *Cook*, 733 F.3d at 4–5.
121. *Id.* at 5.
The Cook court disagreed. The plain, unambiguous meaning of the text of the FDCA “imposes mandatory duties upon the agency charged with its enforcement.” The text of the statute provides that the FDA “shall” refuse admission to any drug shipment that “violates a substantive prohibition of the FDCA.” The court agreed with the plaintiffs that “the ordinary meaning of ‘shall’ is must.” In this case, the preparing facility was owned by Archimedes, which the FDA stipulated was not a registered facility. Moreover, the FDCA imposes a duty on the FDA to deny admission to any shipment that “appears to violate the substantive prohibitions of the FDCA.” The FDA stipulated that “the thiopental in these shipments ‘clearly appears’ to be an unapproved new drug.” By both refusing to examine the thiopental drug shipments—and by allowing the import of those shipments—the FDA had ignored its duty to follow the commands of the FDCA, and therefore, it violated the law.

The appeals court affirmed the ruling of the district court as to the grant of summary judgment and the permanent injunction against the FDA. However, the court vacated the requirement that the thiopental be returned as the district court did not properly join the state DOC. While the ruling in Cook legally precluded state DOCs from importing thiopental from manufacturers, that did not stop them from attempting to obtain the drug; states such as Arizona, Texas, and Nebraska have continued to purchase the drug from international sources.

B. Pentobarbital

Once state DOCs realized they could no longer obtain thiopental for executions, the pressure was on to find a viable alternative. Pentobarbital, another short-acting barbiturate, was still regularly used in for legitimate medical purposes in American hospitals. It should have been easy to procure; however, Lundbeck, the lone supplier of injectable pentobarbital, took umbrage at state DOC’s intention to transition from thiopental to pentobarbital. While Lundbeck’s corporate governance disagreed with the decision, they decreed they “had no way of keeping the

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122. Id. at 12.
123. Id. at 7.
124. Id. (internal quotations omitted).
125. Id. at 11.
126. Id.
127. Id.
128. Id.
129. Id. at 12.
130. Id.
131. Id.
drug out of death chambers [because] once they sell a product, they have no control over how it is used.”135 Part of the issue was that, unlike thiopental, pentobarbital was manufactured at a plant located in Kansas.136 Given pentobarbital’s domestic manufacture, Lundbeck would not be able to use strict import or export rules to keep the drugs from being sold to state DOCs.137

However, Lundbeck soon changed its mind. In a statement from Lundbeck’s chief executive, Ulf Wiinberg, the company outlined its new policy regarding drugs possibly used for capital punishment: a strict down-stream distribution control with a goal of excluding sales to state DOCs.138 “While the company has never sold the product directly to prisons and therefore [cannot] make guarantees, we are confident that our new distribution program will play a substantial role in restricting prisons’ access to [pentobarbital] for misuse as part of lethal injection.”139

C. European Corporate Morality and Abolitionist Sentiment

Drive Shortages

For decades, Europe has sought the world-wide abolition of the death penalty.140 In fact, abolitionist sentiment is such a part of the European Union’s (“EU”) identity that to be admitted to the EU, a country must first ratify, among other laws, Protocol No. 6 to the European Convention of Human Rights,141 a piece of legislation which concerns the abolition of the death penalty.142

The EU, after securing the abolition of the death penalty from the vast majority of Europe,143 set its sights on the rest of the world, including the United States.144 Indeed, the EU touts itself as “the leading institutional actor and largest donor in the fight against [the] death penalty worldwide.”145 For years, the EU has attempted to legally influence America’s decisions on the death penalty, both directly and indirectly, to no avail.146 The EU passed numerous protocols and regulations regarding abolition of capital punishment and attempted to encourage organizations to take

135. Bluestein, supra note 133.
136. Id.
137. Id.
139. Jolly, supra note 134.
142. Id.; see also EUROPEAN UNION, Joining the EU, https://europa.eu/european-union/about-eu/countries_en#joining_the_eu (last visited Apr. 5, 2018) (explaining that joining the EU requires accepting all EU legislation).
143. Belarus is the only remaining hold-out. Oliver Smith, Mapped: The 58 Countries That Still Have the Death Penalty, TELEGRAPH (July 6, 2018, 12:00 PM), http://www.telegraph.co.uk/travel/maps-and-graphics/countries-that-still-have-the-death-penalty/.
145. Fight Against Death Penalty, supra note 140.
146. See id. (providing an overview of the EU’s attempt to abolish the death penalty).
up the banner of abolition; however, it has had no effect on the use of capital punishment in the United States.\textsuperscript{147} The EU filed amicus briefs in capital punishment cases before the Supreme Court.\textsuperscript{148} Additionally, the International Court of Justice ("ICJ") issued its own stay in the case of Angel Breard—a stay the Supreme Court ignored.\textsuperscript{149} Moreover, EU member states "refuse to extradite fugitives to retentionist\textsuperscript{150} states in the absence of assurances that the death penalty will not be sought."\textsuperscript{151} None of this legal maneuvering had any effect whatsoever, so the EU changed tactics.

The EU’s Charter of Fundamental Rights states that "[e]veryone has the right to life" and "[n]o one shall be condemned to the death penalty, or executed."\textsuperscript{152} To that end, the EU has repeatedly proposed guidelines and policies aimed at abolishing the death penalty worldwide.\textsuperscript{153} This legislation has included strict export controls on drugs known to be used in capital punishment.\textsuperscript{154}

In 2005, the EU passed a regulation "ban[ning] the export and import of goods which can only be used to apply the death penalty."\textsuperscript{155} However, this regulation did not explicitly include pharmaceuticals in the list of prohibited goods.\textsuperscript{156} Instead, it included items that could be used in the death chamber, such as automatic injection systems or electric chairs.\textsuperscript{157} This left responsibility for down-stream drug controls to the individual manufacturers.

Some manufacturers, such as Lundbeck, did institute their own controls.\textsuperscript{158} Lundbeck’s system required individual corporate authorization for every order.\textsuperscript{159} Additionally, purchasers had to sign an agreement, averring that the pentobarbital they purchased was to be used exclusively in the treatment center or hospital that

\begin{footnotesize}
\begin{enumerate}
\item[149.] David Stout, \textit{Clemency Denied, Paraguayan is Executed}, N.Y. TIMES (Apr. 15, 1998), http://www.nytimes.com/1998/04/15/us/clemency-denied-paraguayan-is-executed.html (Breard was a Paraguayan citizen who was executed in Virginia in 1998. The ICJ alleged that Breard’s execution and detention were in violation of the Vienna Conventions as, when he was arrested, he was not notified "of his right to confer with Paraguayan consular officials. . . .").
\item[150.] Retentionist states refer to those states that “retain” the death penalty as a legal method of punishment. \textit{Abolitionist and Retentionist Countries}, DEATH PENALTY INFO. CTR., https://deathpenaltyinfo.org/abolitionist-and-retentionist-countries (last visited Nov. 21, 2018).
\item[152.] Charter of Fundamental Rights of the European Union, tit. 1, art. 2, 2012 O.J. (C 326) 1.
\item[153.] \textit{Fight Against the Death Penalty, supra} note 140.
\item[154.] Council Regulation 1236/2005, art. 5, 2005 O.J. (L 200) 1 (EC); Council Regulation 2016/2134, art. 7b, 2016 O.J. (L 338) 1 (EU).
\item[156.] Council Regulation 1236/2005, ch. 2 art. 3, 2005 O.J. (L 200) 1 (EC).
\item[157.] \textit{Id.} at annex II.
\item[159.] Lundbeck, \textit{supra} note 138.
\end{enumerate}
\end{footnotesize}
purchased it. Moreover, the purchaser had to agree to not re-distribute the pento-barbital without express consent from Lundbeck. Such authorizations were available only to hospitals and treatment centers; any order from a prison in a state that carried out capital punishment would be denied.

In 2016, the EU tightened the noose by explicitly banning the export of pharmaceuticals that could be used for capital punishment, including thiopental and pentobarbital, to non-abolitionist countries. However, the ban is not absolute. The regulation sets up a complicated export authorization system, specifically “designed to prevent [the exported goods] from being used for capital punishment.”

This system requires any destination country that has not abolished capital punishment (or “confirmed that abolition through an international commitment”) be subject to a thorough examination prior to any export potentially capable of being used for capital punishment. Such an examination would require a risk assessment regarding the likelihood “that the end-user . . . would use the exported goods for such punishment” and would require “appropriate conditions and requirements . . . be imposed to control sales or transfers to third parties by the end-user.”

Although much of the regulation is targeted towards destination countries that have not abolished capital punishment, there is language acknowledging the danger of export even to abolitionist countries. Even if the destination has abolished the death penalty, “there is [still] a risk of re-export to countries that have not done so [and] certain conditions and requirements should be imposed when authorising [sic] exports to countries that have abolished capital punishment.” Additionally, goods originating from non-EU territories are prohibited from travel through the EU without prior authorization, as they could be destined for use in capital punishment.

The regulation is also forward-thinking. It explicitly states that, not only will exports of goods historically used for capital punishment be subject to scrutiny and authorization, so will “goods whose use for capital punishment [has been] approved, without . . . having [been] used for that purpose yet.” Moreover, language was added to create a procedure to add goods to the list, should the need arise.

While this type of legislation sounds good in theory, it lacks teeth. Penalties for violating this regulation are rare, as the EU has left it up to the individual state to “lay down the rules on penalties applicable to infringements of the provisions of

160. Id.
161. Id.
162. Id.
163. Council Regulation 2016/2134, annex IIIa, 2016 O.J. (L 338) 1 (EU). The list includes “products containing one of the [controlled products].”
164. See id. at art. 7c.
165. Id. at preamble ¶ 3.
166. Id. at preamble ¶ 6.
167. Id.
168. Id. at preamble ¶ 5.
169. Id.
170. Id. at art. 6a.
171. Id. at preamble ¶ 9.
172. Id. at art. 15b.
this Regulation and shall take all measures necessary to ensure that they are implemented. The only guidelines given for penalties are that they should be “effective, proportionate[,] and dissuasive.”

However, it is possible that the offending country could receive some form of sanction for violating EU law. The Court of Justice of the European Union (“CJEU”) exists to ensure that EU law is applied uniformly in all member states. The European Commission, or any other member state, can bring an infringement action before the CJEU to enforce EU law. If the court finds the member state has failed to uphold EU law, the offending state has the opportunity to correct the error. If it refuses to correct the error or it ignores the court’s judgment, the Commission “may, when it deems appropriate, specify the amount of the lump sum or penalty payment to be paid by the Member State concerned which it considers appropriate in the circumstances.” The court can then impose a fine up to the amount specified by the Commission. This is more of a public shaming than an effective sanction as the offending state has several opportunities to correct its actions prior to any true sanction being applied.

Supreme Court decisions changed the legal landscape of the death penalty. While the Court has repeatedly upheld the constitutionality of lethal injection, there are still challenges to its implementation. Manufacturer-driven shortages have contributed to a strange scenario playing out across the country—state DOCs are taking extreme steps to continue executions. These include attempting to import drugs illegally, switching up protocols to try new and untested drugs, and outright deceiving manufacturers and distributors to obtain drugs.

While it could be argued that the choice to switch drugs without any evidence that they will work could create a “substantial risk of serious harm,” the Court has never agreed with that proposition. It seems that states have taken the Court’s refusal to side with inmates as a free pass to experiment with their execution drug choices, and states have proceeded, unconstrained, in their quest to continue executions.

IV. STATE RESPONSE TO SHORTAGES

A. Lethal Injection Drug Choice Hot Potato

Between European manufacturers refusing to provide drugs to states for lethal injection purposes and the holding in Cook, leaving state DOCs scrambling for sources of execution drugs. While some states decided to go back to the drawing

174. Id. For example, the United Kingdom has enacted the embargo on goods that could possibly be used in capital punishment. The penalties for violating the embargo include fines and possible prison time. See Export Control Order, 2008, SI 2008/3231, art. 6, ¶ 34 (UK).
176. 2012 O.J. (C 326) 47 at art. 258.
177. Id. at art. 259.
178. Id. at art. 260.
179. Id.
board to create new drug cocktails, or enact new privacy and secrecy laws, several states decided to attempt to import thiopental illegally.181 In 2015, the FDA stopped a shipment of thiopental bound for Arizona.182 Earlier that same year, the FDA stopped a shipment of thiopental headed for Nebraska.183 Arizona attempted to purchase 1,000 vials of thiopental for use in executions within the state.184 Although the shipping documents for the Arizona shipment were redacted, they were virtually identical to shipping documents contained in the Nebraska shipment.185 Both shipments seemingly came from Harris Pharma, an Indian supplier.186 While the Arizona DOC likely knew importing thiopental was prohibited, it still filled out all the appropriate Drug Enforcement Agency (“DEA”) forms needed to import the drug.187 The DEA accordingly notified the FDA of the attempted purchase, enabling the FDA to stop the shipment before it left for its final destination.188

In response to the inability to obtain thiopental, Arizona switched to using pentobarbital for executions.189 Once pentobarbital also became unavailable, Arizona switched to a drug cocktail containing midazolam.190 However, the change to midazolam was unsustainable as the botched execution of Joseph Wood in 2014 resulted in a lawsuit that kept Arizona from executing anyone since.191 In response, Arizona concocted a novel and bizarre invitation to those on death row: bring your own execution drugs.192 Aside from the impossibility of going to your local drug store and picking up a vial of pentobarbital (or other similar drug), it is highly unlikely that any death-row inmate would willingly hasten their own execution by obtaining their own execution drugs.193

Arizona is not alone in its zealotry. In 2017, the Arkansas DOC was sued by McKesson, a pharmaceutical distributor, in relation to a supply of vecuronium.194

182. Id.
183. Id.
184. Id.
185. Id.
186. Id. While neither the DOC nor the FDA confirmed Harris Pharma as the source of the thiopental, the redacted Arizona documents were nearly identical to documents obtained by the American Civil Liberties Union in relation to the attempted purchase by Nebraska.
187. The main issue with this attempted purchase is that thiopental cannot legally be imported as it has never been approved for use for any purpose by the FDA. See id.
188. Id.
189. Id.
190. Id. Pentobarbital became unavailable because European manufacturers instituted distribution controls on drugs in connection with lethal injections.
192. Arizona Drugs, supra note 191.
193. Id.
McKesson alleged the Arkansas DOC obtained the supply of vecuronium by misrepresenting the intended use for the drug. According to the complaint filed by McKesson, the Arkansas DOC represented that the vecuronium would be used for a legitimate medical purpose—namely, treatment of medical patients. Further, McKesson alleged the Arkansas DOC did all of this with the knowledge that McKesson did not allow sales of vecuronium to facilities that “administer capital punishment.” In fact, the Deputy Director of the Arkansas DOC, Rory Griffin, was aware that McKesson had such distribution controls in place, and that the sales agent who entered the order made a mistake in doing so.

Once McKesson discovered that supplies of its vecuronium had been sent to the DOC facility, it requested the return of the product, issued a full refund to the Arkansas DOC, and sent a prepaid shipping label to facilitate the return of the drug. The Arkansas DOC refused to return the drug unless McKesson would supply an alternative product for use in executions. In response, McKesson sought injunctive relief in Pulaski County Circuit Court, Arkansas, namely because the publication of McKesson’s involvement in this matter could cause “grave reputational harm for being associated with the planned execution of the seven inmates using products the manufacturer banned for such purpose.” McKesson requested the court to grant an injunction barring the Arkansas DOC from using the vecuronium in the upcoming executions and also requested an order requiring the vecuronium to be returned to McKesson.

The circuit court granted a temporary restraining order (“TRO”), finding that McKesson had proven both irreparable harm and a likelihood of success on the merits. The Arkansas DOC appealed, after which McKesson requested the TRO be vacated as a federal preliminary injunction halting the executions rendered the TRO moot. However, McKesson refiled its complaint requesting an injunction on April 18, 2017. The state court again found for McKesson and again issued a

195. McKesson Complaint, supra note 194. This supply became the center of national news when Arkansas attempted to execute eight men in ten days due to the expiration of its supply of midazolam. Only four men were executed; the remaining executions were stayed for various reasons. Background on Arkansas April 2017 Executions, DEATH PENALTY INFO. CTR., https://deathpenaltyinfo.org/Background_on_Arkansas_April_2017_Executions (last visited Nov. 22, 2018).
197. Id. at ¶ 18.
198. Id. at ¶ 30–32.
199. Id. at ¶ 21–22.
200. Id. at ¶ 24.
201. Id. at ¶ 39.
202. Id. at ¶ 13.
TRO. The TRO was stayed by the Arkansas Supreme Court. Executions commenced April 20, 2017, and Ledell Lee was executed with the three drug cocktail that included the vecuronium purchased from McKesson.

B. State Secrecy Laws

In response to shortages and refusal of drug manufacturers to send execution drugs from Europe, states have increasingly turned to compounding pharmacies and concealment. In most cases, these back-room dealings are protected by an ever-increasing litany of privacy laws that shield everyone involved, including both the individuals present in the execution chamber and the drug manufacturers. This secrecy is controversial. On one hand, keeping the manufacturer of the execution drugs a secret could facilitate obtaining the best possible drugs for the execution. On the other hand, states can skirt regulations and processes that ensure safe and effective drugs in the name of privacy. Additionally, some state secrecy laws are being challenged on the grounds that the First Amendment gives citizens the right to know how prisoners are to be executed “in the name of the people.”

As of 2018, 24 states have laws on the books protecting at least some portion of the execution team. Twelve states have laws that explicitly protect the supplier of execution drugs. Some statutes are broader than others. For example, Ohio law requires the state to keep confidential the identity of any person who does the following:

- manufactures, compounds, imports, transports, distributes, supplies, prescribes, prepares, administers, uses, or tests any of the compounding equipment or components, the active pharmaceutical ingredients, the drugs or combination of drugs, the medical supplies, or the medical equipment used in the application of a lethal injection of a drug or combination of drugs.

210. See Dart, supra note 7.
212. Id. This may be the first time a challenge to state secrecy has been brought under the First Amendment.
213. Dart, supra note 7. These states are Arizona, Arkansas, Florida, Georgia, Idaho, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, and Virginia.
214. Dart, supra note 7. These states are Arizona, Florida, Georgia, Mississippi, Missouri, North Carolina, Ohio, Oklahoma, South Dakota, Tennessee, Texas, and Virginia.
215. OHIO REV. CODE ANN. § 2949.221(B) (West 2015).
This statute is incredibly broad and potentially covers every person who encounters the execution, or any of its component parts, in any fashion. While it would make sense to protect the identities of those physically present at the execution, this statute far overreaches that small group of individuals.

Confidentiality in this context applies not only to informational requests, but also to disclosure in judicial proceedings, including “discovery, subpoena, or any other means of legal compulsion.”216 Ohio law does authorize disclosure to the Ohio ethics commission to ensure that drugs are provided in accordance with ethics laws and licensure requirements.217 While this is a step in the right direction, ensuring compliance with licensure requirements is not enough. There appears to be no mechanism for testing a compounded drug’s potency or quality, and such testing should be required for compounded lethal injection drugs.218 A pharmacy may be licensed to compound or provide drugs, but licensure does not ensure the adequacy of the drugs themselves.219

While similar to Ohio’s statute, Georgia has gone a step further and classifies the source of execution drugs as a “state secret.”220 This law has been the subject of continuing challenges by death row inmates, and this is especially problematic given the Court’s decisions in Baze and Glossip regarding the necessary showing for a constitutional challenge.221 To be successful, the challenger must first establish that there is a “substantial risk of serious harm.”222 Then, the challenger must provide an alternative method that is “feasible, readily implemented, and in fact significantly reduces a substantial risk of severe pain.”223 The court will deem the method of execution an Eighth Amendment violation only if the challenger carries this burden, and the state refuses to adopt the alternative method.224

Georgia law has essentially made an Eighth Amendment challenge impossible for its death row inmates. If the inmates do not know which drugs are to be used in their executions, or where the drugs come from, they cannot make a showing that there is “substantial risk of serious harm,”225 let alone provide an alternative method. However, Georgia’s courts have disagreed.

216. Id. § 2949.221(B)(1)-(3).
217. Id. § 2949.221(B)(4)(a).
218. See id. at § 2949.221(B) This section provides for confidentiality of any individual that tests the drugs, if such testing occurs. There is no statutory requirement that the drugs be tested at all.
219. See Press Release, FDA Office of Criminal Investigations, Outbreak was the Largest Public Health Crisis Ever Caused by a Pharmaceutical Product (Oct. 25, 2017), https://www.fda.gov/ICECI/CriminalInvestigations/ucm582187.htm; see also Ed Silverman, Safety Issues at Compounding Pharmacy Undergo Oversight Problems, STAT (Apr. 8, 2016), https://www.statnews.com/pharmalot/2016/04/08/compounding-pharmacy-drug-safety-fda/ (this concern was especially acute in 2012, when 12,000 vials of a steroid contaminated with fungal meningitis were shipped around the country, infecting 753 patients in 20 states, 64 of whom died). Multistate Outbreak of Fungal Meningitis and Other Infections – Case Count, CDC, https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html (last updated Oct. 30, 2015). See also discussion infra Section V.B.
221. Baze v. Rees, 553 U.S. 35, 50 (2008) (requiring the inmate to show, in order to prevail on an Eighth Amendment claim, that the procedure entail an “objectively intolerable risk of harm.”); Glossip v. Gross, 135 S. Ct. 2726, 2737 (2015) (holding that “prisoners must identify an alternative that is feasible, readily implemented, and in fact significantly reduces a substantial risk of severe pain.”).
222. Baze, 553 U.S. at 50.
223. Id. at 52.
224. Id.
225. Id. at 50.
In Owens v. Hill, the Georgia Supreme Court reversed the trial court’s injunction in favor of inmate Warren Hill. The court noted that Hill was provided information that the drug had come from a compounding pharmacy, but there is no indication that Hill was provided with information about whether the drug had been tested for potency or contaminants. The court discounted Hill’s arguments regarding possible harm due to contaminants or potency, stating that while Hill’s claim of possible “side effect[s] obviously would be shockingly undesirable in the practice of medicine, [they are] certainly not a worry in an execution.”

Moreover, the court reasoned if Hill’s challenge was more colorable under the Baze standard, meaning that, but for the secrecy statute Hill’s claim might be meritorious, then the constitutionality of the secrecy statute might legitimately be questioned. However, the court also voiced a reluctance to reach the constitutional question and stated such an analysis might be avoided by providing other forms of “discovery not forbidden by the execution-participant confidentiality statute.”

Brandon Jones mounted a challenge similar to Hill’s in 2016. The Georgia Supreme Court held that Jones did not show the Georgia statute violated his right to due process. Additionally, Jones did not show the method of execution would put him at a substantial risk of harm, nor did he provide a reasonably feasible alternative. While Hill may not have shown an alternative method, such a showing would be nearly impossible given the barrier to access of information regarding the state’s chosen method.

The Missouri secrecy statute has also been a source of debate. The Missouri statute is, at first glance, less broad than that of states such as Ohio and Georgia. The statute states that no one is allowed to “knowingly disclose the identity of a current or former member of an execution team or disclose a record knowing that it could identify a person as being a current or former member of an execution team.” While one would imagine this statute to cover individuals actually present at the execution, it has been interpreted by both Missouri courts and the DOC much more broadly.

In 2006, the identity of the man who had been overseeing Missouri executions for over ten years was discovered by the St. Louis Post-Dispatch. Alan Doerhoff,
who had overseen 54 executions, was deposed by Michael Taylor’s lawyer over the objection of then Governor Jay Nixon.\textsuperscript{240} The evidence adduced at the trial court level showed that Doerhoff was incompetent at best.\textsuperscript{242}

The district court noted inconsistencies in the state’s evidence, particularly where testimony conflicted with dispensary logs.\textsuperscript{243} According to testimony, the state “administers five grams of . . . thiopental, which is a substance that produces anesthesia.”\textsuperscript{244} However, dispensary logs provided during discovery were inconsistent with this testimony.\textsuperscript{245} The state refuted the dispensary log in a letter to the court, stating the following:

Five grams are in fact used. The reference to the 2.5 grams noted in the drug log is not correct. The doctor and the nurse who have prepared the drugs for the last six executions and for plaintiff’s stayed execution confirm that 5 grams has been used in the last six executions and was prepared for plaintiff’s stayed execution.\textsuperscript{246}

The next day, the state changed its tune. It sent the court a second letter stating that, contrary to its previous statement, “2.5 grams of sodium pentothal was prepared and used at the last execution (not 5 grams) and that 2.5 grams was prepared for use at the execution of plaintiff.”\textsuperscript{247} The court, in response, sent interrogatories to Doerhoff, still referred to as John Doe I.\textsuperscript{248} Doerhoff replied he believed he “had the independent authority to change the dose based on his medical judgment.”\textsuperscript{249} Doerhoff further stated he had changed the protocols numerous times before then and without consulting any other individual or entity.\textsuperscript{250} Doerhoff further explained, “it’s not unusual for me to make mistakes . . . in terms of copying one line to another . . . I will sometimes transpose numbers even when I’m staring at the two numbers.”\textsuperscript{251}

Doerhoff testified that the individuals who administer the injections are “in the dark so they have a small flashlight that they’re able to quickly identify the syringes, make the appropriate connections and injections, disconnect, clamp the tube.”\textsuperscript{252}
The district court was, understandably, concerned with the picture Doerhoff’s testimony painted of Missouri’s execution procedures.\(^{253}\) In light of these facts, the district court stayed all executions, pending approval of a new execution protocol, holding “Missouri’s [current] lethal injection procedure subjects condemned inmates to an unnecessary risk that they will be subject to unconstitutional pain and suffering when the lethal injection drugs are administered.”\(^{254}\)

So far, no circuit has recognized a right to pierce the veil of secrecy based on the proposition that such secrecy violates an inmate’s constitutional rights.\(^{255}\) The Fifth, Eighth, and Eleventh Circuits have all declined to side with death row inmates who challenged secrecy statutes the inmates say violated their substantive due process rights.\(^{256}\)

V. THE BEST CHANCE FOR HUMANE LETHAL INJECTION

A. Lessons from Medical Aid-in-Dying

Oregon’s Death with Dignity Act allows for an individual to choose to end their own life with medical assistance, provided they are an Oregon resident, at least 18 years of age, and have a terminal illness.\(^{257}\) While Oregon was the first state to enact a medical aid-in-dying statute,\(^{258}\) several other states have since followed suit. Washington,\(^{259}\) Vermont,\(^{260}\) California,\(^{261}\) and Colorado\(^{262}\) all have specific medical aid-in-dying statutes. Montana has legalized physician-assisted death via a state Supreme Court decision.\(^{263}\)

The drugs used in lethal injection and medical aid-in-dying are generally the same but the administration diverges.\(^{264}\) Lethal injection, as the name suggests, requires an injection of lethal medication (or medications) directly into the bloodstream, whereas medical aid-in-dying is generally accomplished by consuming the medications orally.\(^{265}\) Additionally, the patient does not take a drug cocktail, but

\(^{253}\) Id. at *7 (noting “[t]he Court disagrees and is gravely concerned that a physician who is solely responsible for correctly mixing the drugs which will be responsible for humanely ending the life of condemned inmates has a condition which causes him confusion with regard to numbers.”).

\(^{254}\) Id. at *8.

\(^{255}\) Jones v. Comm’r, Ga. Dep’t of Corr., 811 F.3d 1288, 1293 (11th Cir. 2016).

\(^{256}\) Trottie v. Livingston, 766 F.3d 450, 452 (5th Cir. 2014), cert. denied, 135 S. Ct. 41 (2014); Zink v. Lombardi, 783 F.3d 1089, 1109 (8th Cir. 2015), cert. denied, 135 S. Ct. 2941 (2015); Jones, 811 F.3d at 1293.

\(^{257}\) OR. REV. STAT. ANN. § 127.805 (West 2017).


\(^{259}\) WASH. REV. CODE ANN. § 70.245 (West 2009).

\(^{260}\) VT. STAT. ANN. tit. 18, § 5283 (West 2015).

\(^{261}\) CAL. HEALTH & SAFETY CODE § 443.2 (West 2018).


\(^{263}\) Baxter v. Montana, 224 P.3d 1211, 1222 (Mont. 2009).


\(^{265}\) Riley, supra note 264.
instead consumes a large dose of a single barbiturate, generally secobarbital or pentobarbital.266

Drug-induced death is not new, and neither is the idea of Death with Dignity. The most public proponent of Death with Dignity, Dr. Jack Kevorkian, began helping his patients end their own lives in 1990.267 Additionally, complications from medical aid-in-dying are fairly rare,268 especially compared to their lethal injection counterparts.269 While the same complications that exist in medical aid-in-dying also exist in lethal injections, they are magnified due to the addition of the paralytic and potassium chloride.270 Death row inmates who regain consciousness during the procedure will not necessarily be able to indicate their wakefulness due to the paralytic, and the inmate will likely suffocate before their heart stops.271 Additionally, the administration of the potassium chloride “may well be the chemical equivalent of being burned at the stake.”272

Medical aid-in-dying shows what can be accomplished when the appropriate drugs are available. States should look to these aid-in-dying protocols when trying to determine the most humane method of execution. A single, large dose of a barbiturate would be the best choice for executions, as it seems to produce fewer complications than the current three-drug cocktail. While executions may take longer without the addition of the potassium to stop the heart, they would be more humane and may cause less distress for witnesses than the current implementation of lethal injection.

B. Compounding Pharmacies

The biggest obstacle to implementing a lethal injection procedure with a single dose of barbiturate is obtaining the barbiturate itself. Given drug companies’ refusal to supply state DOCs with drugs, compounding pharmacies represent the best hope for a humane death penalty in the United States. However, any compounding pharmacy that produces a lethal injection drug would need to be highly regulated.

Compounding “combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.”273 While the FDA is responsible for approving new drugs, it “does not verify the safety, or effectiveness of compounded drugs.”274 That does not mean compounded drugs are not subject to any regulation; rather, regulation is left to the individual state boards of pharmacy.275

266. Id.
268. Leonard, supra note 264.
269. See Riley, supra note 264. Medical aid-in-dying complications include, but are not limited to, nausea, vomiting, regaining consciousness, and lapsing into a coma before finally dying.
273. Compounding and the FDA, supra note 12.
274. Id.
275. Id.
The lack of regulation has been problematic. In 2012, a Massachusetts-based compounding pharmacy was tied to a meningitis outbreak that resulted in the deaths of at least 64 people. The New England Compounding Center (“NECC”) manufactured and sold nearly 17,000 vials of preservative-free steroids that were contaminated with 18 different types of fungi. Not only did the supervisory pharmacist, Glenn Chin, ship drugs prior to “confirming their sterility, . . . he directed [the employees] to mislabel drugs to conceal this practice.” Additionally, Chin directed employees to use expired ingredients to compound drugs.

Unfortunately, the NECC problem is not an outlier. In 2001, the FDA did a small-scale study of drugs obtained from 12 compounding pharmacies and the results were alarming. Of the 29 drugs tested, 10 of them failed at least one of the quality tests. Nine of the drugs “failed potency testing, some with less than 70[%] of their declared potency.” In comparison, only four out of 3,000 samples obtained from drug manufacturers, and tested by the FDA, had any quality problems. The difference is that manufacturers are subject to federal oversight.

In response to the NECC contamination disaster, the government increased the number of regulations that applied to bulk compounders like NECC, who were essentially manufacturers. While the FDA has had the authority to regulate manufacturing, compounding “falls into a gray area between state and federal oversight.” For compounding pharmacies, traditionally regulated by the states, the FDA’s role is more reactive than proactive. To combat reporting disparities, and in response to the meningitis outbreak, Congress enacted the Drug Quality & Security Act (“DQSA”)

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278. Id.
279. Id. Chin was convicted of 77 separate counts “including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead” in a federal jury trial. Chin was sentenced to eight years in prison and restitution in an amount as yet undetermined.
281. Id.
282. Id.
283. Id.
284. Id.
287. Begley, supra note 280.
in 2013.\textsuperscript{289} The DQSA exempts traditional compounders who compound for specific patient prescriptions by or under the supervision of a licensed pharmacist.\textsuperscript{290} Additionally, the DQSA creates a new category for “outsourcing facilities” that choose to register with the FDA.\textsuperscript{291}

The absence of regulations for small-scale, traditional compounders is still an issue, particularly when that lack of regulation works in concert with a state’s desire to impose the death penalty. In 2018, a journalist working for BuzzFeed News discovered Missouri’s lethal injection drug supplier was a compounding pharmacy with an alarming record of “hazardous practices.”\textsuperscript{292} Foundation Care, referred to by the State of Missouri as “M7,” has provided drugs for 17 Missouri executions.\textsuperscript{293} Foundation Care has been cited by the FDA for engaging in practices that “could lead to contamination of drugs, potentially putting patients at risk.”\textsuperscript{294}

When the FDA came to inspect Foundation Care in 2013, the CEO attempted to deny the inspectors access to the facility.\textsuperscript{295} The FDA found numerous quality control issues in addition to “inadequate hand-washing and questionable gloving practices, and they determined that a test for sterility and a common toxin had not been conducted since at least the previous year.”\textsuperscript{296}

After releasing the results of its inspection, the FDA sent a letter to the Missouri Board of Pharmacy notifying it of the FDA’s findings and stating “corrective actions can be appropriately overseen by the State.”\textsuperscript{297} Additionally, the FDA is referring this matter to the Missouri State Board of Pharmacy (“BOP”) for follow-up to ensure appropriate corrective action is taken.\textsuperscript{298} The same day the letter was sent to the Missouri BOP, Missouri executed Michael Taylor with drugs obtained from Foundation Care.\textsuperscript{299}

\textsuperscript{290} 21 U.S.C. § 353a.
\textsuperscript{291} Id. §353b (2013). This comes with increased reporting requirements and regulation but could also increase the facility’s credibility with potential purchasers.
\textsuperscript{292} Chris McDaniel, Missouri Fought for Years to Hide Where It Got Its Execution Drugs. Now We Know What They Were Hiding, BUZZFEED (Feb. 20, 2018, 5:55 AM), https://www.buzzfeed.com/chrismcdaniel/missouri-executed-17-men-with-drugs-from-a-high-risk?utm_term=mQ5Wvq7L#a0DN05P.
\textsuperscript{293} Id.
\textsuperscript{297} Miser, supra note 294.
\textsuperscript{298} Id.
\textsuperscript{299} McDaniel, supra note 292; Rizzo, supra note 240.
VI. CONCLUSION

Focusing strictly on the process of physically executing someone, small-scale compounding\(^{300}\) likely is the best hope for a humane death penalty. While difficult to implement, such a solution is not unworkable. It would, however, require balancing the interests of the death row inmate, the state, and individuals tasked with obtaining or creating the drug cocktail used in the execution.

Each state with an active death penalty statute could construct a pharmacy in its prison.\(^ {301}\) Some prisons, including the Federal Bureau of Prisons, already have their own pharmacies.\(^ {302}\) First, this solution would be cost effective. Missouri paid Foundation Care $7,178.88 for four vials of pentobarbital.\(^ {303}\) In 2016, Virginia paid a compounding pharmacy $66,000 for enough midazolam to execute two people.\(^ {304}\)

If a state was to compound its own execution drugs, it would likely save the state a significant amount of money. In 2013 and 2014, Virginia paid less than $250 per execution for lethal injection drugs.\(^ {305}\) In 2015, that price had risen to $525.14.\(^ {306}\) Starting July 1, 2016, that price became more than $16,500 per execution under a contract the Virginia DOC made with an unnamed supplier.\(^ {307}\) That price was for just one of the drugs in the three-drug cocktail, but Virginia officials did not specify which drug.\(^ {308}\) In comparison, the estimated cost of injectable pentobarbital at a pharmacy is $1,025.11.\(^ {309}\)

American pharmacists do not want to participate in executions, largely because once the secret of which pharmacy is supplying the drugs gets out, protests and threats ensue.\(^ {310}\) Moreover, many pharmacists personally oppose the death penalty,
viewing it as unethical.311 This fear of reprisal has led many pharmacies to back away from agreements they had with the DOC.312 The compounder’s fear of reprisal, coupled with the European drug companies’ abolitionist streak, has led to a shortage of lethal injection drugs, and if demand remains static, basic economic principles dictate the price will rise.313 Additionally, by establishing pharmacies in prisons, the state would be able to ensure an availability of supply. With the ability to compound its own drugs, the shortage induced by European manufacturers would no longer affect the scheduling of executions. Moreover, if the state can compound its own execution drugs, the problem of which drugs to use would no longer be at issue. This means not only would states have readily available drugs that provide the best chance of a quick and relatively painless death, it would also be able to ensure the purity and potency of those drugs.

However, it is not so simple. As discussed above, many pharmacists are opposed to providing their services in furtherance of the death penalty.314 While such opposition could make it difficult to find pharmacists willing to compound death penalty drugs, it is not impossible. Given the number of compounding pharmacies outed for providing death penalty drugs to state DOCs, it follows logically that state DOCs could find a pharmacist willing to provide their services to ensure a humane execution.315 Additionally, it may be difficult to obtain the raw materials needed to compound the appropriate drugs. If manufacturers are unwilling to provide drugs to state DOCs, they may also be unwilling to provide the raw materials for compounding to the same facilities, especially if the manufacturers discovered how state DOCs used the raw materials.

Some protection for manufacturers and pharmacists would be necessary to ensure ready access to materials and personnel. However, the secrecy espoused by states like Missouri and Georgia,316 where even the judiciary is in the dark, will only lead to cutting corners and inferior drugs due to a lack of oversight. The exact mechanism for effecting the balance between ensuring the most humane execution possible and the protection of those involved is unclear.

It is clear some states will go to great lengths to execute those on death row. For example, Texas has requested the Department of Justice grant them the ability to expedite death penalty appeals.317 Some states, in response to the lethal injection

drug shortage, are contemplating making a move away from lethal injection altogether. Oklahoma, a state historically associated with experimental execution procedures, adopted nitrogen hypoxia as an alternative method of execution in 2017.318

Despite declining public approval of the death penalty,319 officials in states that actively use capital punishment are unambiguously unwilling to forego executions. If executions are to continue in this country, states must do everything in their power to ensure executions are as humane as possible. Given that manufacturers are recalcitrant in providing drugs to state DOCs, the only option for a humane death penalty is for states to compound their own. Otherwise, states will persist in experimenting in a bid to carry out executions, and the number of botched executions will continue to rise.


318. OKLA. STAT. ANN. tit. 22, § 1014 (West 2017). According to proponents, it is more humane and, because of nitrogen’s ready availability, less likely to postpone executions. Maurice Chammah, Andrew Cohen & Eli Hager, After Lethal Injection, MARSHALL PROJECT (June 1, 2015, 7:15 AM), https://www.themarshallproject.org/2015/06/01/after-lethal-injection?utm_medium=email&utm_campaign=newsletter&utm_source=opening-statement&utm_term=newsletter-20180315-973. However, there is no scientific evidence to back up this claim.