

LETHAL INJECTION SECRECY POST-BAZE

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ABSTRACT

In 2008, with Baze v. Rees, the Supreme Court broke decades of silence regarding state execution methods to declare Kentucky's lethal injection protocol constitutional, yet the opinion itself did not offer much guidance. In the five years after Baze, legal challenges to lethal injection soared as states scrambled to quell litigation by modifying their lethal injection protocols. This Author's unprecedented study of over 300 cases citing Baze reveals that such modifications have occurred with alarming frequency. Moreover, even as states purportedly rely on the Baze opinion, they have changed their lethal injection protocols in inconsistent ways that bear little resemblance to the original protocol evaluated in Baze, and even differ from one execution to the next within the same state. States' continuous tinkering often affects already troubled aspects of their lethal injection procedures. The compendium of these deficiencies has led to some of the most glaring failures in lethal injection history.

An even more disturbing revelation relates to the lethal injection drugs used in these rapidly changing protocols. Recent drug shortages threaten many states' abilities to carry out executions, and this Article presents evidence of the unfettered substitutions states have made in their desperate attempts to adhere to their execution schedules. These include frequent drug switches that take place quickly, without oversight, and based purely on convenience. The resulting unreliability and randomness heighten the risk that the execution process will violate the Eighth Amendment's Cruel and Unusual Punishments Clause. As that risk increases, so does the tendency for states to retreat into secrecy regarding their lethal injection protocols.

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For a growing number of states, alternatives also incorporate the use of compounding pharmacies to produce lethal injection drugs. This trend is problematic for several reasons, including an obvious conflict of interest: compounding pharmacies are regulated by the state—the very entity that is requesting production of the drugs. However, evidence shows that proposed federal regulation of these pharmacies may create major obstacles for the use of compounded drugs in executions, leaving states without even this risky recourse.

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

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INTRODUCTION

Lethal injection has been a controversial method of execution since its inception in 1977, with many critics focusing on problems with the three-drug protocol traditionally used by most death penalty states.¹ By 2007, the growing number of legal challenges and the variance among state responses resulted in a sufficient number of circuit splits for the Supreme Court to grant certiorari to review the issue.² The Court chose *Baze v. Rees*,³ a Kentucky case, to determine the future direction of lethal injection. In *Baze*, a 7-2 plurality opinion,⁴ the Court upheld the constitutionality of Kentucky's lethal injection protocol under the Eighth Amendment's Cruel and Unusual Punishments Clause.⁵ The Court found that the defendants had failed to show that Kentucky's three-drug combination posed a "substantial" or "objectively intolerable" risk of "serious harm"⁶ compared to "known and available alternatives."⁷ The typical formula, which Kentucky was then using, consists of a serial sequence of three drugs: sodium thiopental, a barbiturate anesthetic that brings about deep unconsciousness; pancuronium bromide, a total muscle relaxant that paralyzes all voluntary muscles and causes suffocation; and potassium

¹ *Baze v. Rees*, 553 U.S. 35, 40-63 (2008) (plurality opinion) (examining the issues concerning the three-drug protocol). For a detailed discussion of these problems and developments over the decades see Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 FORDHAM L. REV. 49, 51-101 (2007) [hereinafter Denno, *Lethal Injection Quandary*]; Deborah W. Denno, *When Legislatures Delegate Death: The Troubling Paradox Behind State Uses of Electrocutation and Lethal Injection and What It Says About Us*, 63 OHIO ST. L.J. 63, 90-141 (2002) [hereafter Denno, *When Legislatures Delegate*]; Deborah W. Denno, *Getting to Death: Are Executions Constitutional?* 82 IOWA L. REV. 319, 373-400 (1997) [Denno, *Getting to Death*].

² Richard C. Dieter, *Methods of Execution and Their Effect on the Use of the Death Penalty in the United States*, 35 FORDHAM URB. L.J. 789, 802-03 (2008).

³ *Baze*, 553 U.S. at 35.

⁴ *Id.* at 39. Chief Justice John Roberts announced the judgment of the Court and delivered an opinion in which Justice Anthony Kennedy and Samuel Alito joined, *id.* at 40-63; Justice Alito filed a concurring opinion, *id.* at 63-71; Justice John Paul Stevens filed an opinion concurring in the judgment, *id.* at 71-87; Justice Antonin Scalia filed an opinion concurring in the judgment, which Justice Clarence Thomas joined, *id.* at 87-93; Justice Thomas filed an opinion concurring in the judgment, which Justice Scalia joined, *id.* at 94-107; Justice Stephen Breyer filed an opinion concurring in the judgment, *id.* at 107-13; and Justice Ruth Bader Ginsburg filed a dissenting opinion in which Justice David Souter joined, *id.* at 113-23.

⁵ *Id.* at 41 (plurality opinion). The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. CONST. amend. VIII.

⁶ *Baze*, 553 U.S. at 50 (plurality opinion) (internal quotation marks omitted).

⁷ *Id.* at 61.

chloride, a toxin that induces irreversible cardiac arrest.⁸

A primary concern in *Baze*, and lethal injection challenges generally, rested with the second drug, pancuronium bromide. Without adequate anesthesia, pancuronium can cause an inmate excruciating pain and suffering because the inmate slowly suffocates from the drug's effects while paralyzed and unable to cry out. The inmate's agony increases dramatically when executioners inject the third drug, potassium chloride, which creates an intense and unbearable burning.⁹ The *Baze* Court agreed that if the sodium thiopental is ineffective, it would be reprehensible to inject the second and third drugs into a conscious person.¹⁰ A key issue in litigation was whether prison officials and executioners can determine if an inmate is aware and in torment because pancuronium is such a powerful mask of emotions.¹¹ Starting in 2006, this litigation so successfully prompted death penalty moratoria and execution stalemates across the country that a Supreme Court case like *Baze* appeared inevitable.¹²

Yet in many ways *Baze* was a puzzling choice. The state of Kentucky had conducted only one execution by lethal injection and thus offered an extremely limited record on which to base a lethal injection challenge. Other states had far better evidentiary and execution data.¹³ Moreover, the suit that petitioners brought had not been scrutinized by the federal hearings being carried out in similar kinds of cases. Rather, Kentucky's hearings took place only in state court and concerned only Kentucky's procedures and short execution history.¹⁴ Some death penalty opponents came to believe that the Justices who voted to hear *Baze* did so only because they "regarded the challenge as insubstantial and wanted to dispose of it before many more state and federal courts could be tied up with similar cases."¹⁵

However, the *Baze* opinion had quite the opposite effect. Limits to the *Baze* Court's analysis suggest that the decision is by no means a

⁸ Deborah W. Denno, *The Lethal Injection Debate: Law and Science*, 35 FORDHAM URB. L.J. 701, 702 (2008).

⁹ *Baze*, 553 U.S. at 53-54 (plurality opinion); Denno, *Lethal Injection Quandary*, *supra* note 1, at 55-56.

¹⁰ *Baze*, 553 U.S. at 53 (plurality opinion) ("It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride.").

¹¹ *Id.* at 53-61.

¹² Dieter, *supra* note 2, at 800-08.

¹³ Adam Liptak, *Moratorium May Be Over, But Hardly the Challenges*, N.Y. TIMES, Apr. 17, 2008, at A26.

¹⁴ Dieter, *supra* note 2, at 803-04.

¹⁵ Linda Greenhouse, *Justices Chilly to Bid to Alter Death Penalty*, N.Y. TIMES, Jan. 8, 2008, at A1.

definitive response to the issue of lethal injection's constitutionality.¹⁶ In fact, *Baze* was so splintered that none of its seven opinions comprises more than three votes¹⁷ and the Justices offered a wide range of explanations and qualifications in their reasoning.¹⁸ In addition, the decision was confined to Kentucky and its particular protocol. Voices on both sides of the death penalty debate have emphasized that *Baze* left doors open for future lethal injection challenges.¹⁹ Even members of the *Baze* Court itself anticipated the repercussions of the opinion's shortcomings: in separate concurrences, Justices Stevens,²⁰ Thomas²¹ and Alito²² expressed concern that the *Baze* decision would only lead to additional debate and litigation. Until now, however, criticisms and concerns regarding post-*Baze* developments in lethal injection protocols have been largely predictive.

This Article provides facts where there has been only foresight. As one of a dozen experts who testified in Kentucky in the evidentiary hearing on *Baze*,²³ I took a special interest in the case's outcome and impact. The *Baze* trial court cited my work indicating the lack of medical or scientific scrutiny of the origins of the lethal injection process,²⁴ and several of my articles were cited in the opinions of four *Baze* Justices: Chief Justice Roberts' plurality opinion and the concurring opinions of Justices Stevens, Breyer, and Alito.²⁵ In this Article, I present the results of a unique

¹⁶ See *infra* Part II.

¹⁷ See *supra* note 4 and accompanying text.

¹⁸ For an analysis of the different opinions in *Baze* see Deborah W. Denno, *For Execution Methods Challenges, the Road to Abolition is Paved with Paradox*, in *THE ROAD TO ABOLITION? THE FUTURE OF CAPITAL PUNISHMENT IN THE UNITED STATES* 183, 183 - 214 (Charles J. Ogletree, Jr. & Austin Sarat eds., 2009).

¹⁹ Liptak, *supra* note 13, at A26 (citing commentators' responses to *Baze*).

²⁰ *Baze v. Rees*, 553 U.S. at 71 (Stevens, J., concurring) ("When we granted certiorari in this case, I assumed that our decision would bring the debate about lethal injection as a method of execution to a close. It now seems clear that it will not.").

²¹ *Id.* at 104 (Thomas, J., concurring) (emphasizing that the weaknesses and vagueness of the *Baze* Court's decision would be "sure to engender more litigation").

²² *Id.* at 71 (Alito, J., concurring) (warning that "[t]he Court should not produce a de facto ban on capital punishment by adopting method-of-execution rules that lead to litigation gridlock").

²³ See Deborah W. Denno, *Death Bed*, 124 TRIQUARTERLY J. 141, 141-68 (2006) (discussing the author's experience testifying in the evidentiary hearings).

²⁴ *Baze v. Rees*, No. 04-CI-010194, 2005 WL 5797977 (Ky. Cir. Ct., Div. I, July 8, 2005), *aff'd*, 217 S.W.3d 207 (Ky. 2006), *aff'd*, 553 U.S. 35 (2008).

²⁵ The articles and respective citations are as follows: Denno, *Lethal Injection Quandary*, *supra* note 1 (cited in *Baze*, 553 U.S. at 52 n.2, by Chief Justice Roberts; *id.* at 66, by Justice Alito; *id.* at 74 n.5, by Justice Stevens; *id.* at 108, by Justice Breyer); Denno, *When Legislatures Delegate*, *supra* note 1 (cited in *Baze*, 553 U.S. at 76, by Justice Stevens; *id.* at 110-11, by Justice Breyer); Denno, *Getting to Death*, *supra* note 1 (cited in *Baze*, 553 U.S. at 41, 42, by Chief Justice Roberts); Deborah W. Denno, *Perspective Roundtable: Physicians and Execution - Highlights from a Discussion of Lethal Injection*,

empirical study in which I collected and analyzed over 300 cases citing *Baze* in the five years since the decision (2008-2013). My analysis of these cases indicates that states can—and do—modify virtually any aspect of their lethal injection procedures with a careless frequency that is unprecedented among execution methods in this country’s history. There have been more changes in lethal injection protocols during the past five years than there have been in the last three decades. The resulting protocols differ from state to state, and even from one execution to the next within the same state. As a result, many states’ lethal injection issues and procedures scarcely resemble those evaluated by the *Baze* Court. Furthermore, this continuous tinkering often affects already troubled aspects of states’ lethal injection procedures, such as the paltry qualifications of executioners, the absence of medical experts, and the failure to account for difficulties injecting inmates whose drug-using histories diminish the availability of usable veins.²⁶ Despite states’ efforts to improve their procedures, the compendium of such deficiencies has led to some of the most glaring and gruesome failures ever documented in the history of lethal injection.²⁷

Baze ushered in a perfect storm for litigation. Although the Supreme Court’s grant of certiorari in *Baze* was remarkable given the Court’s long history of silence regarding the constitutionality of execution methods, *Baze* did little to resolve the problems that plagued lethal injection prior to 2008. The *Baze* Court’s vague and diffuse Eighth Amendment analysis engendered greater coverage of lethal injection research and litigation in medical journals, as well as controversy over physician involvement. Combined with widely publicized botched executions, the post-*Baze* lethal injection debate encompassed problems even worse and more varied than those that existed before the Court’s intervention.²⁸ Yet no one—not even the more clairvoyant Justices of the *Baze* Court—could have foreseen the more pragmatic threats to the continuation of executions that were to come with rampant drug shortages that started in 2010.

As death penalty states face the daunting reality of diminishing or depleted drug supplies and ever-increasing restrictions on importation, they are struggling to match their protocols to drug availability. Some states have put lethal injection executions on hold until the drug situation is resolved,²⁹ while others have turned to the Justice Department for help.³⁰

358 NEW ENG. J. MED. 448 (2008) (with Atul Gawande, Robert D. Truog & David Waisel) (cited in *Baze*, 553 U.S. at 68, by Justice Alito).

²⁶ See *supra* Part II.

²⁷ See *supra* notes x-x and accompanying text.

²⁸ See *supra* notes x-x and accompanying text.

²⁹ Kimberly Leonard, *Lethal Injection Drug Access Could Put Executions on Hold*, THE CTR. FOR PUBLIC INTEGRITY: HEALTH (July 11, 2012, 4:23 PM), <http://www.publicintegrity.org/2012/04/04/8589/lethal-injection-drug-access-could-put->

Many continue to search for manufacturers that will agree to produce drugs for lethal injections. As states' desperation increases, so does their tolerance for risk.³¹ Most recently, death penalty states have pinned their hopes on "compounded" drugs: individualized prescription medications created in facilities referred to as "compounding pharmacies." Unlike commercial pharmaceutical manufacturers, which are regulated by the Food and Drug Administration ("FDA") and subject to intense oversight,³² compounding pharmacies (and pharmacies generally) are regulated relatively permissively by the state.³³

Over the past few decades, however, the FDA has discovered a disturbing trend in which compounding pharmacies have capitalized on their ability to produce and sell large batches of medications to a broad market without meeting the stringent safety and efficacy standards required of commercial drug manufacturers. Essentially, these facilities act like large-scale pharmaceutical companies while hiding behind small-scale pharmacy licenses.³⁴ In early October 2012, a contaminated steroid produced by the New England Compounding Center (NECC) in Massachusetts led to a fungal meningitis outbreak that has killed a current total of 61 people and sickened almost 750 others across the nation.³⁵ The

executions-hold.

³⁰ Bill Mears, *States Urge Feds to Help Import Lethal Injection Drugs*, CNN.COM (May 21, 2012, 7:40 PM), <http://www.cnn.com/2012/05/21/politics/states-lethal-injection-drugs> (citing a statement released by the state attorneys general from 15 states asking for help, noting "at the very core of the states' police powers are their powers to enact laws to protect their citizens against violent crimes. As state attorneys general, we are tasked with enforcing those laws, including in instances where capital punishment is authorized for the most heinous of crimes").

³¹ Meredith Clark, *US Execution Strategy Threatened By Drug Shortfall*, MSNBC.COM (May 3, 2013, 11:20 AM), <http://tv.msnbc.com/2013/05/03/us-execution-strategy-threatened-by-drug-shortfall/>.

³² SEN. EDWARD J. MARKEY, U.S. H.R., STATE OF DISARRAY: HOW STATES' INABILITY TO OVERSEE COMPOUNDING PHARMACIES PUTS PUBLIC HEALTH AT RISK 6 (2013) [hereinafter STATE OF DISARRAY] (a report written by the staff of then Congressman (D-MA), now Senator Edward J. Markey using the responses to an investigation which examined the state oversight of compounding pharmacies).

³³ See Jesse M. Boodoo, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 AM. J.L. & MED. 220, 232-34 (2010).

³⁴ OFFICE OF CONGRESSMAN EDWARD J. MARKEY, COMPOUNDING PHARMACIES – COMPOUNDING RISK 5 (2012) [hereinafter COMPOUNDING RISK] (a report prepared in response to the fungal meningitis outbreak in Boston that addresses current regulatory oversight and gaps in legal authority over compounding pharmacies); Editorial, *Fix 'Compounding Pharmacy' Oversight: Our View*, USA TODAY (Apr. 29, 2013), <http://www.usatoday.com/story/opinion/2013/04/28/compounding-pharmacy-fda-editorials-debates/2119621>.

³⁵ Ctrs. for Disease Control and Prevention, *Multi-State Meningitis Outbreak -*

NECC was alleged to be a prime example of a compounding pharmacy that operated like large drug manufacturing company,³⁶ and the meningitis tragedy brought concerns about this practice to an apex.

The FDA inspected 31 compounding pharmacies over the next six months, and made a series of disquieting discoveries:³⁷ “unidentified black particles floating in vials of supposedly sterile medicine; rust and mold in ‘clean rooms’ where sterile injectable medications were produced; technicians handling supposedly sterile products with bare hands; and employees wearing non-sterile labcoats.”³⁸ Moreover, a study released in April 2013 by the United States House of Representatives revealed that almost all states provide grossly inadequate and often altogether ineffective oversight and regulation of the compounding pharmacies within their borders. Issues include poor record keeping, a lack of uniformity among states, ignorance of dangerous processes and products from other states, and minimal preventative and safety assurance measures.³⁹ In response to these findings, legislation has been proposed that would require FDA approval of

Current Case Count, CDC.GOV (July 1, 2013, 2:30 PM), http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table [hereinafter CDC TABLE]. For more information on the meningitis outbreak and the continually developing outcomes see Scott Gottlieb, M.D., *Compounding A Crisis At FDA*, FORBES (May 24, 2013), <http://www.forbes.com/sites/scottgottlieb/2013/05/24/compounding-a-crisis-at-fda/>.

³⁶ COMPOUNDING RISK, *supra* note 34, at 10.

³⁷ U.S FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH, SUMMARY: 2013 FDA PHARMACY INSPECTION ASSIGNMENT (April 11, 2013), *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm> (last visited July 19, 2013) [hereinafter 2013 INSPECTION SUMMARY].

³⁸ Margaret A. Hamburg, M.D., *Proactive Inspections Further Highlight Need for New Authorities for Pharmacy Compounding*, FDA VOICE (Apr. 11, 2013), <http://blogs.fda.gov/fdavoices/index.php/2013/04/proactive-inspections-further-highlight-need-for-new-authorities-for-pharmacy-compounding/> (Margaret A. Hamburg, M.D., is the commissioner of the Food and Drug Administration.). In her post, Dr. Hamburg linked to the Summary of the 2013 FDA Pharmacy Inspection Assignment to reference the inspections conducted. Reportedly, the FDA used “highly-skilled, certified drug investigators who have specialized experience and specific training to evaluate pharmaceutical production and determine a firm’s compliance with sterile production standards.” 2013 INSPECTION SUMMARY, *supra* note 37. In the inspections, investigators observed “the production environment, equipment used to make the drugs, the design of the facility, and personnel practices and behavior.” *Id.* The FDA also interviewed the technicians who worked at each pharmacy to learn about the operations, standard operating procedures, and products as well as the effectiveness of any sterilization methods and drug stability programs. If necessary, investigators collected samples of abnormalities and compliance failures. *Id.*

³⁹ COMPOUNDING RISK, *supra* note 34, at 2-3.

not only pharmacies engaged in interstate commerce, but also those involved in high-risk compounding.

As the FDA continues to explore methods of increasing its authority over compounding pharmacies,⁴⁰ state pharmacy boards are working hastily to improve their regulatory systems in response to the negative attention. Proposed state regulations include stricter licensure requirements for local compounding pharmacies and out-of-state pharmacies that deliver in state, clearer definitions of compounding, additional inspection programs and requirements, and the installment or improvement of prescription monitoring programs.⁴¹

Death penalty states may thus be confronted with an ironic outcome in which their quest for lethal injection drugs is thwarted both by the problems and the proposed solutions associated with the regulation of compounding pharmacies. The historically dismal safety standards and haphazard daily practices of many compounding pharmacies all but invite lethal injection challenges, while public health calamities such as the meningitis outbreak seem to ensure that increased regulation is inevitable. Death penalty states have a tendency to retreat into secrecy when legal challenges appear threatening, yet currently proposed regulations would likely make such retreat impossible. If any compounded lethal injection drugs are considered high risk—and they possibly could be—then the compounding pharmacies that produce them will be subject to FDA oversight. The new regulations may require public disclosure of all the drugs the pharmacies produce, to whom they intend to sell them, and advance evidence of individual prescriptions. The FDA, in turn, may be required to share information on inspected compounding pharmacies with relevant state agencies.⁴² Finally, and perhaps most significantly, several of the proposed restrictions would effectively negate altogether the ability of compounding pharmacies to produce lethal injection drugs.

Part I of this Article briefly describes the history of lethal injection methods, and provides context for the current debate regarding lethal injection drugs. Part II presents evidence to support the remarkable assertion that current events have rendered the *Baze* opinion largely irrelevant a mere five years after its issuance. Part III discusses post-*Baze* legal challenges, as well as states' attempts to quell litigation by switching

⁴⁰ See Andrew Pollack, *Checks Find Unsafe Practices at Compounding Pharmacies*, N.Y. TIMES, Apr. 12, 2013, at A12.

⁴¹ See Kara Net Hinkley, *Compounding Pharmacies: Compounding Interest*, 06.2013 NAT'L CONF. OF STATE LEGIS. MAG. 22, 23 (2013); Nat'l Conf. of State Legis., *State Regulation of Compounding Pharmacies*, NCSL.ORG (June 24, 2012), <http://www.ncsl.org/issues-research/health/regulating-compounding-pharmacies.aspx>.

⁴² H.R. 2186, 113th Cong. (2013).

their lethal injection protocols from three-drug to one-drug procedures. Part IV explains how these legal challenges have been overshadowed by an even bigger obstacle to lethal injection: unanticipated national shortages in lethal injection drugs, which have resulted in a new wave of litigation and protocol changes. Part V reveals the dangers associated with states' attempts to address those shortages by seeking compounded drugs from pharmacies that lack federal oversight, and explains how proposed (and seemingly inevitable) regulations may impede states' increasingly frantic efforts to procure lethal injection drugs. Part VI explores the trend toward secrecy that has accompanied these efforts as states attempt to protect the identities and conceal the dangers of their drug sources, even as the risks associated with compounding pharmacies seem to demand increased transparency. This Article concludes by emphasizing the likelihood that new regulations will force such transparency—a desirable and constitutionally-sound outcome for the public, if not for the states that will have to begin yet again the search for drugs to dole out death.

I. A BRIEF HISTORY OF LETHAL INJECTION

This country's adoption of lethal injection follows more than a century of searching for humane methods of execution,⁴³ starting with hanging and the firing squad and then replaced by seemingly more acceptable techniques. The increasingly modern quest for an execution method began with electrocution in 1890, then lethal gas in 1921, and, in an evolving pattern, ended in 1977 with lethal injection.⁴⁴ An analysis of lethal injection's history, however, shows little excuse for its adoption or its perpetuation. Lethal injection's deficiencies persisted over the decades, yet were simply ignored.⁴⁵ New York State considered using one form of lethal injection (cyanide injection) as early as 1888,⁴⁶ yet a State

⁴³ AUSTIN SARAT, *WHEN THE STATE KILLS: CAPITAL PUNISHMENT AND THE AMERICAN CONDITION* 84 (2001) (referring to the “unending search for technologies that in their capacity to kill with a pretense of humanity allow those who kill both to end life and, at the same time, to believe themselves to be guardians of a moral order that, in part, bases its claims to superiority in its condemnation of killing”).

⁴⁴ For discussions of legislative changes in execution methods over time, see Denno, *Lethal Injection Quandary*, *supra* note 1, at 59-75; Denno, *When Legislatures Delegate*, *supra* note 1, at 82-85, 90-92, 130-31, 188-206; Denno, *Getting to Death*, *supra* note 1, at 75; Deborah W. Denno, *Is Electrocution an Unconstitutional Method of Execution? The Engineering of Death over the Century*, 35 WM. & MARY L. REV. 551, 559-77 (1994) [hereinafter Denno, *Engineering of Death*].

⁴⁵ See generally Denno, *Lethal Injection Quandary*, *supra* note 1 (documenting the history and perpetuation of lethal injection).

⁴⁶ THE COMMISSION TO INVESTIGATE AND REPORT THE MOST HUMANE AND PRACTICAL METHOD OF CARRYING INTO EFFECT THE SENTENCE OF DEATH IN CAPITAL

commission rejected that choice because the medical profession believed that the public would begin to link the practice of medicine to death.⁴⁷ Of course, this concern about lethal injection remains today.⁴⁸

In 1953, Great Britain's Royal Commission on Capital Punishment also dismissed a form of lethal injection, concluding after a five-year study that injection was no better than Great Britain's long-standing method of execution by hanging.⁴⁹ The host of problems the Royal Commission detected with lethal injection still exists, ranging from the physical limitations presented by individuals with inaccessible veins to the recognition that lethal injection requires medical skill because of the technique's complexity.⁵⁰ In 1976, the United States started to examine the lethal injection issue more intently after the Supreme Court reinstated the death penalty in *Gregg v. Georgia*,⁵¹ a case that marked the end of a nine-year pause in this country's executions.⁵² Remarkably, no state legislature addressed the evidence gathered and conclusions reached on injection procedures either from the New York or British commissions.⁵³

Such disregard for past medical investigations was clear in May 1977, when Oklahoma became the first state to adopt lethal injection without even considering the research provided by the New York and British commissions.⁵⁴ Rather, an Oklahoma legislator asked Jay Chapman, M.D., the state's medical examiner, to create a lethal injection protocol that the state could implement even though Dr. Chapman was clear about his lack of expertise in fulfilling such a request.⁵⁵ According to Dr. Chapman, when lawmakers initially contacted him, his "first response was that [he] was an expert in dead bodies but not an expert in getting them that way."⁵⁶

My research has uncovered that with virtually no scientific study or relevant medical background, Dr. Chapman quickly concocted the three-drug formula formerly used by Kentucky.⁵⁷ Yet, within days of the Oklahoma legislature adopting his method, Chapman warned the public of lethal injection's hazards.⁵⁸ In the *Daily Oklahoman*, for example, he noted

CASES, REPORT OF THE COMMISSION 85 (1888).

⁴⁷ Denno, *Engineering of Death*, *supra* note 44, at 572-73.

⁴⁸ Denno, *Lethal Injection Quandary*, *supra* note 1, at 80.

⁴⁹ ROYAL COMMISSION ON CAPITAL PUNISHMENT 1949-53, REPORT 258-61 (1953).

⁵⁰ *Id.* at 258.

⁵¹ 428 U.S. 153, 207 (1976) (plurality opinion).

⁵² *Baze v. Rees*, 553 U.S. 35, 42 (2008) (plurality opinion).

⁵³ Denno, *The Lethal Injection Quandary*, *supra* note 1, at 65.

⁵⁴ Denno, *Getting to Death*, *supra* note 1, at 375.

⁵⁵ Denno, *The Lethal Injection Quandary*, *supra* note 1, at 66.

⁵⁶ *Id.* (citing e-mail communications between Dr. Chapman and the author).

⁵⁷ *Id.* at 66-75.

⁵⁸ See Jim Killackey, *Execution Drug Like Anesthesia*, DAILY OKLAHOMAN, May 12, 1977, at 1.

that “if the death-dealing drug is not administered properly, the convict may not die and could be subject to severe muscle pain.”⁵⁹ Other news articles at the time stressed the tentative status of Oklahoma’s protocol. A 1979 *Daily Oklahoman* article emphasized that “officials with the State Department of Corrections say it may be years – if ever – before they are required to carry out mandates of the 1977 Legislature.”⁶⁰ The article also noted that “officials feel that if and when they have to use the injection law, *new and better drugs may be available.*”⁶¹ Such statements suggest that officials had minimal confidence in the effectiveness of the chemicals that Dr. Chapman introduced, and even anticipated that they might never be applied. Initial concerns over the lack of medical testing were sufficient to stall Oklahoma’s lethal injection bill prior to state senate approval.⁶² At one point, the Oklahoma legislature considered requiring that injection could not supplant electrocution without “being ruled legal by the U.S. Supreme Court.”⁶³ Legislative history indicates that lethal injection was not to be used quickly or confidently, if at all.

Despite the benefits of hindsight, states did not medically improve upon the lethal injection method that consistently had resulted in documented debacles.⁶⁴ As the trial court in *Baze v. Rees*⁶⁵ concluded in 2005 (citing to this Author’s research), “[T]here is scant evidence that ensuing States’ adoption of lethal injection was supported by any additional medical or scientific studies . . . [R]ather, the various States simply fell in line relying solely on Oklahoma’s protocol.”⁶⁶ Indeed, after Oklahoma adopted the method, state after state followed suit. From 1977 to 2009, 39 states joined this movement, switching to lethal injection in falling-domino-like fashion.⁶⁷ Many of these states simply copied the language of

⁵⁹ *Id.*

⁶⁰ See Jim Killackey, *Officials Draw Grim Executions Lethal*, DAILY OKLAHOMAN, Nov. 12, 1979, at 1.

⁶¹ *Id.* (emphasis added).

⁶² See John Greiner, *Drug Execution Plan Suffers Senate Setback*, DAILY OKLAHOMAN, Feb. 16, 1977, at 16 (explaining that one senator “apparently had drummed up enough votes to have killed the bill had it been brought to a final vote” and noting the concerns of a former assistant district attorney that “the legislature and Senate should study [the bill] more carefully”).

⁶³ See AN ACT RELATING TO CRIMINAL PROCEDURE; AMENDING 22 O.S. 1971, SECTION 1014; AND SPECIFYING THE MANNER OF INFLECTING PUNISHMENT OF DEATH; AND MAKING PROVISIONS SEPARABLE, S.B. 10, 36TH LEG., 1ST SESS. (Okla. 1977).

⁶⁴ Denno, *The Lethal Injection Quandary*, supra note 1, at 64-117.

⁶⁵ *Baze v. Rees*, No. 04-CI-010194, 2005 WL 5797977 (Ky. Cir. Ct., Div. I, July 8, 2005), *aff’d*, 217 S.W.3d 207 (Ky. 2006), *aff’d*, 553 U.S. 35 (2008).

⁶⁶ *Id.* at 2.

⁶⁷ The following lists the 39 state adopting lethal injection by the year of adoption:

1977 Oklahoma • Texas

Oklahoma's lethal injection statute.⁶⁸

The 39-state figure alone is remarkable. Even more extraordinary is that six states, including Oklahoma, made the switch by 1982,⁶⁹ the year this country's first lethal injection execution took place.⁷⁰ Another seven states changed in 1983 alone.⁷¹ Therefore, within a year of the country's first lethal injection execution, thirteen states—over one-third of all death penalty states at that time—had decided to engage in executions with the new method.⁷² In addition, 12 states enacted lethal injection in the nine-year stretch between 1994, when Kansas, Maryland, and Virginia adopted the method, and 2002, when Alabama did.⁷³ Nebraska was a lone wolf, switching to lethal injection in 2009 a year after the Nebraska Supreme

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|------|--|
| 1978 | Idaho |
| 1979 | New Mexico |
| 1981 | Washington |
| 1982 | Massachusetts |
| 1983 | Arkansas • Illinois • Montana • Nevada • New Jersey • N. C. • Utah |
| 1984 | Mississippi • Oregon • South Dakota • Wyoming, |
| 1986 | Delaware • New Hampshire |
| 1988 | Colorado • Missouri |
| 1990 | Louisiana • Pennsylvania |
| 1992 | Arizona • California |
| 1993 | Ohio |
| 1994 | Kansas • Maryland • Virginia |
| 1995 | Connecticut • Indiana • New York • South Carolina |
| 1998 | Kentucky • Tennessee |
| 2000 | Florida • Georgia |
| 2001 | Ohio |
| 2002 | Alabama |
| 2009 | Nebraska |

See Denno, supra note 18, at 197-88.

⁶⁸ *See generally* Denno, *Lethal Injection Quandary*, *supra* note 1; Denno, *When Legislatures Delegate*, *supra* note 1; Denno, *Getting to Death*, *supra* note 1.

⁶⁹ *See supra* note 67 (showing that Idaho, New Mexico, Washington, and Massachusetts followed the lead set by Oklahoma and Texas by adopting lethal injection before an actual execution took place).

⁷⁰ *See Denno, Getting to Death, supra* note 1, at 375 (discussing the 1982 execution of Charles Brooks, Jr. in Texas).

⁷¹ *See supra* note 67 (showing that Arkansas, Illinois, Montana, Nevada, New Jersey, North Carolina, and Utah adopted lethal injection in 1983).

⁷² By the end of 1983, 38 states had the death penalty. U.S. DEPARTMENT OF JUSTICE, BUREAU OF JUSTICE STATISTICS, CAPITAL PUNISHMENT 1983, at 6-7 (Washington, D.C.: U.S. Government Printing Office, 1983).

⁷³ *See supra* note 67 (showing that a series of states adopted lethal injection between 1994-2002, starting with Kansas, Maryland, Virginia (all in 1994), Connecticut, Indiana, New York, South Carolina (all in 1995), Kentucky, Tennessee (both in 1998), Ohio (in 2001), and Alabama (in 2002).

Court finally declared electrocution unconstitutional.⁷⁴ By 2009, then, all death penalty states in this country had switched to lethal injection, either entirely or as an option,⁷⁵ and nearly all states used a protocol consisting of the same three drugs.⁷⁶

Of the 32 death penalty states that exist today, lethal injection is the sole method of execution in 21 states.⁷⁷ Three states—Utah, Kentucky, and Tennessee—have also adopted lethal injection as their sole execution method, but have done so with non-retroactive provisions.⁷⁸ Lethal injection is one of two possible methods of execution in 11 states, including Utah (which allows some inmates the choice of firing squad), as well as Kentucky and Tennessee (which allow some inmates the choice of electrocution).⁷⁹ A growing number of states, eighteen in total, no longer have the death penalty, a figure that includes New Mexico, New Jersey, and Maryland, the most recent state to join this list.⁸⁰

⁷⁴ In 2008 the Nebraska Supreme Court held electrocution to be unconstitutional. *State v. Mata*, 745 N.W.2d 229, 278 (Neb. 2008). A year later the Nebraska legislature adopted lethal injection. Nev. Rev. Stat. Ann. § 176.355 (West 2013).

⁷⁵ See *supra* notes x-x and accompanying text.

⁷⁶ *Baze v. Rees*, 553 U.S. 35, 40-63 (2008) (plurality opinion)

⁷⁷ See Ariz. Rev. Stat. Ann. § 13-704 (2013); Ark. Code Ann. § 5-4-617 (2013); Colo. Rev. Stat. Ann. § 18-1.3-1202 (West 2013); Del. Code Ann. tit. 11, § 4209 (2013); Ga. Code Ann. § 17-10-38 (2013); Idaho Code Ann. § 19-2716 (2013); Ind. Code Ann. § 35-38-6-1 (West 2013); Kan. Stat. Ann. § 22-4001 (2013); La. Rev. Stat. Ann. § 15:569 (2013); Miss. Code Ann. § 99-19-51 (2013); Mont. Code Ann. § 46-19-103 (2013); Neb. Rev. Stat. § 29-2532 (2012); Nev. Rev. Stat. Ann. § 176.355 (West 2013); N.C. Gen. Stat. Ann. § 15-187 (West 2013); Ohio Rev. Code Ann. § 2949.22 (West 2013); Okla. Stat. Ann. tit. 22, § 1014 (West 2013); Or. Rev. Stat. § 137.473 (2013); 61 Pa. Stat. Ann. § 3004 (West 2013); S.D. Codified Laws § 23A-27A-32 (2013); Tex. Code Crim. Proc. Ann. art. 43.14 (Vernon 2013); Wyo. Stat. Ann. § 7-13-904 (2013). The New York Court of Appeals held the state's death penalty statute unconstitutional in 2004, preventing executions. See *People v. LaValle*, 817 N.E.2d 341, 367 (N.Y. 2004). However, the chosen method of execution in New York remains lethal injection. N.Y. Correct. Law § 658 (McKinney 2013).

⁷⁸ See Ky. Rev. Stat. Ann. § 431.220 (West 2013); Tenn. Code Ann. § 40-23-114 (West 2013); Utah Code Ann. § 77-18-5.5 (West 2013).

⁷⁹ These eleven states are divided according to the alternative execution method they allow apart from lethal injection. Alabama, Florida, South Carolina, and Virginia allow for electrocution. See Ala. Code §§ 15-18-82 to 82.1 (2013); Fla. Stat. Ann. § 922.105 (West 2013); S.C. Code Ann. § 24-3-530 (2013); Va. Code Ann. § 53.1-234 (West 2013). New Hampshire and Washington also have hanging as a method. See N.H. Rev. Stat. Ann. § 630:5 (2013); Wash. Rev. Code Ann. § 10.95.180 (West 2013). California and Missouri both have lethal gas as an alternative. See Cal. Penal Code § 3604 (West 2013); Mo. Ann. Stat. § 546.720 (West 2013). This footnote does not include statutes designating a choice only if an inmate was sentenced before a certain date, or any of the other myriad variations in statutes that have been documented in detail elsewhere. See Denno, *When Legislatures Delegate*, *supra* note 1, at 188-206.

⁸⁰ The statutes for these eighteen states are listed in chronological order as follows

Yet statistics demonstrating lethal injection's dominance ignore the effect that lethal injection challenges can have on capital punishment generally. The events leading up to *Baze* illustrated this effect. In 2006, for example, executions plunged to about half their 1999 numbers, a trend that continued in 2007 and 2008. Numerous states, and the federal government, ceased executions entirely, often at least partly due to lethal injection-

beginning with the first state without the death penalty: *see* Mich. Const. art. IV, § 46 (West 2012) (establishing a legislative ban on the death penalty since 1846); Act to Abolish the Death Penalty, ch. 103, 1853 Wis. Sess. Laws 100; Act to Abolish the Death Penalty, ch. 103, 1887 Me. Laws 104; ACT RELATING TO PUNISHMENT FOR MURDER, CH. 387, SEC. 1, § 4876, 1911 MINN. LAWS 572, 572 (revising Minnesota's sentence for first degree murder to "life imprisonment"); ACT ABOLISHING CAPITAL PUNISHMENT, NO. 282, 1957 HAW. SESS. LAWS 314 (changing Hawaii's sentence for first and second degree murder to "imprisonment at hard labor" and repealing the law permitting capital punishment); ALASKA STAT. ANN. § 12.55.015 (West 2013) (providing the authorized sentences for convicted criminals, and does not include a death sentence. Note, the Territorial Legislature of Alaska abolished the death penalty before Alaska gained statehood, and as a state, Alaska has never created a statute for the death penalty); An Act to Abolish the Death Penalty, No. 30, sec 1, § 2303, 1965 Vt. Pub. Acts 28 (current version at VT. STAT. ANN. tit. 13, § 2303 (2013)); W. Va. Code Ann. § 61-11-2 (West 2013) (abolishing capital punishment in West Virginia in 1965); Death Penalty Abolition Act, ch. 436, sec. 3, §763.1, 1965 Iowa Acts 828, 828; Criminal Law Revision Act, ch. 116, §§ 31, 41, 1973 N.D. Laws 215, 293-94, 300 (repealing North Dakota's capital punishment statute and creating new criminal sentencing guidelines of imprisonment); An Act to Repeal the Death Penalty, No. 3-113, 27 D.C. Reg. 5624 (Feb. 26, 1981) (repealing the death penalty and substituting life imprisonment instead); Commonwealth v. Colon-Cruz, 470 N.E.2d 116 (Mass. 1984) (holding that Massachusetts' death penalty statute violated the state constitution); Act of July 1, 1984, ch. 221, 1984 R.I. Gen. Laws. Adv. Legis. Serv. 524 (West 2013) (removing the punishment of death from sentencing provisions for first degree murder); *People v. LaValle*, 817 N.E.2d 341 (N.Y. 2004) (holding the death penalty statute, N.Y. Crim. Proc. Law § 400.27 (McKinney 2004), in violation of the state constitution. In 2007, the New York Court of Appeals applied its prior holding in *LaValle* to the last remaining person on death row, and has not passed a new law to reinstate the death penalty since. The remaining states without a death penalty are as follows: *People v. Taylor*, 878 N.E.2d 969 (N.J. 2007); An Act to Eliminate the Death Penalty, ch. 204, 2007 N.J. Laws 1427 (amending N.J.S.2C and repealing P.L. 1983); Act of July 1, 2009, ch. 11, 2009 N.M. Laws 133 (abolishing the death penalty in New Mexico and providing for life imprisonment without possibility of release or parole); Act effective July 1, 2011, No. 96-1543, 2010 Ill. Legis. Serv. 7778-79 (S.B. 3539) (West 2013) (creating a death penalty abolition fund and abolishing the death penalty in Illinois); Act Revising the Penalty for Capital Felonies, No. 12-5, 2012 Conn. Legis. Serv. 13 (West 2013) (providing for a definite sentence of imprisonment for capital felonies); Death Penalty Repeal Act effective Oct. 1, 2013, ch. 156, 2013 Md. Laws __ (repealing the death penalty and substituting for life without the possibility of parole). Notably, the abolishment of the death penalty was retroactive in every state except for New Mexico, 2009 N.M. Laws 133, Connecticut, 2012 Conn. Legis. Serv. 13, and Maryland, Death Penalty Repeal Act, ch. 156, therefore leaving several people on each of the three states' death rows, respectively.

related problems and legal challenges.⁸¹ Beginning on September 26, 2007, the day the Court granted certiorari in *Baze*, no additional executions were conducted until May 6, 2008.⁸² While the Court did not declare a general moratorium on executions during this seven-month period, a de facto moratorium evolved when the Court granted stays of execution for individual cases that came before it.⁸³ Historically, such a lengthy hiatus is rare. After *Baze* was decided, those stays ended when the Justices denied the underlying appeals. But given the narrowness and ineffectiveness of *Baze*, the Court's decision has had minimal effect in the way that the *Baze* plurality intended.⁸⁴ Executions began again but so did lethal injection litigation, and with a vengeance.

II. BAZE AS PRECEDENT

When the Supreme Court affirmed Kentucky's three-drug protocol in *Baze*, some commentators predicted that there would be a surge of executions because the de facto moratorium had created a backlog of death row inmates.⁸⁵ That prediction was never realized; apart from a slight rise in 2009, executions have continued their downward trend.⁸⁶ One reason for this decline may be that the death penalty's popularity has weakened in recent years.⁸⁷ Whether because of discoveries of innocence among death

⁸¹ See Death Penalty Information Center, *Searchable Execution Database*, <http://deathpenaltyinfo.org/executions> (July 11, 2013).

⁸² Shaila Dewan, *Releases From Death Row Raise Doubts Over Quality of Defense*, N.Y. TIMES, May 7, 2008, A1.

⁸³ Linda Greenhouse, *Justices Uphold Lethal Injection in Kentucky Case*, N.Y. TIMES, Apr. 17, 2008, at A1.

⁸⁴ Dieter, *supra* note 2, at 806.

⁸⁵ Liptak, *supra* note 13, at A26.

⁸⁶ The number of executions (in parentheses) by year is as follows: 2008 (37), 2009 (52), 2010 (46), 2011 (43), 2012 (43), and up to August 1, 2013 (18). See Death Penalty Information Center, *Searchable Execution Database*, <http://deathpenaltyinfo.org/executions> (July 11, 2013, 4:40 PM).

⁸⁷ A recent Gallup Poll measured Americans' abstract support for the death penalty at 63%, the second-lowest level of support for capital punishment since 1978, and a significant decline from 1994, when 80% of respondents were in favor of the death penalty. In 2011, Gallup found 61% in support of the death penalty, the lowest level in 40 years. Lydia Saad, *U.S. Death Penalty Support Stable at 63%*, Gallup (January 9, 2013), http://www.gallup.com/poll/159770/death-penalty-support-stable.aspx?utm_source=alert&utm_medium=email&utm_campaign=syndication&utm_content=morelink&utm_term=All%20Gallup%20Headlines%20-%20Politics; see also *The Death Penalty in 2012: Year End Report*, Death Penalty Information Center (December 2012), <http://deathpenaltyinfo.org/documents/2012YearEnd.pdf>. The Report noted that the number of new death sentences in 2012 was the second lowest since the death penalty was reinstated in 1976, representing a nearly 75% decline since 1996, when there were 315 new

row inmates, a reduction in the number of individuals eligible for execution, racial disparities, botched executions, or other reasons, the courts and the public have shown more skepticism of the capital punishment process in the twenty-first century than they have since the early 1970s.⁸⁸ Yet, without a doubt, lethal injection challenges have spearheaded this skepticism. According to one death penalty commentator, lethal injection challenges “have already held up more executions, and for a longer time than appeals involving such . . . issues as race, innocence, and mental competency.”⁸⁹

This Article also demonstrates that the legal issues and procedures evaluated by the *Baze* Court have been overshadowed by far more pragmatic threats to the continuation of executions by lethal injection. Considered together with the ongoing mass of lethal injection challenges and protocol changes that have ensued in the past five years, it can be argued that *Baze* has rendered itself moot.⁹⁰ Yet this is a remarkable conclusion to reach regarding a Supreme Court opinion merely five years after its issuance, particularly in a case that marks the Court’s first foray into the constitutionality of an execution method in over six decades.⁹¹

In Part II, I evaluate *Baze* as precedent, based on my analysis of all 333 cases that have cited the *Baze* Court’s plurality opinion (as well as the concurrences and dissent) from the time *Baze* was decided until June 1, 2013.⁹² In conducting this analysis, I reviewed the nature of each case’s citation and reference to *Baze*, and then categorized the cases into one or more of the following categories: “substantial risk standard,” “concurring and dissenting opinions,” and “Eighth Amendment standard.”⁹³ In the next

death sentences. *Id.*

⁸⁸ Ronald J. Tabak, *Capital Punishment: The State of Criminal Justice*, A.B.A. CRIM. J. SEC. 305, 305-324, 328-338, 343-345 (2013).

⁸⁹ Dieter, *supra* note 2, at 789.

⁹⁰ See *infra* notes x-x and accompanying text.

⁹¹ This six-decade demarcation was offered by the Court. See *Baze v. Rees*, 553 U.S. 35, 48-50 (2008) (plurality opinion) (discussing the Eighth Amendment precedent of *Wilkerson v. Utah*, 99 U.S. 130 (1878), *In re Kemmler*, 136 U.S. 436 (1890), and *Louisiana ex rel. v. Resweber*, 329 U.S. 459 (1947)). There is room for disagreement, however, on when the Court last reviewed evidence concerning the constitutionality of an execution method given that the cases the Court cites were decided before the Eighth Amendment’s incorporation into the Due Process Clause. See Denno, *Getting to Death*, *supra* note 1, at 321-34.

⁹² A total of 406 cases cited *Baze*; however, 73 cases were lower court decisions that eventually evolved into the appellate court decisions that this Article analyzes. Thus the final 333 cases are not redundant. All 406 cases, however, are categorized and documented in detail in a manuscript on file with the author. See Deborah W. Denno, *Analyzing Precedent in Baze v. Rees: 2008-2013* (Aug. 1, 2013) (on file with the author).

⁹³ See Denno, *supra* note 92. In total, 14 cases were not included in this analysis because their use of *Baze* was not directly relevant. For example, six of these cases cited *Baze* for the purpose of declaring that states are subject to the Excessive Fines Clause of

three subsections, I will discuss each category in turn. I conclude that Baze's already limited precedential force is altogether inapplicable to recent litigation spurred by this country's unanticipated drug shortages.

A. Substantial Risk Standard

The substantial risk standard in *Baze* was the most encompassing category in my study. While *Baze* alludes to a number of risk standards,⁹⁴

the Eighth Amendment. See *Betha v. Salazar*, No. EDCV 05-1168 DOC (FFM), 2008 WL 4381545, at *13 n.24 (C.D. Cal. Sept. 23, 2008) (citing *Baze* in a footnote stating that the Eighth Amendment provides that excessive bail shall not be required, nor excessive fines imposed. (quotations and citations omitted)); *State v. Cottrell*, 271 P.3d 1243, 1256 n.4 (Idaho App. 2012) (citing *Baze* in a footnote explaining that states are subject to the Excessive Fines Clause because the whole of the Eighth Amendment is applicable to the states). Eight cases cited *Baze* in ways that do not coincide with the three major categories. Most of these cases mentioned *Baze* in a footnote or in combination with other cases to reinforce a briefly mentioned point. See *Barrett v. US*, No. 09-CIV-105-JHP, 2010 WL 774192, at *1 (E.D. Okla. Feb. 26, 2010) (citing the statement "death is different" from *Baze* in the sentence, "[w]hile the Court understands that 'death is different,' the issues in this particular case are not significantly more complex than any other criminal case tried in this district."); *Karban v. Ryan*, No. CV 10-0406-TUC-DCB, 2011 WL 320559, at *3 (D. Ariz. Jan. 27, 2011) (using *Baze* as a citation for the statement, "'speculation cannot substitute for evidence' of irreparable harm."); *Schwab v. Sec'y, Dep't of Corr.*, 284 F.App'x. 643, 644 (stating that the plaintiff "has abandoned the argument he made in the district court that it had misinterpreted its November 14, 2007 order providing that unless Schwab filed a motion to re-open the case within 30 days after a final decision in *Baze v. Rees*"); *State v. Hartman*, No. 25055, 2010 WL 4867370, at *4 (Ohio App. Nov. 24, 2010) (stating that in *Baze*, the "United States Supreme Court recognized a condemned prisoner's right to challenge the method of execution and adopted the appropriate standard to be applied in considering that challenge"); *State v. Jackson*, No. 92003717DI, 2008 WL 5048424, at *3 (Del. Super. Nov. 25, 2008) ("A trial in the District Court litigation was then postponed pending a decision of the United States Supreme Court in *Baze v. Rees*."); *Walker v. Epps*, 550 F.3d 407, 416 (5th Cir. 2008) (stating that *Baze v. Rees* has permitted inmates to challenge the state's method of execution under §1983 and a constitutional standard.); *Wilson v. Strickland*, No. 2:09-cv-271, 2009 WL 1362511, at *3 (S.D. Ohio May 13, 2009) ("The Supreme Court's decision in *Baze* did not create a new constitutional right that applies retroactively..."); *Zack v. Tucker*, 704 F.3d 917, 925 (stating that the Supreme Court in *Baze* has "observed that the purpose of the habeas statute of limitations is to end delays in criminal cases").

⁹⁴ *Baze*, 533 U.S. at 47-50. For a discussion and criticism of these standards see Ty Alper, *The Truth About Physician Participation in Lethal Injection Executions*, 88 N.C.L. REV. 11, 14-16, 39-40 (2009); Eric Berger, *In Search of a Theory of Deference: The Eighth Amendment, Democratic Pedigree, and Constitutional Decision Making*, 88 WASH. U.L. REV. 1, 9-10, 24-25 (2010); Denno, *supra* note 18, at 196-201; Deborah W. Denno, *When Willie Francis Died: The "Disturbing" Story Behind One of the Eighth Amendment's Most Enduring Standards of Risk*, in DEATH PENALTY STORIES 17, 89-93 (John H. Blume & Jordan M. Steiker eds., 2009); Nadia N. Sawicki, "There Must Be a Means –The Backward Jurisprudence of *Baze v. Rees*", 12 U. PA. J. INT'L. 1407, 1409-14 (2011).

the cases in this study tended to favor a particularly high hurdle for the petitioner: in order to constitute an Eighth Amendment violation, a risk must be “*sure or very likely* to cause serious illness and needless suffering, and give rise to sufficiently *imminent* dangers.”⁹⁵ Altogether, 248 cases cited this standard in response to four potential Eighth Amendment challenges related to state protocols: (1) execution team training, (2) drug type and protocol procedure, (3) use of foreign-sourced drugs, or (4) failure to protect inmates from alleged violent and assaultive prison conditions.⁹⁶

1. Execution Team Training

A number of cases (29 in total) cited *Baze* in discussions of execution team or supervisor training levels and protocols.⁹⁷ All cases, with the exception of one that was remanded,⁹⁸ referenced *Baze* in questioning evidence of improper training. As noted in one representative case, any risk of mistake on the execution team’s part connected to the team’s lack of practice using a certain drug “is speculative and fails to rise to the level required to demonstrate a substantial risk of serious harm under Eighth Amendment jurisprudence.”⁹⁹

2. Drug Type and Protocol Procedure

Most cases (215 cases or 87%) cite *Baze*’s substantial risk standard to refute challenges concerning a protocol’s use of particular lethal injection drugs or procedures.¹⁰⁰ Many of the cases argue that the protocol’s implementation violated the Eighth Amendment,¹⁰¹ while others involve

⁹⁵ *Baze*, 533 U.S. at 50 (emphasis provided).

⁹⁶ Denno, *supra* note 92.

⁹⁷ *Id.*

⁹⁸ See *Morales v. Cate*, 757 F. Supp. 2d 961, 967 (N.D. Cal. 2010) (noting that a prior California case found that “the execution team improperly mixed, prepared, and administered sodium thiopental during executions . . . that members of California’s execution team were insufficiently qualified, that the IV team members were not adequately prepared to deal with any complications that may arise, that the walk-throughs in which the execution team participated were incomplete and the team did not receive meaningful training”).

⁹⁹ See *Beatty v. Brewer*, 791 F. Supp. 2d 678, 684-85 (D. Ariz. 2011); see also *Campbell v. Wood*, 18 F.3d 662, 687 (9th Cir. 1994) (“The risk of accident cannot and need not be eliminated from the execution process in order to survive constitutional review.”).

¹⁰⁰ See Denno, *supra* note 92.

¹⁰¹ See *Jackson v. Danberg*, 656 F.3d 157, 163 (3d Cir. 2011) (“Simply because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of ‘objectively intolerable risk of harm’ that qualifies as

challenges to the type of drug being injected, such as the choice of pentobarbital in place of sodium thiopental.¹⁰² Almost every court relied on the *Baze* substantial risk standard to establish that the method of injection and the drugs administered did not pose a risk sufficient to constitute an Eighth Amendment violation.¹⁰³

A breakdown of these cases provides more specific insight into the kinds of issues addressed. For example, 195 of the 215 cases concern challenges to a state protocol's method or procedure.¹⁰⁴ These include challenges to the type of method used—a one-drug¹⁰⁵ or three-drug¹⁰⁶ method—and/or the state protocol's lethal injection procedure in general.¹⁰⁷ As stated above, each court presented with a protocol challenge found that the plaintiff(s) in question could not establish that the protocol created a

cruel and unusual.”); *Batiste v. State*, No. 2010–DP–00510–SCT, 2013 WL 2097551, at *52 (Miss. May 16, 2013) (finding Mississippi's protocol “substantially similar” to Kentucky's protocol, so an Eighth Amendment challenge is unfounded).

¹⁰² See *Pavatt v. Jones*, 627 F.3d 1336, 1338 (10th Cir. 2010) (finding that the State's use of pentobarbital in a lethal injection protocol fell short of the level of risk that was needed to establish an Eighth Amendment claim); see also *Jackson*, 656 F.3d at 160 (stating that “Delaware, along with a number of other states, revised its protocol to allow for the use of an alternative barbiturate, pentobarbital, as the first chemical to be administered”); *State v. Santiago* 305 Conn. 101, 317 (Conn. 2012) (noting that “[i]n light of recent developments that have seriously restricted the availability of sodium thiopental for use in executions, those death penalty jurisdictions that more actively implement death sentences have turned to pentobarbital as a substitute drug”); *Lucas v. Upton*, No. 5:09–CV–289 (CAR), 2011 WL 4526754, at *8 n.3 (M.D. Ga. Sept. 28, 2011) (“Since confiscation of its supply of sodium thiopental, Georgia as well as other states have started to use pentobarbital as the first drug in the 3 step lethal injection process.”); *State v. Rizzo* 303 Conn. 71, 193 (Conn. 2011) (noting the shortage of thiopental sodium generally).

¹⁰³ *Denno*, *supra* note 92.

¹⁰⁴ *Id.*

¹⁰⁵ See *Pardo v. Palmer*, 500 F.App'x 901, 901-905 (11th Cir. 2012) (upholding a one-drug lethal injection protocol); *Cooley v. Strickland*, 589 F.3d 210, 210 (6th Cir. 2012) (holding that the “risk of improper implementation of one-drug protocol did not render protocol cruel and unusual in violation of Eighth Amendment”).

¹⁰⁶ See *Peterson v. State*, 2 So. 3d 146, 157 (Fla. 2009) (finding that the plaintiff's argument that Florida's lethal injection process is unconstitutional because it employs a three-drug protocol that may cause undue pain does not qualify as a substantial risk); *Thomas v. State*, No. W2008–01941–CCA–R3–PD, 2011 WL 675936, at *46-47 (Tenn. Crim. App. Feb. 23, 2011) (upholding a three-drug lethal injection protocol).

¹⁰⁷ See *State v. Odom*, No. W2008-02464-CCA-R3-DD, 2010 LEXIS 223, at *104-107 (Tenn. Crim. App. Mar. 4, 2010) (ruling against the plaintiff's argument that the state's written protocol lacks safeguards and other written provisions and is thus unconstitutional); *Grant v. Workman*, No. 05–CV–0167–TCK–TLW, 2010 WL 5069853, at *41-42 (N.D. Okla. Dec. 2, 2010) (ruling against the plaintiff's argument that the state's lethal injection protocol violates the Eighth Amendment because it “creates a substantial risk of inmate suffering intense pain” due to the fact that “there is no assurance that Oklahoma's procedure will render him unconscious during the execution”).

demonstrated risk of severe pain, as explicated in *Baze*, or that the risk was substantial compared to other known methods.¹⁰⁸ In coming to this conclusion, many courts compared the challenged state protocol to Kentucky's protocol and found the two protocols to be "substantially similar," and thus, the challenged protocol constitutional.¹⁰⁹

Additionally, 26 of the 215 cases dealt with challenges to the drug being used for the procedure,¹¹⁰ with 19 specific challenges to the use of pentobarbital as a replacement for sodium thiopental in a state's one-drug or three-drug method.¹¹¹ Despite its limited testing and use in lethal injection procedures, courts consistently upheld the implementation of pentobarbital and found that its substitution for sodium thiopental did not create a substantial risk of harm to the inmate.¹¹²

3. Foreign-Sourced Drugs

With the increasing scarcity of lethal injection drugs in this country,

¹⁰⁸ See *Harbison v. Little*, 723 F.2d 1032, 1038-1044 (6th Cir. 2009) (finding that the inmate failed to show that the protocol retained an inherent risk of severe pain, which was substantial compared to the alternatives).

¹⁰⁹ See *Batiste v. State*, No. 2010-DP-00510-SCT, 2013 WL 2097551 at *52 (Miss. May 16, 2013); see also *Jackson v. Danberg*, 656 F.3d 157, 163 (3d Cir. 2011) (affirming the District Court's conclusion that the state's lethal injection protocol was constitutional since it was found to be "substantially similar" to Kentucky's protocol); *Brown v. Sec'y, Dep't of Corr.*, No. 8:01-cv-2374-T-23TGW, 2009 WL 4349320, at *21 (M.D. Fla. Nov. 25, 2009) (adopting a trial court's analysis concluding that "Florida's lethal-injection protocol is 'substantially similar' to that of Kentucky"); *Emmett v. Johnson*, 532 F.3d 291, 300 (4th Cir. 2008) (concluding that "Virginia's protocol is substantially similar to Kentucky's protocol" and that the plaintiff has "failed as a matter of law to demonstrate a substantial or objectively intolerable risk that he will receive an inadequate dose of thiopental").

¹¹⁰ See *Brewer v. Landrigan*, 131 S. Ct. 445, 445 (2010) (ruling against a plaintiff who challenged the use of potentially non-FDA approved sodium thiopental); see also *Kerr v. Thaler*, 384 F.App'x 400, 405 (5th Cir. 2009) (citing *Baze* to find that the use of pancuronium bromide in a three-drug injection method, which was contested by the plaintiff, was not a violation of the Eighth Amendment).

¹¹¹ *Denno*, *supra* note 92.

¹¹² See *Valle v. State*, 70 So. 3d 530, 538-553 (Fla. 2011) (upholding the use of pentobarbital in the state's three-drug lethal injection method); *Creech v. Reinke*, No. 1:12-cv-00173-EJL, 2012 WL 1995085, at *16-24 (D. Idaho June 4, 2012) (finding that the plaintiff could not show that the use of the pentobarbital in a three-drug method would be substantially different from its use in a one-drug method and would not cause an Eighth Amendment violation.); *Beaty v. Brewer*, 791 F. Supp. 2d 678, 681-686 (9th Cir. 2011) (holding that the inmate failed to establish a likelihood of success in his claim that the State's last minute substitution of pentobarbital for sodium thiopental violated the Eighth Amendment.); see also *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011); *Arthur v. Thomas*, 674 F.3d 1257 (11th Cir. 2011).

especially sodium thiopental, departments of corrections started purchasing drugs from other countries.¹¹³ Some drug protocol challenges attacked the use of foreign-sourced drugs, and 13 cases cite *Baze* for support.¹¹⁴ Strikingly, almost every court presented with a foreign drug challenge found that the plaintiff did not have sufficient evidence to show that the use of a foreign-produced drug would be likely to create a substantial risk of unconstitutional harm.¹¹⁵ Today, such determinations would no longer be viable. On July 23, 2013 the D.C. Circuit held that the FDA violated the Food, Drug and Cosmetic Act and the Administrative Procedure Act by allowing the importation of unapproved or misbranded sodium thiopental for use in lethal injection procedures.¹¹⁶

4. Failure to Protect

Not surprisingly, courts have relied on *Baze* for challenges apart from problems associated with lethal injection. Altogether, 33 cases cited *Baze* in the context of “failure to protect” claims under the Eighth Amendment, most typically raised against a prison official for failing to protect an inmate from harm or for a violation of a duty to protect from future harm.¹¹⁷ *Baze* was most often cited to affirm that in order to establish such a claim, the plaintiff must “allege facts from which a court could conclude that he faces a substantial risk of serious harm, and that the defendants knew of and disregarded that risk.”¹¹⁸ The finding in *Baze* that an “isolated mishap” or “an accident with no suggestion of malevolence”¹¹⁹ would not give rise to an Eighth Amendment violation is often used to support the rejection of the failure to protect claims brought about in these cases.¹²⁰ Most of the “failure to protect” cases are in reference to prison

¹¹³ See *infra* notes x-x and accompanying text.

¹¹⁴ Denno, *supra* note 92.

¹¹⁵ See *Valle*, 70 So. 3d at 546 (finding that the use of a potentially FDA-unapproved drug “did not show that the modified procedure was sure or very likely to cause serious illness and needless suffering or result in substantial risk of serious harm”); *Towery v. Brewer* 672 F.3d 650, 654-661 (9th Cir. 2012) (rejecting the plaintiffs’ argument that use of foreign-obtained pancuronium bromide will subject them to a risk of pain and suffering because foreign-sourced drugs do not have FDA approval).

¹¹⁶ See *Cook v. FDA*, No. 12-5176, at *2-21 (D.D.C. July 23, 2013) (affirming the judgment from *Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012) which permanently enjoined the FDA from allowing the importation of apparently misbranded or unapproved sodium thiopental based on the finding that the use of such drugs create an unnecessary risk of improper anesthetization).

¹¹⁷ Denno, *supra* note 92.

¹¹⁸ *Wilson v. Ryker*, 451 Fed.Appx. 588, 589 (7th Cir. 2011).

¹¹⁹ *Baze v. Rees*, 553 U.S. 35, 50 (2008).

¹²⁰ See *Mitchell v. Cnty. of San Bernardino*, No. CV 09-5531-SJO (AGR), 2011 WL

violence, assault and/or abuse; however, some cases discuss different settings in which a substantial risk first must be established.¹²¹ While such a use of *Baze* is predictable given the dearth of Eighth Amendment precedent, it seems a stretch in light of more relevant doctrine specifically dealing with prison violence in a way *Baze* does not.¹²²

B. Concurring and Dissenting Opinions

Over one-fifth of the 333 cases cited opinions other than the *Baze* plurality.¹²³ These 73 cases primarily included references to Justice Thomas' and Justice Stevens' concurrences as well as Justice Ginsberg's dissent, nearly in equal number.¹²⁴ In total, 34 cases cited to Justice Thomas' concurrence which required inmates to show that a lethal injection protocol is "deliberately designed to inflict pain" to establish an Eighth Amendment violation.¹²⁵ These cases concluded that if there was sufficient evidence to uphold a lethal injection procedure under the Eighth Amendment standard set by the *Baze* plurality, there was also sufficient evidence to uphold the procedure under Justice Thomas' more rigorous intent-based standard.¹²⁶ A disproportionate number of these cases (16 in total) originated in Florida and frequently cited the following quote from the Florida Supreme Court:¹²⁷ "Florida's current lethal-injection protocol passes muster under any of the risk-based standards considered by the *Baze* Court (and would also easily satisfy the intent-based standard advocated by Justices Thomas and Scalia)."¹²⁸ Although seemingly dicta, the repeated

4801890, at *5 (C.D. Cal June 13, 2011); *Porter v. Cash*, No. CV 11-10308-DMG (AGR), 2012 WL 5308369, at *3 (C.D. Cal. Sept. 20, 2012); *Wallace v. Moberg*, No. CV 07-6-VAP (AGR), 2009 WL 91079, at *8 (C.D. Cal. Jan. 10, 2009)

¹²¹ *See Betts v. New Castle Youth Dev. Ctr.*, 621 F.3d 249, 252-261 (3d Cir. 2010) (presenting a case in which a delinquent juvenile brings an Eighth Amendment failure to protect challenge against a youth development center for a spinal injury that occurred during a "pick up" football game at the Center).

¹²² Prison condition and violence cases have, in the past, been justifications for dismissing execution methods claims. *See Denno, Getting to Death, supra* note 1, at 327-48.

¹²³ *Denno, supra* note 92.

¹²⁴ *Id.*

¹²⁵ *Baze*, 553 U.S. at 94 (Thomas, J., concurring).

¹²⁶ *See Jackson v. Danberg*, 594 F.3d 210, 222-23 (3d Cir. 2010); *see also Brown v. Sec'y, Dep't of Corr.*, No. 8:01-cv-2374-T-23TGW 2009 WL 4349320, at *20 (M.D. Fla. 2009) (explaining that Justice Thomas renounced any risk-based standard in favor of a rule of law that would uphold any method of execution that does not involve the *purposeful* infliction of "pain and suffering beyond that necessary to cause death").

¹²⁷ *Denno, supra* note 92.

¹²⁸ *Ventura v. State*, 2 So. 3d 194, 200 (Fla. 2009) (quoting *Henry v. State*, 992 So. 2d 120 (Fla. 2008), the court discusses the variety of opinions in *Baze* and notes that it

use of this particular quote by the Florida Supreme Court in its holdings was noticeable and unique among those courts approving lethal injection protocols.

In turn, a comparable number of cases (34 in total) cited Justice Stevens' concurrence,¹²⁹ a particularly noteworthy opinion because it was the first time he voiced his general opposition to the death penalty.¹³⁰ Justice Stevens explained that he concurred in *Baze* because he felt obligated under the Court's precedents; however, like Justices before him, he had gradually changed his mind about the death penalty for a range of reasons that he articulated in great detail.¹³¹ In my study, some cases cited Justice Stevens' commentary regarding the risk of error in capital cases,¹³² while other cases cited his reservations regarding the value of the death penalty.¹³³

Justice Ginsburg's dissent, which Justice Souter joined, focused more narrowly on the perils of lethal injection, emphasizing that a number of other states had instituted far more adequate procedures than Kentucky to ensure that an inmate is anesthetized before execution.¹³⁴ "[I]f readily available measures can materially increase the likelihood that the protocol will cause no pain, a State fails to adhere to contemporary standards of decency if it declines to employ those measures."¹³⁵ The 36 cases in my

believes Florida's protocol would meet all the risk-based standards mentioned by the *Baze* Court).

¹²⁹ Denno, *supra* note 92.

¹³⁰ *Baze*, 553 U.S. at 78-86 (Stevens, J., concurring).

¹³¹ For example, Justice Stevens observed the problems with the way capital punishment is actually implemented and the paradoxical result that "more recent cases have endorsed procedures that provide less protections to capital defendants than to ordinary offenders." *Id.* at 84. In his eyes, capital punishment is the "product of habit and inattention rather than any acceptable deliberative process that weighs the costs and risks of administering that penalty against its identifiable benefits." *Id.* at 78. Therefore, the punishment "represents 'the pointless and needless extinction of life with only marginal contributions to any discernible social or public purposes.'" *Id.* at 86.

¹³² See *People v. Runge*, 234 Ill. 2d 68, 172 (2009) (The dissent in *Runge* notes that the "risk of error in capital cases may be greater than in other cases because the facts are often so disturbing"); *Noling v. Bradshaw (In re Noling)*, 651 F.3d 573, 576 (2011) (Justice Stevens' concurrence in *Baze* "brings to mind the fact that many innocent people are convicted of crimes they did not commit before being vindicated by the timely revelation of exculpatory facts. Some of those people are capital defendants.").

¹³³ See *Brown v. Sec'y, Dep't of Corr.*, No. 8:01-cv-2374-T-23TGW, 2009 WL 4349320, at *20 (M.D. Fla. 2009) (citing Justice Stevens' "general disagreement with the death penalty"); *Jackson v. Danberg*, 594 F.3d 210, 218 (3d Cir. 2010) (quoting Justice Stevens' opinion that "the imposition of the death penalty represents the pointless and needless extinction of life with only marginal contributions to any discernible social or public purposes").

¹³⁴ *Baze*, 553 U.S. at 119-21 (Ginsburg, J., dissenting).

¹³⁵ *Id.* at 117 (Ginsburg, J., dissenting)

study that cited to Justice Ginsburg's dissent stressed the safeguards states had implemented in their lethal injection protocols.¹³⁶ The majority went even further, comparing a specific state's lethal injection safeguards to Kentucky's lack of safeguards as a way to further affirm the constitutionality of the specific state's lethal injection protocol.¹³⁷

C. Eighth Amendment Standard

Altogether, 54 cases cited *Baze* in reference to the Eighth Amendment and/or to affirm the constitutionality of lethal injection by the Court's holding that injection does not constitute cruel and unusual punishment.¹³⁸ Some cases, for example, referenced the *Baze* plurality's characterization of the Eighth Amendment merely to affirm that citizens are privy to the rights listed within the Amendment.¹³⁹ Other cases focused more specifically on lethal injection. *Broom v. Strickland*,¹⁴⁰ for instance, cited the *Baze* Court's determination that Kentucky's lethal injection protocol is constitutional in order to compare a situation in which a lethal injection attempt may be considered unconstitutional.¹⁴¹

¹³⁶ Denno, *supra* note 92.

¹³⁷ See *Henyard v. Does*, 543 F.3d 644, 648 (2008) (citing to the finding by Justice Ginsberg that revisions to Florida's lethal injection protocols provide additional safeguards in comparison to Kentucky's protocol); *Chester v. Wetzel*, No. 1:08-cv-1261, 2012 WL 5439054, at *11 (M.D. Penn. Nov. 6, 2012) ("Justice Ginsburg noted that Kentucky's protocol did not require anyone to call the inmate's name, shake the inmate, brush his eyelashes, or apply noxious stimulus to gauge his response. . . . [S]uch a consciousness check could be easily implemented and could reduce the risk of dreadful pain.").

¹³⁸ Denno, *supra* note 92; *see e.g.*, *Fields v. Commonwealth*, 274 S.W.3d 375, 420 (Ky. 2008) (citing *Baze* to support the statement, "[l]ethal injection is not cruel and unusual punishment"); *Alba v. Quarterman*, 621 F. Supp. 2d 396, 432 (5th Cir. 2008) (citing *Baze* to state that lethal injection is a constitutionally permissible form of execution); *Hartman v. Bobby*, 319 F.App'x. 370, 372 n.1 (6th Cir. 2009) (stating that the court "cannot authorize a successive petition or grant a stay on this ground, because the Supreme Court's decision in *Baze* did not create a new constitutional right that applies retroactively. . ."); *see also*, *Riley v. McDaniel*, No. 3:01-cv-0096-RCJ-VPC, 2010 WL 3786070, at *59 (D. Nev. Sept. 10, 2010); *Scott v. Houk*, No. 4:07-CV-0753, 2011 WL 5838195, at *45-46 (N.D. Ohio Nov. 18, 2011); *Thompson v. Bell*, 580 F.3d 423, 448 (6th Cir. 2009).

¹³⁹ *See Trinidad y Garcia v. Thomas*, 683 F.3d 952, 964 (9th Cir. 2012) (using *Baze* as a citation for the statement, "the Constitution guarantees an individual a broad range of 'rights, privileges, and immunities' against the United States government, including the right to be free from torture").

¹⁴⁰ *Broom v. Strickland*, No. 2:09-cv-823, 2010 WL 3447741, at *2 (S.D. Ohio Aug. 27, 2010).

¹⁴¹ *Id.* (stating that a "series of abortive execution attempts could potentially indeed present an unconstitutional violation").

D. Summary of Findings

Baze has not been entirely void of precedential force over the last five years; yet this study clearly demonstrates that numbers of citations are not always indicators of an opinion's efficacy. For that matter, citations to *Baze* have decreased substantially in the last three years,¹⁴² most likely because the nature of lethal injection challenges now bear on issues that have only remote or nonexistent parallels to those that prompted *Baze* in the first place.¹⁴³ In addition, recent developments have shown that some of the purposes for which *Baze* may have been used in the past are no longer viable, foreign-drug use being a particularly striking example.¹⁴⁴ Indeed, post-*Baze* lethal injection litigation is so prolific and variable that it seemingly dwarfs the extent to which *Baze* has been used to dismiss challenges.

III. POST-BAZE LITIGATION AND RISK

On June 10, 2008, less than two months after *Baze* was decided, an Ohio state court judge ruled in *State v. Rivera*¹⁴⁵ that Ohio could no longer employ the standard three-drug protocol (used in Kentucky) for executing inmates because the drug combination contravened Ohio's own lethal injection statute and therefore violated due process.¹⁴⁶ In making this determination, the court heard testimony from two of the key medical experts who also testified for the defense and the State respectively in *Baze*.¹⁴⁷ Yet the *Rivera* court reached different conclusions from *Baze*, holding specifically that "the use of two drugs in the lethal injection protocol (pancuronium bromide and potassium chloride) creates an unnecessary and arbitrary risk that the condemned will experience an agonizing and painful death."¹⁴⁸ This recognition prompted the court to hold that the state's lethal injection protocol should apply only "a lethal injection of a single, anesthetic drug."¹⁴⁹

¹⁴² The distributions by year are as follows: 2008: 52 cases; 2009: 74 cases; 2010: 80 cases; 2011: 61 cases; 2012: 53 cases; 2013: 13 cases. Denno, *supra* note 92.

¹⁴³ See *infra* notes x-x and accompanying text.

¹⁴⁴ See *supra* notes x-x and accompanying text; *infra* notes x-x and accompanying text.

¹⁴⁵ No. 04CR065940, slip op. at 1 (Ohio Ct. Com. Pl., Lorain County, June 10, 2008).

¹⁴⁶ *Id.* at 1, 9.

¹⁴⁷ *Id.* at 1. The two doctors were Mark Heath, M.D. for the defense and Mark Dershwitz, M.D. for the government. See Susi Vassallo, *Thiopental in Lethal Injection*, FORDHAM URB. L.J. 957, 958-59 (2008).

¹⁴⁸ *Rivera*, No. 04CR065940, slip op. at 6.

¹⁴⁹ *Id.* at 9.

By way of affirming these dangers, the *Rivera* court listed as a finding of fact nearly every criticism made of the three-drug combination, ranging from the difficulties in assessing the condemned person's depth of anesthesia before administering the second and third drugs, to the heightened risk from physicians' refusal to participate in the process, to the number of mistakes made in the delivery of anesthesia even in a clinical setting.¹⁵⁰ The *Rivera* court also recognized "[c]ircumstantial evidence . . . that some condemned prisoners have suffered a painful death, due to a flawed lethal injection."¹⁵¹

One reason for the seeming divergence of *Rivera*'s holding from that of *Baze* is Ohio's lethal injection statute. That statute requires "a lethal injection of a drug or combination of drugs of sufficient dosage to quickly and painlessly cause death."¹⁵² In contrast, "the Kentucky lethal injection statute has no mandate that an execution be painless."¹⁵³ Therefore, an interpretation of Kentucky's statute "is not applicable" in *Rivera*, because, unlike Ohio's statute, "the [U.S.] Constitution does not demand the avoidance of all risk of pain in carrying out its executions."¹⁵⁴

Rivera was the first case in which a court ordered a state to employ only a single anesthetic drug, thus reflecting the momentum created by other judges and commissions that had long criticized the three-drug combination.¹⁵⁵ The *Baze* Court emphasized the uniqueness of this very situation by noting that the petitioners' proposed alternative protocol (the use of a single barbiturate) was "one that . . . has not been adopted by any State and has never been tried."¹⁵⁶ With *Rivera*, the "uniqueness" claim from *Baze* would no longer be accurate. By breaking away from the three-

¹⁵⁰ *Id.* at 3-4.

¹⁵¹ *Id.* at 4.

¹⁵² Ohio Rev. Code Ann. § 2949.22(A) (West 2008). The *Rivera* court emphasized that the statute's purpose "is to provide the condemned person with an execution that is 'quick' and 'painless;'" and the legislature's use of the word, 'shall,' when qualifying the state's duty to provide a quick and painless death signifies that the duty is mandatory." *Rivera*, No. 04CR065940, slip op. at 5. Because "the duty of the state to the individual is mandatory, a property interest is created in the benefit"; the statute confers on the condemned person a property interest in a painless death. *Id.* For the state to then execute the condemned person in a manner that carries an "unnecessary risk of pain, and, as well, any unnecessary expectation by the condemned person that his execution may be agonizing, or excruciatingly painful," *id.* at 7, violates the Due Process Clause of the Fifth and Fourteenth Amendments. *Id.* at 8. As a result, the *Rivera* court ordered that "the words, 'or combination of drugs,' be severed" from the Ohio statute in light of the court's ruling that only one anesthetic drug be employed. *Id.* at 9.

¹⁵³ *Id.* at 7.

¹⁵⁴ *Id.*

¹⁵⁵ Adam Liptak & Adam B. Ellick, *Judge Orders Ohio to Alter Its Method of Execution*, N.Y. TIMES, June 11, 2008, at A16.

¹⁵⁶ *Baze v. Rees*, 553 U.S. 35, 41 (2008) (plurality opinion).

drug-formula pact, *Rivera* started to weaken the safety-in-numbers argument states had embraced in determining that a shared lethal injection formula provides a humane death.

Like *Morales v. Hickman*¹⁵⁷ and earlier cases,¹⁵⁸ *Rivera* also cut through much of the paradox in *Baze* that even the Supreme Court was unable to avoid. For example, with the single-barbiturate injection, *Rivera* provided a potential solution to the absence of a medical professional in the execution chamber because a one-drug formula was considered so much easier to use.¹⁵⁹ This solution was aided by the *Rivera* court's focus on the constitutional viability of the execution method itself, and not the larger topic of the death penalty generally. After all, medical professionals have recommended abolition as a solution for avoiding the potential hazard of physician involvement in executions.¹⁶⁰ Without the distraction of having to grapple with death penalty debates more broadly, the *Rivera* court was better able to evaluate different types of lethal injection procedures.

As it would turn out, however, Ohio's breaking from the pack, even to satisfy legislative requirements, would garner substantial notice. This switch was a huge development in the death penalty world, and the first such inroad with lethal injection, especially coming on the heels of *Baze*.¹⁶¹ *Baze* was supposed to be the Supreme Court's effort to end the lethal injection story, not push it full throttle.

The next post-*Baze* chapter would be even more critical because it would involve all three administrative layers in the execution process: the legislature, the courts, and the department of corrections. No matter what lethal injection statute a legislature has in place or how a court interprets that statute, both legislatures and courts delegate the actual business of executions to a department of corrections.¹⁶² Until Ohio's change to a single-drug protocol, the Southern Ohio Correctional Facility ("Ohio Facility") in Lucasville held a striking record of ineptitude in the execution or attempted execution of inmates, the Romell Broom case being the most

¹⁵⁷ 415 F. Supp. 2d 1037 (N.D. Cal. 2006), *aff'd per curiam*, 438 F.3d 926 (9th Cir. 2006), *cert. denied*, 546 U.S. 1163 (2006).

¹⁵⁸ See Denno, *Lethal Injection Quandary*, *supra* note 1, at 102-17.

¹⁵⁹ See *Death Penalty: States Transition to One-Drug Executions*, PBS NEWSHOUR, (Jul. 19, 2012, 6:56pm), <http://www.pbs.org/newshour/rundown/2012/07/death-penalty-states-transition-to-one-drug-executions.html>.

¹⁶⁰ See Atul Gawande, *When Law and Ethics Collide – Why Physicians Participate in Executions*, 354 NEW ENG. J. MED. 1229 (2006).

¹⁶¹ See *infra* notes x-x and accompanying text.

¹⁶² See generally Denno, *When Legislatures Delegate*, *supra* note 1 (discussing the extent to which legislatures delete the execution process to departments of corrections who are typically not in a position to handle such responsibility).

egregious example.¹⁶³

As stung as the Ohio Facility was by its experiences with the three-drug procedure, however, officials were also concerned about the results of using a one-drug procedure that had never before been used on anyone, anywhere.¹⁶⁴ Wanting to ensure that history did not repeat itself in the upcoming execution of Kenneth Biros, in November 2009 the Ohio Facility issued a two-part lethal injection protocol (“Plan A” and “Plan B”).¹⁶⁵ In the first part (“Plan A”), executioners would inject only sodium thiopental. If the execution team failed at Plan A, Plan B directed the team to inject directly into the inmate’s arm or leg muscles an overdose of two drugs never before used in any execution in the world.¹⁶⁶

Plan B’s potential problems are vast. According to expert commentary, the two Plan B drugs, hydromorphone and midazolam, could produce a slow, lingering death with the inmate in a state confusion, disorientation, and intense psychological anguish and torment. The nauseating effect of hydromorphone could cause the prisoner to vomit, before or after drifting into unconsciousness.¹⁶⁷ While Ohio’s own lethal injection

¹⁶³ See *State v. Broom*, No. 96747, 2012 WL 504504, at *1 (Ohio Ct. App. Feb. 16, 2012). All executions in Ohio are conducted at the Southern Ohio Correctional Facility in Lucasville, Ohio. *Id.* In 2007 a nearly two-hour execution of an Ohio prisoner who appeared to be suffocated alive followed a comparably controversial ninety-minute execution a year earlier that had compelled the state to revise its procedures. *Id.* at *8. Yet, those revisions did not take hold. On September 15, 2009, Romell Broom would undergo one of the most egregious efforts by any department of corrections to attempt to inject an inmate to death, *id.* at 16, even though he would be the first inmate ever to survive a lethal injection procedure. *Id.* at *7. For over two hours, Broom withstood nearly twenty “puncture wounds,” as the execution team made “numerous, unsuccessful” attempts to search for a viable vein that would not collapse when drugs were injected. *Id.* at 1, 20. During this time, the team took breaks, changed execution strategies, probed different access sites on Broom’s body, as well as garnered the direct assistance of a staff doctor who was not part of the team. *Id.* at 1. After the first forty-five minutes of the execution process, for example, the prison director ordered the team to stop so that they could confer about what to do because nothing was working. *Id.* Ten-to-twenty minutes later, the team reconvened to try to establish an intravenous line (“IV”) in Broom’s biceps, forearms, and hands. When this strategy failed, they called upon the staff doctor to try something else. That doctor unsuccessfully attempted to insert the IV catheters on top of Broom’s foot and ankle bone, an excruciating experience for Broom who claimed that the needle entered his ankle bone. *Id.* Ultimately, the execution was halted and Broom remains alive, awaiting the possibility of a second execution attempt.

¹⁶⁴ See Ariane de Vogue & Dennis Powell, *Ohio Killer Executed in First Use of Single-Drug Lethal Injection*, ABC NEWS, Dec. 8 2009, <http://abcnews.go.com/Politics/lethal-injection-ohio-perform-execution-single-drug/story?id=9277599> (describing the use of an untested, single-drug formula).

¹⁶⁵ *Cooley v. Strickland*, 604 F.3d 939, 942-43 (6th Cir. 2010).

¹⁶⁶ de Vogue & Powell, *supra* note 164.

¹⁶⁷ *Cooley*, 604 F.3d at 942-43.

statute requires that death be “quick and painless,” commentary suggests that Plan B is probably the slowest execution method ever proposed in the United States.¹⁶⁸ Likewise, Plan B directly contravenes Ohio’s veterinary euthanasia laws because the particular drugs and intramuscular method are all prohibited for animals.¹⁶⁹

Plan B has not yet been applied in Ohio although it still remains in effect. Regardless, Kenneth Biros’ Plan A execution on December 8, 2009, was fraught with problems. Executioners required a half-hour, and nine unsuccessful attempts, to finally find a vein in which to put an IV catheter.¹⁷⁰ Ohio officials warned journalists witnessing the execution that Biros could end up vomiting and convulsing if in fact the backup plan went into effect.¹⁷¹

Ohio’s move to a single-drug statute served as an impetus to other states to also make the switch, irrespective of Ohio’s difficulties with Biros’ execution and the state’s unique statute. For over a century states have closely followed the execution strategies of other states,¹⁷² and Ohio’s change would be no exception. The key change from the past was the greater rapidity and extent to which states would follow Ohio’s decision to use only sodium thiopental. As Charts 1 and 2¹⁷³ of this Article show, eleven states – or over one-third of all the death penalty states – have moved from three drugs to one drug in less than four years (from 2009-2013). Ohio’s decision to move at the end of 2009 would be quickly followed, respectively, over the next two years by Washington (in 2010) and South Dakota (2011), and then by five states in 2012 (Arizona, Georgia, Idaho, Missouri, and Texas).¹⁷⁴ So far three states have switched from three drugs to one in 2013 (Arkansas, Kentucky, and Louisiana).¹⁷⁵ Kentucky’s switch to a single-drug protocol is particularly striking as it creates a situation in which the “model” state at the heart of *Baze* is no longer “substantially similar” to the procedure the *Baze* Court hailed as the

¹⁶⁸ de Vogue & Powell, *supra* note 164.

¹⁶⁹ Ohio Rev. Code Ann. § 4729.532 (West).

¹⁷⁰ See Aaron Marshall, *Kenneth Biros Becomes First Inmate Executed Using Single-Drug Method*, PLAIN DEALER, Dec. 8, 2009, http://blog.cleveland.com/metro/2009/12/biros_becomes_first_inmate_exe.html.

¹⁷¹ Andrew Welsh-Huggins, *States: Death-Penalty Drug Scramble, Higher Cost*, BLOOMBERG BUS. WEEK, July 9, 2011, <http://www.businessweek.com/ap/financialnews/D9OC9L100.htm>

¹⁷² For detailed examinations of these trends see generally Denno, *Lethal Injection Quandary*, *supra* note 1; Denno, *When Legislatures Delegate*, *supra* note 1; Denno, *Getting to Death*, *supra* note 1.

¹⁷³ See *infra* Charts 1 & 2.

¹⁷⁴ See *infra* Charts 1 & 2.

¹⁷⁵ See *infra* Charts 1 & 2.

standard for other states to follow.¹⁷⁶

Like other states' changes, Kentucky's was prompted by efforts to quell continuing litigation over the state's three-drug protocol despite the outcome of *Baze*.¹⁷⁷ For example, from a resource standpoint, obtaining one drug is simpler than three drugs; in addition, the process is presumably less risky because there is just one injection and no controversial paralytic agent (pancuronium bromide).¹⁷⁸ At the same time, death by sodium thiopental alone typically takes longer and the procedure is less predictable because it is far less known.¹⁷⁹ Regardless, perhaps the primary source of the one-drug method's popularity with states is that it was, at least, a move away from a three-drug process with a long and documented record of trouble. In 2013, two-thirds of the lethal injection executions used a one-drug protocol compared to one-half of the lethal injection executions in 2012.¹⁸⁰

IV. POST-*BAZE* DRUG SHORTAGES

Death penalty states would soon encounter an obstacle that the switch from three drugs to one drug would not alleviate. In 2009, the United States confronted a national shortage of sodium thiopental when Hospira Inc., the sole U.S. manufacturer of the drug, ceased production due to difficulties procuring its active ingredient from another company.¹⁸¹ Hospira originally intended to resume production of the drug at its plant in Italy, but Italian authorities threatened legal action if Hospira could not successfully prevent the drug from "being diverted to departments of corrections for use in capital punishment procedures."¹⁸² In late 2010, the

¹⁷⁶ *Baze v. Rees*, 553 U.S. 35, 41 (2008) (plurality opinion) (upholding Kentucky's three-drug protocol).

¹⁷⁷ As Franklin Circuit Judge Phillip Shepherd postulated, by moving to a one-drug protocol in Kentucky, "any claims of cruel and unusual punishment by inmates will be rendered moot." *Death Penalty: States Transition to One-Drug Executions*, PBS NEWSHOUR, (Jul. 19, 2012, 6:56pm), <http://www.pbs.org/newshour/rundown/2012/07/death-penalty-states-transition-to-one-drug-executions.html>.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ See *State-by-State Lethal Injection*, DEATH PENALTY INFO.CTR., (Jul. 25, 2013, 8:36 PM), <http://www.deathpenaltyinfo.org/state-lethal-injection>.

¹⁸¹ See *Cook v. FDA*, No. 12-5176, at *5 (D.D.C. July 23, 2013) (noting that "[i]n 2009, the last domestic manufacturer of thiopental stopped making it"); Kevin Sack, *Shortage of Widely Used Anesthetics Is Delaying Executions in Some States*, N.Y. TIMES, Sept. 30, 2010, at A23.

¹⁸² See Hospira, *Hospira Statement Regarding Pentothal™ (sodium thiopental) Market Exit* (Jan. 21, 2011), <http://phx.corporate-ir.net/phoenix.zhtml?c=175550&p=irol->

British government also banned the export of sodium thiopental to the United States after learning that the drug would be solely used for executions.¹⁸³ Unwilling to take that risk, in January 2011 Hospira stopped manufacturing sodium thiopental entirely.¹⁸⁴ Europe's prohibition of the death penalty had become an American problem.¹⁸⁵

Hospira's exit from the sodium thiopental market created the most serious challenge yet to the continuation of lethal injection. The shortage of sodium thiopental led prison officials to seek out questionable alternative sources of the drug throughout the world, ranging from England to Pakistan.¹⁸⁶ Until recently, for example, the London wholesaler Dream Pharma Ltd. purchased sodium thiopental manufactured in Austria and then shipped it to various states in this country for use in lethal injections,¹⁸⁷ raising concerns that prisoners may be injected with drugs that are impure, expired, unsafe, or ineffective.¹⁸⁸

Many death penalty states experienced an onslaught of litigation challenging the use of foreign sourced sodium thiopental in lethal injection proceedings.¹⁸⁹ Then in 2011, the Drug Enforcement Administration ("DEA") began to seize some states' supplies of foreign sourced sodium thiopental on grounds that the seized drugs did not meet importation standards. Other states voluntarily relinquished their supply.¹⁹⁰ But the most striking legal development occurred in March 2012. In *Beaty v. FDA*,¹⁹¹ the United States District Court for the District of Columbia ultimately banned the importation of sodium thiopental, finding that the

newsArticle&ID=1518610&highlight=; *Lethal Injection Overview*, DEATH PENALTY INFO.CTR., <http://www.deathpenaltyinfo.org/lethal-injection-moratorium-executions-ends-after-supreme-court-decision> (last visited July 26, 2013).

¹⁸³ Dominic Casciani, *US Lethal Injection Drug Faces UK Export Restrictions*, BBC NEWS (Nov. 29, 2010, 8:47 AM), <http://www.bbc.co.uk/news/uk-11865881>.

¹⁸⁴ See Hospira, *supra* note 182; Erik Eckholm & Katie Zezima, *States Face Shortage of Key Lethal Injection Drug*, N.Y. TIMES (Jan. 21, 2011), www.nytimes.com/2011/01/22/us/22lethal.html.

¹⁸⁵ Makiko Kitamura & Adi Narayan, *Europe Pushes to Keep Lethal Injection Drugs From U.S. Prisons*, BLOOMBERG BUSINESS WEEK (Feb. 7, 2013), www.businessweek.com/articles/2013-02-07/europe-pushes-to-keep-lethal-injection-drugs-from-u-dot-s-dot-prisons.

¹⁸⁶ Lethal Injection, *"Lethal Injection Scramble" Map from ACLU of Northern California*, Death Penalty Information Center (May 16, 2011), <http://www.deathpenaltyinfo.org/lethal-injection-moratorium-executions-ends-after-supreme-court-decision>.

¹⁸⁷ *Id.*

¹⁸⁸ See *Beaty v. FDA*, 853 F. Supp. 2d 30, 32 (D. Columbia 2012).

¹⁸⁹ See *supra* notes x-x and accompanying text.

¹⁹⁰ See *State-by-State Lethal Injection Information*, Lethal injection, Death Penalty Information Center (July 23, 2013), http://www.deathpenaltyinfo.org/state-lethal-injection_

¹⁹¹ See *Beaty*, 853 F. Supp. 2d at 32.

drug did not follow FDA regulations and exposed plaintiffs “to the risk that the drug will not function as intended”; therefore, plaintiffs were able to show “at least a modest increment of risk that the use of foreign thiopental in their executions would result in conscious suffocation, pain, and cardiac arrest.”¹⁹² On July 23, 2013, a federal appeals court in *Cook v. FDA*¹⁹³ affirmed *Beatty* with an unambiguous holding: “The FDA acted in derogation of [its] duties by permitting the importation of thiopental, a concededly misbranded and unapproved new drug, and by declaring that it would not in the future sample and examine foreign shipments of the drug despite knowing they may have been prepared in an unregistered establishment.”¹⁹⁴

As a consequence of *Beatty*, *Cook*, and the events leading up to both cases, many death penalty states amended their lethal injection protocols to either replace sodium thiopental with pentobarbital or to allow states a choice between the two drugs.¹⁹⁵ Indeed, in 2012 and currently in 2013, pentobarbital has been the primary drug employed in executions by lethal injection.¹⁹⁶ Pentobarbital, a drug most commonly used as a sedative or to control convulsions, was first used in a three-drug lethal injection execution in Oklahoma in 2010,¹⁹⁷ and in a one-drug execution in Ohio the following year.¹⁹⁸ As Charts 1 & 2 of this Article show, an unprecedented number of states—thirteen in total (including Ohio)—switched from sodium thiopental to pentobarbital in 2011 alone.¹⁹⁹ Only Kentucky and Louisiana changed thereafter (both in 2013).²⁰⁰

The quick switch to pentobarbital has done little, if anything, to address the issues surrounding lethal injection. In fact, states’ inclusion of the drug in their protocols has engendered a new wave of legal challenges.²⁰¹ Much of the litigation involves Eighth Amendment Cruel

¹⁹² *Id.* at 37.

¹⁹³ No. 12-5176, at *21 (D.D.C. July 23, 2013).

¹⁹⁴ *Id.* The court did, however, reverse another portion of the lower court’s order and enabled departments of corrections to retain the sodium thiopental that they already had in their possession. *Id.*

¹⁹⁵ See *infra* Charts & 2.

¹⁹⁶ *Executions in 2012*, Lethal Injection, Death Penalty Information Center (2013), <http://www.deathpenaltyinfo.org/execution-list-2012>.

¹⁹⁷ Robert Boczkiewicz, *Appeals Court Rejects Convicted Killer’s Challenge to Oklahoma Execution Method*, THE OKLAHOMAN, (Dec. 15, 2010), <http://newsok.com/court-rejects-bid-to-halt-executions/article/3523778>.

¹⁹⁸ Rob Stein, *Ohio Executes Inmate Using New, Single-Drug Method for Drug Penalty*, WASH. POST, (March 11, 2011), <http://www.washingtonpost.com/wp-dyn/content/article/2011/03/10/AR2011031006250.html>; Mears, *supra* note 30.

¹⁹⁹ See *infra* Charts 1 & 2.

²⁰⁰ See *infra* Charts 1 & 2.

²⁰¹ See *e.g.*, *Florida v. Valle*, 132 S. Ct. 54 (2011); *Blankenship v. Owens*, 131 S. Ct.

and Unusual Punishment challenges,²⁰² and is based in part on the sparse data available regarding the drug's effects on humans.²⁰³ Of the first eight documented pentobarbital challenges, seven focused on the lack of substantial data concerning the efficiency of pentobarbital as an execution drug, that is, whether or not it is actually successful in anesthetizing the prisoner.²⁰⁴ In fact, it appears that the drug is not always successful for that purpose; as some of the litigation notes, even the drug's manufacturers have cautioned against its use in lethal injection proceedings.²⁰⁵

Eighth Amendment challenges are not the only issue facing states with pentobarbital protocols. As with sodium thiopental, states that have included pentobarbital in their protocols have had great difficulty obtaining it. The Dutch manufacturer Lundbeck, Inc. worked vehemently to prevent the use of its pentobarbital—which it sold for treatment of seizures—in executions.²⁰⁶ Lundbeck announced in July 2011 that it “would require customers to buy [pentobarbital] through a single wholesaler and to sign a form confirming they won't resell it, aren't a prison, and know Lundbeck opposes executions.”²⁰⁷ When Ohio became the first state to employ

3054 (2011); *Jackson v. Danberg*, 594 F.3d 210 (3d Cir. 2010); *Pavatt v. Jones*, 627 F.3d 1336 (10th Cir. 2010); *Arthur v. Thomas*, 674 F.3d 1257 (11th Cir. 2011); *Powell v. Thomas*, 643 F.3d 1300 (11th Cir. 2011); *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011).

²⁰² See, e.g., *Thomas*, 674 F.3d at 1259 (alleging that pentobarbital takes substantially longer to render an inmate fully insensate than sodium thiopental and, as a result of this delayed effect, there is a significant risk that Alabama administers the second and third drugs in its lethal injection procedure before pentobarbital has taken effect...constituting cruel and unusual punishment).

²⁰³ See *Danberg*, 594 F.3d at 213 (arguing that (1) pentobarbital is neither FDA-approved nor used clinically for induction of anesthesia; (2) pentobarbital does not have a known track record for determining dosage or time of action, and no research data exist about its reliability or efficacy for inducing anesthesia; and (3) in at least two recent executions using this drug in similar three-drug procedures, the prisoners were not adequately anesthetized).

²⁰⁴ See *Florida v. Valle*, 132 S. Ct. 54 (2011); *Blankenship v. Owens*, 131 S. Ct. 3054 (2011); *Jackson v. Danberg*, 594 F.3d 210 (3d Cir. 2010); *Pavatt v. Jones*, 627 F.3d 1336 (10th Cir. 2010); *Arthur v. Thomas*, 674 F.3d 1257 (11th Cir. 2011); *Powell v. Thomas*, 643 F.3d 1300 (11th Cir. 2011); *DeYoung v. Owens*, 646 F.3d 1319 (11th Cir. 2011).

²⁰⁵ *Danberg*, 594 F.3d 210 (3d Cir. 2010).

²⁰⁶ See *Corporate Responsibility, Activities, Human Rights*, Lundbeck (March 13, 2013), <http://www.lundbeck.com/global/corporate-responsib/report/activities/human-rights>; Letter from Staffan Schüberg, President, Lundbeck Inc., to Gary C. Mohr, Director, Department of Rehabilitation and Corrections, Columbus, OH (Jan. 26, 2011) (on file with author), available at <http://www.deathpenaltyinfo.org/documents/LundbeckLethInj.pdf>; *Lundbeck Overhauls Pentobarbital Distribution Program to Restrict Misuse*, Death Penalty Information Center (July 1, 2011), <http://www.deathpenaltyinfo.org/files/LundbeckPR070111.pdf>.

²⁰⁷ Press Release, *Lundbeck, Lundbeck Overhauls Pentobarbital Distribution*

pentobarbital while following a one-drug protocol for lethal injection,²⁰⁸ Lundbeck reacted by restricting the use of the drug in future executions.²⁰⁹ In December 2011, Lundbeck sold its pentobarbital rights to the Illinois-based pharmaceutical company Akron Inc., but first insisted upon an agreement that the drug would not be sold for the purpose of executing inmates.²¹⁰ While it is not entirely clear how much pentobarbital is still available, ultimately it will either run out or expire.²¹¹

Like sodium thiopental, pentobarbital's effects are most difficult to measure when a state uses a three-drug protocol because the subsequent paralytic agent (pancuronium bromide) can mask the first drug's effects.²¹² The first three-drug execution using pentobarbital in Georgia—that of Roy Blankenship²¹³—was so seriously botched²¹⁴ that the next pentobarbital execution in Georgia—that of Andrew Grant DeYoung—was videotaped as a safeguard.²¹⁵ Notably, the only other videotaped execution in this

Program to Restrict Misuse (July 1, 2011), <http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=605775>; Kitamura & Narayan, *supra* note 185.

²⁰⁸ See *supra* note x; Stein, *supra* note 198.

²⁰⁹ See Press Release, Lundbeck, *supra* note 207 and accompanying text; Leonard, *supra* note 29.

²¹⁰ Kimberly Leonard, *Pentobarbital, Now Most-Commonly Used Execution Drug, Likely to Face Barriers in Coming Months*, THE CTR. FOR PUBLIC INTEGRITY: HEALTH (July 11, 2012, 4:23 PM), <http://www.publicintegrity.org/2012/04/04/8589/lethal-injection-drug-access-could-put-executions-hold>; David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions*, N.Y. TIMES (July 21, 2011), <http://www.nytimes.com/2011/07/02/world/europe/02execute.html>; *Lethal Injection Overview*, *supra* note 182.

²¹¹ See Leonard, *supra* note 29 (“[T]hough some states may soon run out of pentobarbital, the drug could also expire. Like most pharmaceuticals, pentobarbital has an expiration date of about 18 months.”).

²¹² See *supra* notes x-x and accompanying text.

²¹³ *Fact Sheet, Death Penalty Information Center* (Jul. 23, 2012), <http://www.deathpenaltyinfo.org/roy-blankenship>

²¹⁴ See Rachel Quigley, *‘He Suffered Greatly’: Medical Expert Describes How Prisoner Thrashed Desperately During ‘Botched’ Execution with New Drug*, DAILY MAIL ONLINE (June 30, 2011), <http://www.dailymail.co.uk/news/article-2009873/He-suffered-greatly-Medical-expert-describes-prisoner-thrashed-desperately-botched-execution-new-drug.html>.

²¹⁵ See Rhonda Cook, *DeYoung Executed with Videographer Documenting His Death*, ATLANTA J. CONST. (July 22, 2011), <http://www.ajc.com/news/news/local/deyoung-executed-with-videographer-documenting-his/nQJq5/>; see also Deborah Denno, *Should Executions be Televised?*, ENCYCLOPEDIA BRITANNICA BLOG (Aug. 16, 2011), <http://www.britannica.com/blogs/2011/08/should-executions-be-televised/> (discussing the history of televised executions).

country's history was the 1992 gas chamber execution of Robert Alton Harris in California, due to that state's horrific problems with lethal gas.²¹⁶

These events make clear that the use of pentobarbital in lethal injection proceedings is not a lasting solution. Most likely, death penalty states soon will have to switch to yet a different drug, which will bring with it a new host of problems. In May 2012, for example, Missouri amended its lethal injection protocol to permit the use of propofol in one-drug executions.²¹⁷ Less than a month after the drug's adoption, concerns were raised about its implementation²¹⁸ and on July 1, 2012, the United Kingdom announced its ban on the exportation of propofol for execution purposes.²¹⁹ In September 2012, the German healthcare company Fresenius Kabi USA, a main supplier of propofol, announced it would not sell the drug to corrections departments,²²⁰ thereby following in the footsteps of countries banning sales of thiopental and pentobarbital.²²¹ Despite the drug's unavailability, Missouri's lethal injection protocol still includes the use of propofol, although it has yet to be used in a lethal injection procedure.²²² No state other than Missouri has indicated plans to adopt the drug.

Meanwhile, as recently as May 2013, yet another drug company withdrew from the lethal injection market. Hikma, a Britain-based pharmaceutical company that produces phenobarbital, announced a plan to limit distribution of the drug in an effort to prevent it from being considered as a potential new drug for executions. This announcement came shortly

²¹⁶ Dan Moran, *Witness to the Execution: A Macabre, Surreal Event*, LOS ANGELES TIMES (Apr. 22, 1992), http://articles.latimes.com/1992-04-22/news/mn-509_1_gas-chamber.

²¹⁷ See *Lethal Injection*, DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org/lethal-injection-missouri-intends-use-propofol-one-drug-lethal-injection>

²¹⁸ Jim Salter, *Missouri Opts for Untested Drug for Executions*, U.S. NEWS & WORLD REP. (May 24, 2012), <http://www.usnews.com/news/us/articles/2012/05/24/missouri-opts-for-untested-drug-for-executions>

²² See *id.* ("Litigation over Missouri's new protocol is possible. Attorneys for death row inmates told The Associated Press that they are still gathering information on the new process and no decision has been made on whether to seek an injunction.").

²¹⁹ Juliette Jowit, *UK to Ban Export of Drug Approved for Use in US Executions*, GUARDIAN (Jul. 12 15.00 ETD), <http://www.guardian.co.uk/world/2012/jul/10/uk-ban-export-drug-us-executions>.

²²⁰ Letter from Scott Meacham, Exec. Vice President and CCO, Fresenius Kabi USA, to various healthcare providers (Aug. 28, 2012), *available at* <http://deathpenaltyinfo.org/documents/FreseniusPropofolStatement.pdf>; Associated Press, *Another Manufacturer Blocks Propofol For Execution Use*, USA TODAY (Sept. 28, 2012), <http://www.usatoday.com/story/money/business/2012/09/27/manufacturer-blocks-propofol-execution-use/1598109/>.

²²¹ See *supra* notes x-x and accompanying text.

²²² *Lethal Injection Overview*, *supra* note 182.

after Arkansas declared its intent to be the first state to employ phenobarbital for lethal injections²²³ in lieu of the other two execution drugs, pentobarbital or sodium thiopental, which states currently use. Phenobarbital has been prescribed to treat seizures but has never been used for executions in the United States, and some experts had expressed their concern that it could have dire and unpredictable effects on inmates.²²⁴ According to the Arkansas Department of Corrections, they selected phenobarbital after attorneys for several death row inmates mentioned in a lawsuit that it might be an available drug.²²⁵ The Department has revealed little other information about the selection process apart from explaining that their agency also consulted other unidentifiable medical sources.²²⁶ As of July 2013, Arkansas still does not have a valid execution statute²²⁷ and as of July 25, the Department of Corrections has now changed its mind about incorporating phenobarbital because it can no longer acquire sufficient quantities of the drug.²²⁸ The department has yet to select another drug.²²⁹

V. THE HIGH-RISK ROLE OF COMPOUNDING PHARMACIES

Given that every drug used or intended for use in executions has been withdrawn from potential use by corrections facilities,²³⁰ it should come as no surprise that states are seeking help internally from local

²²³ Press Release, Hikma Pharm. PLC, Hikma Pharmaceuticals Strongly Objects to the Use of Its Products in Capital Punishment (May 15, 2013), <http://www.hikma.com/en/media-center/news-and-press-releases/all-news/2013/15-05-2013.aspx?p=1>; Jeannie Nuss, *Arkansas Turns to Different Lethal Injection Drug*, ASSOC. PRESS, April 19, 2013, <http://news.yahoo.com/arkansas-turns-different-lethal-injection-drug-214639034.html>.

²²⁴ Press Release, Hikma Pharm. PLC, *supra* note 223.

²²⁵ Nuss, *supra* note 223.

²²⁶ *Id.*

²²⁷ *Arkansas Lethal Injection Procedure*, April 11, 2013, <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html>; <https://www.documentcloud.org/documents/700843-arkansas-protocol.html>.

²²⁸ Jeannie Nuss, *Dustin McDaniel: Options 'Limited' for Future of Arkansas Death Penalty*, ASSOC. PRESS, July 25, 2013, <http://www.arkansasbusiness.com/article/93707/dustin-mcdaniel-options-limited-for-future-of-arkansas-death-penalty?page=all>.)

²²⁹ *Id.*

²³⁰ *State by State Lethal Injection*, DEATH PENALTY INFO. CTR., <http://www.deathpenaltyinfo.org/state-lethal-injection> (last visited July 26, 2013); Tim Hoover, *Wanted: Execution Drug*, DENVER POST, Mar. 13, 2013, at A4.

²³⁰ Ariane de Vogue, *Drug Shortage Disrupts Lethal-Injection Mix*, ABCNEWS.COM (Mar. 16, 2011), <http://abcnews.go.com/Politics/death-penalty-drug-shortage-disrupts-execution-lethal-injection/story?id=13148874>.

compounding pharmacies for the production of lethal injection drugs.²³¹ There are a number of reasons why states may view compounding pharmacies as better suited for the job than large-scale drug manufacturers. Most obvious is the reason discussed in Part IV: large-scale companies that are based in Europe but have subsidiaries in the U.S. have been strictly prohibited from facilitating the death penalty in the United States in any way.²³² Even if they were permitted to do so, big pharmaceutical companies have a much larger reputation at stake when they consider associating themselves with lethal injection.

Another key reason that states are turning to compounding pharmacies is the lack of regulation compared to large-scale manufacturers.²³³ The latter are governed by strict FDA regulations, while compounding pharmacies fall under the relatively lax authority of the state. Leaving aside the conflict of interest that arises when the same entity charged with regulating a facility is also requesting its services, state regulations 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. These seemingly permissive regulations stem from the traditional view of compounding pharmacies as small-scale productions that lend themselves to easy quality control and present a low risk of public health concerns.²³⁴ Yet recent events suggest that this perspective may be outdated. The remainder of Part V provides a brief history of compounding pharmacies as well as a discussion of current legislation aimed at improving oversight of these facilities.

A. A Brief Overview of Compounding Pharmacies

Traditionally, all compounded drugs were custom-made in small batches for individual patients pursuant to a medical prescription.²³⁵ Physicians typically prescribe compounded medications when commercial drugs are unavailable, or, for example, if the use of existing commercial alternatives is prohibited by allergies.²³⁶ When compounding drug pharmacies were first conceived in the 1800s, they typically served as the only source of prescription medication.²³⁷ Their prevalence was somewhat

²³¹ See *infra* notes x-x and accompanying text.

²³² See *supra* Part IV.

²³³ See *infra* notes x-x and accompanying text.

²³⁴ See Boodoo, *supra* note 33, at 32-34.

²³⁵ *The Special Risks of Pharmacy Compounding*, FDA CONSUMER HEALTH INFORMATION, (U.S. Food and Drug Admin., Silver Spring, MD), May 31, 2007, at 1, available at www.fda.gov/consumer/updates/compounding053107.html.

²³⁶ *Id.*

²³⁷ See DAVID L. COWEN & WILLIAM H. HELFAND, PHARMACY: AN ILLUSTRATED

diminished during the Industrial Revolution when mass drug manufacturing companies emerged with a superior capacity to produce generic drugs,²³⁸ but those companies did not dominate the market until around 1950.²³⁹ Today, there are about 56,000 compounding pharmacies in the United States.²⁴⁰ Recent estimates show that approximately “three thousand facilities practice sterile compounding and supply most of the injectable drugs in the United States.”²⁴¹

Compounded drugs are prepared by licensed pharmacists who practice in a licensed compounding pharmacy.²⁴² Pharmacist licensure requirements are regulated by state pharmacy boards²⁴³ and therefore vary by state,²⁴⁴ but all pharmacists are required to pass a national, standardized licensure exam, and all states require pharmacists to pass an examination on compounding.²⁴⁵ Pharmacists and pharmacy students who wish to become better educated in drug compounding can enroll in expanded learning programs offered by pharmacist networks and organizations such as the International Academy of Compounding Pharmacists²⁴⁶ and the Professional Compounding Centers of America.²⁴⁷

HISTORY 186 (1990).

²³⁸ *Id.*

²³⁹ See Boodoo, *supra* note 33, at 222.

²⁴⁰ Hinkley, *supra* note 41, at 23.

²⁴¹ *Id.* at 23.

²⁴² U.S. Food and Drug Admin., Ctr. for Drug Eval. and Research, *Pharmacy Compounding*, FDA.GOV (June 13, 2013), <http://www.fda.gov/drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/> (last visited July 15, 2013); ACCREDITATION STANDARDS AND GUIDELINES FOR THE PROF'L PROGRAM IN PHARM. LEADING TO THE DOCTOR OF PHARM. DEGREE (Accreditation Council for Pharm. Educ. 2011), *available at* <https://www.acpe-accredit.org/standards/default.asp>.

²⁴³ See Nat'l Conf. of State Legis., *supra* note 41.

²⁴⁴ See Nat'l Ass'n of Boards of Pharmacy, *Licensure Transfer*, NABP.NET, <http://www.nabp.net/programs/licensure/licensure-transfer> (last visited July 26, 2013) (noting that each state board of pharmacy provides their own set of requirements that a prospective pharmacist must meet before a license is issued, and providing a link to each state board of pharmacy for further information on their requirements).

²⁴⁵ SCOTT GIBERSON, SHERRI YODER & MICHAEL P. LEE, OFFICE OF THE CHIEF PHARM., IMPROVING PATIENT AND HEALTH SYSTEM OUTCOMES THROUGH ADVANCED PHARMACY PRACTICE: A REPORT TO THE U.S. SURGEON GENERAL 26 (2011). In New York State, for example, part III of the pharmacist licensing examinations is a written and practical examination where the pharmacist must complete written math compounding components as well as hands-on drug compounding components. *Pharmacist License Requirements*, N.Y. STATE EDUC. DEP'T., <http://www.op.nysed.gov/prof/pharm/pharmlic.htm#exam> (last visited July 15, 2013).

²⁴⁶ *About IACP*, INT'L ACAD. OF COMPOUNDING PHARM., <http://www.iacprx.org/> (last visited July 15, 2013).

²⁴⁷ Prof'l Compounding Ctrs. Of Am., *Compounding & Pharmacists*, PCCARX.COM,

Compounded drugs must be prescribed to a patient by a licensed physician. Providing such a prescription carries some risk. According to a recent article published by the American Medical Association, many patients have successfully sued their doctors based on negligence and failure to warn claims with respect to defective or dangerous compounded medications.²⁴⁸ Indeed, when considering use of a compounding facility, doctors are often advised to weigh the risk of liability, which is exacerbated by the fact that medical malpractice insurance typically excludes coverage for claims involving non-FDA approved medications and procedures.²⁴⁹ The lack of FDA-regulation²⁵⁰ is in fact the very root of physician liability. Because compounding pharmacies are not FDA regulated, they are “less legally secure alternatives” than regular pharmacies and regulated medications.²⁵¹ Doctors are required to know whether or not a given compounding pharmacy meets applicable safety standards.²⁵²

B. Regulatory Oversight of Compounding Pharmacies

In the early 1990s, the FDA became aware of compounding

<http://www.pccarx.com/pharmacists/compounding-pharmacists> (last visited July 15, 2013). Compounding pharmacies vary in access to the consumer. Today, there are certain large compounding companies that supply most of the sterile products used in health facilities and have almost completely replaced in-hospital production, Hinkley, *supra* note 41, at 23, where there is no direct client interaction. Some compounding pharmacies have storefronts and operate like regular drug stores with customer contact, and others are strictly compounding laboratories that ship out their products, with a physician playing the middleman between the pharmacist and the patient. For example, of the eleven Pharmacy Compounding Accreditation Board-approved pharmacies in New York State, six of them function as actual pharmacies with a compounding lab inside, while the other five operate as strictly compounding laboratories with an online website. *New York State Compounding Pharmacies*, PHARM. COMPOUNDING ACCREDITATION BD., <http://www.pcab.org/state/ny> (last visited July 15, 2013) (listing eleven accredited pharmacies in New York state including Fallon Wellness Pharmacy in Latham, Fallon Wellness Pharmacy in Saratoga, HM Compounding, MasterPharm, LLC, Nate’s Pharmacy, Nekos-Dedrick’s Pharmacy, Pharmacy Innovations, Pine Pharmacy, Rockwell Compounding, Vernak Farms Country Store, Village Apothecary).

²⁴⁸ Alicia Gallegos, *Physicians Entangled In Tainted Drugs Lawsuits*, AM. MED. NEWS (Am. Med. Ass’n, Chi., Ill.), Feb. 11, 2013, www.amednews.com/article/20130211/profession/130219977/2.

²⁴⁹ Jennifer Gudeman et al., *Potential Risks of Pharmacy Compounding*, 13 DRUGS IN R&D 1, 6 (2012), available at Springerlink.com, File No. 10.1007/s40268-013-0005-9.

²⁵⁰ U.S. Food And Drug Admin., *Pharmacy Compounding and the FDA: Questions and Answers*, FDA.GOV (Mar. 1, 2013), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764>.

²⁵¹ Gallegos, *supra* note 248.

²⁵² *Id.*

pharmacies whose practices did not align with the traditional individualized, prescription-based schema.²⁵³ In response to this discovery, the FDA issued a “Compliance Guide” in 1992,²⁵⁴ which effectively alerted compounding pharmacies that they were not unconditionally exempt from FDA regulation: If a compounding pharmacy’s actions exceeded its traditional scope, the FDA had the authority to intervene.²⁵⁵ Five years later, however, the FDA acknowledged continued confusion regarding the actual scope of that authority²⁵⁶ and proposed legislation to clarify the matter.

Section 127 of the Federal Food and Drug Association Modernization Act (FDAMA)²⁵⁷ represented the first time that specific federal or state laws governed the practices of compounding pharmacies. With unprecedented clarity, the FDAMA distinguished drug manufacturers from compounding pharmacies,²⁵⁸ and listed nine requirements for classification as a “true” compounding pharmacy. These requirements stipulated the need to produce compounded drugs for identified individual patients pursuant to a prescription from a licensed physician, and prohibited the production of drugs that were effectively identical to “commercially available drug products.”²⁵⁹ Pharmacies that met these requirements fell within the scope of regulatory exemptions that the FDA had created for “true” compounding pharmacies²⁶⁰ and would not be required to register with the FDA or obtain its approval or comply with any “Good Manufacturing Practices” or safety and efficacy standards.²⁶¹ The FDA’s goal was to create a framework that would enable true compounding pharmacies to continue to produce customized drugs, but prevent large-scale manufacturers from operating under the guise of compounders.²⁶²

Since passage of the FDAMA in 1997, several lawsuits and FDA actions have triggered reexamination of the legislation, but, rather

²⁵³ COMPOUNDING RISK, *supra* note 34, at 5 (a report prepared in response to the fungal meningitis outbreak in Boston that addresses current regulatory oversight and gaps in legal authority over compounding pharmacies).

²⁵⁴ COMPLIANCE POLICY GUIDE FOR FDA STAFF AND INDUSTRY: PHARMACY COMPOUNDING §460.200 (U.S. Food and Drug Admin. 2002) (reissued May 29, 2002).

²⁵⁵ COMPOUNDING RISK, *supra* note 34, at 5.

²⁵⁶ S. Rep. No. 105-43, at 67 (1997).

²⁵⁷ Food and Drug Association Modernization Act of 1997, Pub. L. No. 105-115, § 127, 111 Stat. 2296, 2328 (1997).

²⁵⁸ § 127, 111 Stat. at 2328.

²⁵⁹ § 127, 111 Stat. at 2328-29.

²⁶⁰ *Id.* at 2328-30.

²⁶¹ Jessica Dye, *U.S. Senate Committee Advances Drug Compounding Bill*, REUTERS (May 23, 2013), <http://www.reuters.com/article/2013/05/22/us-fda-drugs-legislation-idUSBRE94L1AU20130522>.

²⁶² H.R. Conf. Rep. No. 105-399, at 94 (1997).

remarkably, no substantial changes have been made.²⁶³ Beginning in the early 2000s, however, the FDA has sent 75 publicly available warning letters to compounding pharmacies in 28 states, as well as Puerto Rico, Canada, and Brazil, noting a series of problems: failed inspections, the discovery of problematic compounded drugs, potential and actual violations of the FDA regulations, failed safety and efficacy standards, false or misleading statements, and other disturbing issues.²⁶⁴ As concern grew that some pharmacies were exceeding the scope of traditional compounding practices,²⁶⁵ the FDA issued reports in 2003²⁶⁶ and 2006²⁶⁷ revealing the discovery of compounded drugs that failed safety and efficacy tests, as well as serious illnesses and deaths that had occurred in association with compounded drugs.²⁶⁸ Yet in 2007, legislation aimed at reassessing and increasing the FDA's limited authority over compounding pharmacies was met with criticism and disregard. The prevailing notion remained that state board pharmacies were better equipped to regulate compounding pharmacies than the FDA.²⁶⁹ By October 2012, however, sentiments had

²⁶³ COMPOUNDING RISK, *supra* note 34, at 7.

²⁶⁴ See U.S. Food And Drug Admin., *FDA'S Electronic Reading Room – Warning Letters*, FDA.GOV, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (follow hyperlink; scroll down to “browse warning letters” search bar; type “Compounding Pharmacy;” press search) (last visited July 19, 2013) (States that have received warning letters include Texas, Illinois, California, New Hampshire, Arkansas, Michigan, New Jersey, Florida, Ohio, Mississippi, Wyoming, Maryland, Arizona, Minnesota, Kentucky, North Carolina, Utah, Massachusetts, Oklahoma, Connecticut, Alabama, Pennsylvania, New York, Missouri, Virginia, Indiana, Idaho, Oregon, and South Carolina.); see also COMPOUNDING RISK, *supra* note 34, at 19 appendix A (listing a detailed timeline of media reports and FDA enforcement actions on compounding pharmacies).

²⁶⁵ JANET HEINRICH, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-195T, PRESCRIPTION DRUGS: STATE AND FEDERAL OVERSIGHT OF DRUG COMPOUNDING BY PHARMACIES (2003).

²⁶⁶ U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH, REPORT: LIMITED FDA SURVEY OF COMPOUNDED DRUG PRODUCTS (2003), *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm> (last visited July 19, 2013).

²⁶⁷ U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH, REPORT: LIMITED FDA SURVEY OF COMPOUNDED DRUG PRODUCTS (2006), *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm204237.htm> (last visited July 19, 2013).

²⁶⁸ COMPOUNDING RISK, *supra* note 34, at 7.

²⁶⁹ Reid Paul, *Drug Topics: New Bill on Pharmacy Compounding Stirs Concern*, MODERNMEDICINE.COM (Apr. 2, 2007), <http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-feature-articles/new-bill-pharmacy-compounding-stirs>.

shifted. As noted in the Introduction to this Article, a contaminated steroid produced by a compounding center in Massachusetts caused an outbreak of fungal meningitis that has killed at least 61 people and sickened many more.²⁷⁰ The facility that had compounded the contaminated drug was suspected to be operating on a larger-than-permissible scale, and the tragic public health consequences triggered a new receptiveness to increased oversight of compounding pharmacies.²⁷¹

C. Pending Legislation

There are currently three proposed bills related to the regulation of compound pharmacies. In large part, these bills address the question of which government body should enforce regulations and penalize violations. Other features of the bills include the need to clearly and consistently distinguish between the terms “compounding” and “manufacturing;” the definition of “compounding,” “sterile,” and “non-sterile” practices; guidelines for the frequency, funding, and performance of inspections; and the scope of transparency.²⁷² The bills also create three separate categories of pharmacies, distinguishing among those that engage in basic compounding and those that engage in “high-risk sterile”²⁷³ compounding.²⁷⁴

In May 2013, the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP) unanimously approved the Pharmaceutical Compounding Quality and Accountability Act, clarifying which kinds of compounding pharmacies are regulated by the state and which are regulated by the FDA.²⁷⁵ The legislation distinguishes FDA-regulated drug manufacturers from state-regulated small-scale traditional compounding pharmacies, and separately identifies large-scale compounding manufacturers who operate more like mass drug producers.²⁷⁶ The bill then

²⁷⁰ See *supra* notes x-x and accompanying text.

²⁷¹ See *supra* notes x-x and accompanying text.

²⁷² Nat’l Conf. of State Legis., *supra* note 41.

²⁷³ High risk sterile compounding is termed as such because the practice involves drug products that require a heightened level of unique safeguards during compounding to prevent injury or death to patients who receive them. HEINRICH, *supra* note 265, at 3. “Sterile compounding requires cleaner facilities than nonsterile compounding, as well as specific training for pharmacy personnel and testing of the compounded drug for sterility.” *Id.*

²⁷⁴ Despite the many similarities among the bills, they do vary in several important areas, including their definitions of true compounding and the requirements needed to satisfy that classification.

²⁷⁵ Pharmaceutical Compounding Quality and Accountability Act of 2013, S. 959, 113th Cong. (2013).

²⁷⁶ *Id.*

categorizes these large-scale businesses as manufacturers, eliminating their “pharmacy” status altogether and removing their ability to be licensed as such.²⁷⁷ If it is passed, the legislation would grant the FDA full authority to be the sole regulator of these compounding manufacturers through measures such as conducting regular inspections and ensuring that all products manufactured are reported to the FDA.²⁷⁸ Under this bill, however, compounding manufacturers still would not be subject to the same kinds of regulations as traditional drug manufacturers under FDA authority, since, for example, drugs produced by these kinds of manufacturers are by their very nature compounded rather than FDA-approved.²⁷⁹ The Senate HELP Committee continues to urge the Senate to bring this legislation to the floor for a vote in order to “prevent further tragedies.”²⁸⁰

On May 23, 2013, a House bill was proposed that also appears to close the gap in FDA authority.²⁸¹ The Verifying Authority and Legality in Drug (VALID) Compounding Act of 2013 also separates pharmacies into three categories and recognizes that small traditional compounding pharmacies that produce drugs for an “identified individual patient,” should remain under the authority of the state.²⁸² However, the VALID Act still acknowledges large-scale compounders as pharmacies, in contrast to the Senate bill.²⁸³ The legislation seeks to give the FDA exclusive authority over compounding pharmacies that ship products across state lines or engage in “high-risk sterile compounding,”²⁸⁴ while other compounding

²⁷⁷ See Memorandum from the H. Comm. on Energy & Commerce Democratic Staff on the Hearing on Reforming the Drug Compounding Regulatory Framework to the H. Comm. on Energy & Commerce Democratic Members & Staff and the H. Subcomm. on Health (July 15, 2013), <http://democrats.energycommerce.house.gov/sites/default/files/documents/Memo-Health-Drug-Compounding-Reform-2013-7-15.pdf>.

²⁷⁸ Press Release, Ranking Member Lamar Alexander, Senate Comm. on Health, Educ., Labor and Pensions, Senate Health Comm. Passes Alexander and Colleagues’ Bill to Fix Responsibility for Safety of Sterile Compounded Drugs (May 22, 2013), <http://www.help.senate.gov/newsroom/press/release/?id=63b96a98-9b19-4c5f-8a6f-b0df57afe138&groups=Ranking>.

²⁷⁹ See *id.*; Dye, *U.S. Senate Advances Bill*, *supra* note 261.

²⁸⁰ Letter from Tom Harkin and Lamar Alexander, Chairman and Ranking Member, Senate Comm. on Health, Educ., Labor and Pensions, to Harry Reid and Mitch McConnell, Senate Majority Leader and Senate Republican Leader (June 7, 2013), <http://www.help.senate.gov/newsroom/press/release/?id=c57674f7-e3cf-4d1c-a119-7d3cabd78013&groups=Ranking>.

²⁸¹ Verifying Authority and Legality In Drug Compounding Act of 2013, H.R. 2186, 113th Cong. (2013).

²⁸² *Id.*

²⁸³ See Memorandum, Drug Compounding, *supra* note 277.

²⁸⁴ As defined by the VALID act, “high-risk sterile compounding means compounding sterile drug products using nonsterile ingredients, nonsterile devices, or

pharmacies must follow different FDA regulations in addition to state regulations.²⁸⁵ Compounding pharmacies would be subject to inspections, reporting, and labeling requirements.²⁸⁶ The VALID Act does create exceptions for compounding manufacturers to produce non-patient-specific drugs and commercially available drugs under certain circumstances, including the ability to compound drugs listed on the drug shortage list, or drugs that are “necessary to protect public health or well-being.”²⁸⁷

The House also recently proposed a second bill, the Compounding Clarity Act of 2013 (“Clarity Act”), which is currently a discussion draft authored by Representative Morgan Griffith.²⁸⁸ Like both the Senate bill and the VALID Act, this legislation recognizes that traditional pharmacy compounding is a separate practice that should remain subject to only state regulation, and exempt from various FDA regulations.²⁸⁹ Also similar to the other bills, the Clarity Act creates a new category for non-traditional compounding pharmacies that do not operate like a traditional, small-scale compounding pharmacy.²⁹⁰

The Clarity Act differs from the other bills on what kind of pharmacy is considered a “traditional compounding pharmacy,” and what regulations those pharmacies must follow. For example, the Clarity Act creates a broad exception allowing traditional compounding pharmacies to compound both limited and unlimited quantities of drugs in advance of a prescription, subject to a variety of specific terms, while the Senate bill has a similar but much more limited provision, particularly with respect to the unlimited quantities portion.²⁹¹ In even sharper contrast, the VALID Act strictly requires that a drug only be compounded pursuant to a valid and existent prescription, without exception.²⁹² Finally, the Clarity Act has not yet provided much detail on what kind of pharmacy would be identified as a large-scale manufacturing compounding pharmacy, or what regulations

nonsterile components.” H.R. 2186 § 503A(1)(3).

²⁸⁵ H.R. 2186; *Updated House Bill Would Require FDA to Regulate Pharmacies Involved in High-Risk Compounding and Interstate Commerce*, NAT’L ASS’N OF BDS. OF PHARM. E-NEWS (June 5, 2013, 5:20 PM), <http://www.nabp.net/news/updated-house-bill-would-require-fda-to-regulate-pharmacies-involved-in-high-risk-compounding-and-interstate-commerce>.

²⁸⁶ H.R. 2186.

²⁸⁷ *Id.*

²⁸⁸ Compounding Clarity Act, H.R. _____, 113th Cong. (2013), *available at* <http://docs.house.gov/meetings/IF/IF14/20130716/101137/BILLS-113DiscussionDraftpjh-DiscussionDraft-U1.pdf>.

²⁸⁹ *Id.*

²⁹⁰ *Id.*

²⁹¹ See Memorandum, Drug Compounding, *supra* note 277.

²⁹² H.R. 2186.

manufacturing compounders must follow.²⁹³

On July 16, 2013, the United States House Energy and Commerce Committee and Subcommittee on Health held a hearing to discuss all three proposed bills and examine their differences, as well as the general need for stricter compounding regulation.²⁹⁴ At the hearing, a representative from the National Association of Boards of Pharmacy (NABP) testified regarding the proposed compounding regulatory bills.²⁹⁵ The representative's statements provided a great deal of support for the Senate bill, specifically with respect to the distinction between a compounding pharmacy and a compounding manufacturer, and the clarity afforded by the provision to prohibit compounding manufacturers from becoming licensed as pharmacies.²⁹⁶ Additionally, the NABP representative stated that the House bills seemed too permissive and left open several gaps for businesses to potentially operate as licensed "compounding pharmacies" despite being engaged in large-scale compounded drug manufacturing.²⁹⁷

D. Implications for Death Penalty States

Heightened oversight of compounding pharmacies seems inevitable even if the sources of authority have yet to be determined. This development is unlikely to further the goals of death penalty states, for a number of reasons. One feature of the proposed VALID Act, for example, prohibits even small, state-regulated pharmacies from producing copies or effective copies of commercial drugs—no matter the quantity, and with few exceptions.²⁹⁸ This would be problematic for states seeking lethal injection drugs, given that many such drugs are simply high doses of commercially available medication.²⁹⁹ Another notable aspect of the VALID Act is its strict prescription requirements, which would prohibit a compounding pharmacy from issuing a "supply" of lethal injection drugs.³⁰⁰ Instead, a physician would have to specifically order a prescription for an identified,

²⁹³ See Memorandum, Drug Compounding, *supra* note 277.

²⁹⁴ *Reforming the Drug Compounding Regulatory Framework: Hearing on H.R. 2186, H.R. ____ ("The Compounding Clarity Act of 2013"), and S. 959 Before the H. Energy & Commerce Comm., and the H. Subcomm. on Health, 113th Cong. (2013).*

²⁹⁵ *Reforming the Drug Compounding Regulatory Framework: Hearing on H.R. 2186, H.R. ____ ("The Compounding Clarity Act of 2013"), and S. 959 Before the H. Energy & Commerce Comm., and the H. Subcomm. on Health, 113th Cong. (2013)* (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy).

²⁹⁶ *Id.*

²⁹⁷ *Id.*

²⁹⁸ H.R. 2186, 113th Cong. (2013).

²⁹⁹ *State by State Lethal Injection, supra* note 230.

³⁰⁰ *Id.*

individual patient in advance of the drug being compounded, which would raise the issue of finding a licensed physician willing to write a prescription for an execution drug.³⁰¹ As previously discussed, physicians who prescribe compounded drug prescriptions are already placing themselves at considerable risk for liability.³⁰² Physicians who participate in executions also face a broad range of potential repercussions, a topic discussed in depth elsewhere.³⁰³ Presumably, writing a prescription would qualify as “participation,” in which case, again, departments of corrections may struggle to find a physician willing to take such a professional risk.

Whether under state or federal oversight, compounding pharmacies may soon also find themselves facing an unprecedented barrage of regulations and requirements that will complicate every aspect of their operations, ranging from systems of communication to sterilization procedures to the need for lengthy and strict memorandums with each individualized prescription.³⁰⁴ The additional complications associated with producing lethal injection drugs may be too great a burden. Perhaps most significantly, however, these regulations would require an unprecedented degree of transparency from death penalty states regarding their execution methods. Death penalty states have a history of gravitating toward secrecy when their execution methods are questioned,³⁰⁵ yet the proposed regulations would prevent them from doing so.

VI. POST-BAZE SECRECY

As states home in on local compounding pharmacies as a potential source of lethal injection drugs, they are becoming increasingly less willing to share information about executions with the public, which raises the disturbing possibility that states are knowingly trying to hide the risks associated with compounded drugs. South Dakota, after switching to a one-drug protocol and carrying out an execution in October 2012, was said to have obtained its order of pentobarbital from a local compounding pharmacy.³⁰⁶ Alarming, the compounded drug was contaminated with

³⁰¹ See *supra* notes x-x and accompanying text.

³⁰² See *supra* notes x-x and accompanying text.

³⁰³ See generally Denno, *Lethal Injection Quandary*, *supra* note 1.

³⁰⁴ H.R. 2186, 113th Cong. (2013).

³⁰⁵ See generally Denno, *Lethal Injection Quandary*, *supra* note 1; Denno, *When Legislatures Delegate*, *supra* note 1; Denno, *Getting to Death*, *supra* note 1.

³⁰⁶ Hoover, *supra* note 230; Press Release, Reprieve, South Dakota Carries Out Execution Using Contaminated Compounded Drugs, (Oct. 17, 2012), http://www.reprieve.org.uk/press/2012_10_17_compound_pharmacy_death_penalty/; *State by State Lethal Injection*, *supra* note 230.

fungus³⁰⁷—a discovery that was only made because the drug was analyzed after the inmate began choking and then remained open-eyed as he was executed.³⁰⁸ Shortly after the South Dakota execution, Pennsylvania also announced that it would be using compounded drugs in its lethal injection protocol for an execution the following month.³⁰⁹ That announcement came only after enormous judicial pressure, including two federal court orders to disclose the drug source in a ruling pursuant to a class action lawsuit challenging the constitutionality of the state's protocol.³¹⁰ The Pennsylvania Department of Corrections initially refused to reveal the identity of their drug supplier because they feared disclosure would lead to public pressure on the pharmacy to withdraw its agreement to provide the drugs.³¹¹ Indeed, it seems that states are keenly aware that their difficulties in obtaining lethal injection drugs stem largely from transparency issues, and thus seek to block that transparency at every turn.

This secrecy regarding lethal injection practices and risk is particularly troublesome given that the number of states reaching out to compounding pharmacies is only increasing. In March 2013, the Colorado Department of Corrections sent a letter to almost 100 local compounding pharmacies seeking to “acquire sodium thiopental or other equally or more effective substances to cause death” in accordance with state law.³¹² In July 2013, Georgia became the fourth state to join the effort, acknowledging the increasing difficulty of obtaining lethal injection drugs after its existing supply of pentobarbital expired in March.³¹³ When the Georgia Department

³⁰⁷ Press Release, Reprive, South Dakota Covers Up Source of ‘DIY’ Death Penalty Drugs Ahead Of Execution (Oct. 30, 2012), http://www.reprive.org.uk/press/2012_10_30_South_Dakota_execution_drugs/ (providing a link to the certificate of compounded drug analysis at http://www.reprive.org.uk/media/downloads/2012_10_30_PUB_diy_drugs_cert_of_analysis.pdf.)

³⁰⁸ See Associated Press, *South Dakota Murderer Executed By Lethal Injection for Beating to Death Prison Guard With Pipe During Botched Escape*, DAILY MAIL (Oct. 15, 2012, 3:00 PM), <http://www.dailymail.co.uk/news/article-2218181>.

³⁰⁹ Donald Gilliland, *Pennsylvania Gets Its Execution Drugs From Same Type of Pharmacy as the One Responsible for Bacterial Meningitis Outbreak*, THE PATRIOT NEWS (Nov. 06, 2012, 7:45 AM), http://www.pennlive.com/midstate/index.ssf/2012/11/pennsylvania_gets_its_executio.html.

³¹⁰ *Id.*

³¹¹ Donald Gilliland, *Lawsuit Has Potential to Stay All Executions in Pennsylvania*, THE PATRIOT NEWS (Nov. 5, 2012, 6:27 AM), http://www.pennlive.com/midstate/index.ssf/2012/11/pennsylvania_death_row.html.

³¹² Hoover, *supra* note 230.

³¹³ Kate Brumback, Associated Press, *Georgia to Use Compounding Pharmacy for Execution Drug*, THE AUGUSTA CHRONICLE (July 11, 2013), <http://chronicle.augusta.com/news/metro/2013-07-11/georgia-use-compounding-pharmacy-execution-drug>.

of Corrections revealed in July 2013 that it would use a compounding pharmacy to obtain its supply of pentobarbital for an upcoming execution, that information was only acquired from an email received through an open-records request.³¹⁴ In March 2013, Georgia passed the “Lethal Injection Secrecy Act,” enabling the identities of lethal injection suppliers to be shielded from disclosure to the public and the media, and possibly even the judiciary.³¹⁵ According to the Act’s provisions, this information is considered a “state secret.”³¹⁶ Several states have proposed or passed new regulations that exclude the death penalty protocol from required disclosure, thereby keeping both the method itself as well as the source of the pharmacy, compounding or otherwise, completely confidential.³¹⁷

Certain states have addressed this issue more candidly than others. An Arkansas bill that was approved in February 2013 simply addresses all matters of lethal injection administration, and provides that all execution procedures are not subject to disclosure under the state’s Freedom of Information Act.³¹⁸ Similarly, a Tennessee bill passed in April 2013 expanded the existing law that broadly protects the identity of individuals who have been or may be involved in an execution to include protecting the identity of “entities” as well.³¹⁹ A South Dakota bill passed in February 2013 is a bit more explicit, openly stating that the Act’s specific purpose is to “protect the identity of the person or entity supplying” the lethal injection drug.³²⁰

In spite of compelling public interest in ensuring that lethal injection protocols are acceptable, legal, and constitutional—not to mention the First Amendment right of access to certain information (including the viewing of executions)—custom, and in some cases state regulation, dictate that the identities of execution teams are concealed.³²¹ States profess crucial reasons to shield the identities of all parties who are involved in the lethal injection process (including doctors, pharmacists, drug providers and wholesalers or retailers, manufacturers, and anyone else who may play any kind of role in the execution).³²² Currently the American Medical Association, American Nurses’ Association, American Society of Anesthesiologists, and National Commission on Correctional Health Care

³¹⁴ *Id.*

³¹⁵ O.C.G.A. § 42-5-36 (d).

³¹⁶ *Id.*

³¹⁷ See *infra* notes x-x and accompanying text.

³¹⁸ S. 237, 89th Gen. Assemb., Reg. Sess. (Ak. 2013).

³¹⁹ S. 154, 107th Gen. Assemb. (Tn. 2013).

³²⁰ S. 36, 88th Leg., Res. Sess. (Sd. 2013).

³²¹ Ellyde Roko, *Executioner Identities: Toward Recognizing A Right to Know Who Is Hiding Beneath the Hood*, 75 FORDHAM L. REV. 2791, 2829 n.39 (2007).

³²² *Id.* at 2799-800.

all have ethical rules and guidelines opposing participation in lethal injections.³²³ Without guaranteed anonymity, states argue, companies and medical professionals would be disinclined to assist the state with its execution duties for fear of a blight on their personal or professional reputations, while executioners and correctional facilities might face threats from death penalty opponents.³²⁴ Yet these fears are carryovers from past methods of execution, which employed a substantially smaller execution team. In contrast, lethal injections involve multiple participants,³²⁵ none of whom presumably are wholly responsible for the execution, including the producer of the lethal injection drugs.³²⁶ Given states' current desperation to obtain such drugs, the need for states to ensure safe and constitutional practices with regard to procurement and protocol far outweighs antiquated notions regarding the perceived risk to a lone executioner. Greater transparency of the entire lethal injection process is a feasible solution. Indeed, my own research indicates that in modern times, death penalty states' aversion to transparency is far more rooted in the desire to conceal inconsistencies and incompetence.³²⁷

In 2001, I conducted a nationwide study of lethal injection protocols for all thirty-six states that used the method at that time ("Study One"). Study One focused on a number of key criteria common to many lethal injection protocols, including the types and amounts of chemicals that are injected; the selection, training, and qualifications of the lethal injection team; and the involvement of medical personnel. One of Study One's most problematic findings, however, was that the criteria set out in many of the protocols were far too vague to allow for adequate assessment. When the protocols did offer details, such as the amount and type of chemicals that executioners inject, they often revealed striking errors and a shocking level of ignorance about the procedure.³²⁸ Four years later, in 2005, I conducted

³²³ Denno, *Lethal Injection Quandary*, *supra* note 1, at 53-59, 77-91.

³²⁴ Roko, *supra* note 321, at 280 9-12; *see also* Associated Press, *State Appeals Stay of Execution in Hill Case*, WALB NEWS (July 26, 2013, 5:44 PM), <http://www.walb.com/story/22943909/state-appeals-stay-of-execution-in-hill-case>.

³²⁵ Denno, *Lethal Injection Quandary*, *supra* note 1, at 56.

³²⁶ The possible usage of compounded drugs, however, introduces a new component into the execution process because of the heightened risk of problems associated with compounding pharmacies. Specifically, certain compound pharmacies have been found to encounter serious dosage errors, delivering drugs with up to 450% of the prescribed dosage. Gilliland, *supra* note 309. Even further, there are significant compliance and contamination issues already associated with compounded drugs, evidenced by the recent reports revealed after the 2013 FDA investigation. Hamburg, *supra* note 38.

³²⁷ *See generally* Denno, *Lethal Injection Quandary*, *supra* note 1 (detailing the challenges with lack of transparency in this country's execution process).

³²⁸ *See generally* Denno, *When Legislatures Delegate*, *supra* note 1 (explaining and analyzing the results of Study One).

a second nationwide study (“Study Two”). One of the goals of Study Two was to determine if states had changed their protocols during the years in which lethal injection litigation gained traction. In other words, Study Two provides a snapshot of lethal injection protocols at a key point in time – at the cusp of the increased scrutiny of protocols, but unaffected by the onslaught of lethal injection challenges starting in 2006.³²⁹

For the most part, I found that over the four-year period between Study One and Study Two, states typically withheld more information than in the past. For example, one aspect of Study Two showed that the number of states with complete protocols fell to less than one-third of the Study One numbers. In addition, in Study Two, the number of states claiming confidentiality about their protocols increased nearly fourfold. Likewise, in Study Two, two states said protocols did not exist and one state provided no information whatsoever. In total, one-half of the states that applied lethal injection did not allow any evaluation of their protocols, either because the information is confidential or nonexistent.³³⁰

In 2008, death penalty states had safety in numbers because, at least superficially, they appeared to follow essentially the same kind of protocol in terms of lethal injection drug usage.³³¹ By 2013, however, there is a hodgepodge of protocols among states that has no parallel pre-*Baze*, whether that comparison is being made relative to 2008, or 1977, or as far back as 1890.³³² The lethal injection procedure is more dangerous and inconsistent than ever, and the result is a perpetual effort by states to maintain secrecy at a time when transparency is most paramount.

Recognizing this need for transparency, state justice departments have started to intervene.³³³ In 2011, the Chief Deputy Attorney General of Delaware ordered that the state Department of Corrections violated the Freedom of Information Act, 29 Del. C. ch. 100 (“FOIA”), by denying a request from a reporter for access to all information regarding its purchase and inventory of pentobarbital and sodium thiopental.³³⁴ A year later in Texas, Assistant Attorney General Sean Opperman ordered the Department of Criminal Justice to respond to requests for public access to information regarding the details about and amount of a specific lethal injection drug in the Department’s possession, as well as information about the lethal injection protocol.³³⁵ He acknowledged that such information is not

³²⁹ See Denno, *Lethal Injection Quandary*, *supra* note 1, at 91-101 (explaining and analyzing the results of Study Two).

³³⁰ *Id.* at 96-101.

³³¹ See *supra* notes x-x and accompanying text.

³³² See *supra* notes x-x and accompanying text.

³³³ Mr. Randall Chase, Del. Op. Atty. Gen. 11-IIB14 (2011), 2011 WL 4062225.

³³⁴ *Id.*

³³⁵ Ms. Patricia Fleming, Tex. Atty. Gen. Op. OR2012-07088 (2012), 2012 WL

considered confidential under state code in conjunction with a physical safety exception recognized by the Texas Supreme Court one year earlier,³³⁶ and concluded that the information is not exempt from public disclosure. Opperman further stated that safeguarding the identity of the Department's suppliers of lethal injection drugs so that they are free from harassment and harm by certain interest groups is not a compelling enough reason to inhibit access. In June 2013, a federal judge ruled that the Louisiana Department of Corrections is required to publicly disclose details of its intended death penalty protocol, including inventory records, the drugs to be used, and expiration dates issued by the supplying pharmacy.³³⁷ Most recently, an Atlanta Judicial Circuit judge granted injunctive relief to a death row inmate who challenged Georgia's Lethal Injection Secrecy Act as a violation of his due process rights in a potential Eighth Amendment claim.³³⁸ As a result, the court found unacceptable the potential for the death row inmate to be barred from any knowledge about the drugs, including whether they would facilitate an execution that is cruel and unusual.³³⁹

In May 2013 the American Civil Liberties Union of Colorado sued the Colorado Department of Corrections over the secrecy of its death penalty procedures, and asked the court to compel the Department to make publicly available information pertaining to agreements with lethal injection drug pharmacies, as well as details of its execution protocol.³⁴⁰ On August 1, 2013, a district court judge ordered the Department to release a redacted version of its execution protocol, reasoning that it would facilitate a necessary public discussion of the death penalty in Colorado.³⁴¹ However,

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³³⁶ *Id.* (citing *Texas Dept. of Public Safety v. Cox Texas Newspapers, L.P. & Hearst Newspapers, L.L.C.*, 343 S.W.3d 112, 117 (Tex. 2011) (“[F]reedom from physical harm is an independent interest protected under law, untethered to the right of privacy.”)).

³³⁷ Della Hasselle, *State Must Reveal Details of Death-Penalty Practices, Federal Magistrate Rules*, THE LENS (June 5, 2013, 3:15 PM), <http://thelensnola.org/2013/06/05/state-must-reveal-details-of-death-penalty-practices-federal-judge-rules/>.

³³⁸ *Hill v. Georgia Department of Corrections, et al*, Case No. 2013-CV-233771 (Filed July 18, 2013), *available at* <http://www.deathpenaltyinfo.org/documents/HillStayOrder.pdf>.

³³⁹ *Id.* As of July 26, 2013, the state has filed an appeal to the Georgia Supreme Court seeking to overturn the lower court decision. *See* WALB NEWS, *supra* note 324.

³⁴⁰ Karen Augé, *ACLU Suit: Public is Entitled to Know How Nathan Dunlap Will Be Killed*, DENVER POST (May 21, 2013, 10:52 PM), http://www.denverpost.com/breakingnews/ci_23291066/aclu-suit-public-is-entitled-know-how-nathan.

³⁴¹ *ACLU of Colo. v. Colo. DOC*, No. 13CV32325 (Denver Dist. Ct. filed Aug. 1, 2013), *available at* <http://aclu-co.org/case/aclu-v-colorado-department-of-corrections>.

the judge decided that details about the drug supplier should be part of the redacted information.³⁴² The judge rejected the ACLU request for the Department to release the identity of the source of the drugs, specifically reasoning that exposing the pharmacy could negatively impact their business or employees, “which far outweighs” the need for public disclosure.³⁴³ Yet the judge’s decision contrasts sharply with developments in other states which allow scrutiny of the drug supplier *and* the drug protocol, not just the protocol alone. Providing cover solely to compounding pharmacies—now such a key component of the lethal injection process—fails to recognize the complex interdependency among the many different participants in the machinery of death. No participant should be holding secrets.

CONCLUSION

As risk and confusion surround lethal injection procedures, the only overarching constant appears to be states’ desire for secrecy regarding execution practices. Indeed, the current chaos may be viewed at least in part as a repercussion of that reticence: any efforts to “fix” the system via legal challenges and legislation are hindered by the difficulty in gathering enough information to even understand its problems. Until death penalty states are willing to focus more on solutions than secrecy, lethal injection as a method of execution will remain mired in an endless cycle of difficulty and disorder.

* * *

³⁴² See Associated Press, *Judge: Redacted Execution Protocol Can Be Released*, CBS NEWS (Aug. 1, 2013, 6:40 PM), <http://denver.cbslocal.com/2013/08/01/judge-redacted-execution-protocol-can-be-released/>.

³⁴³ *ACLU of Colo. v. Colo. DOC*, No. 13CV32325.

Chart 1

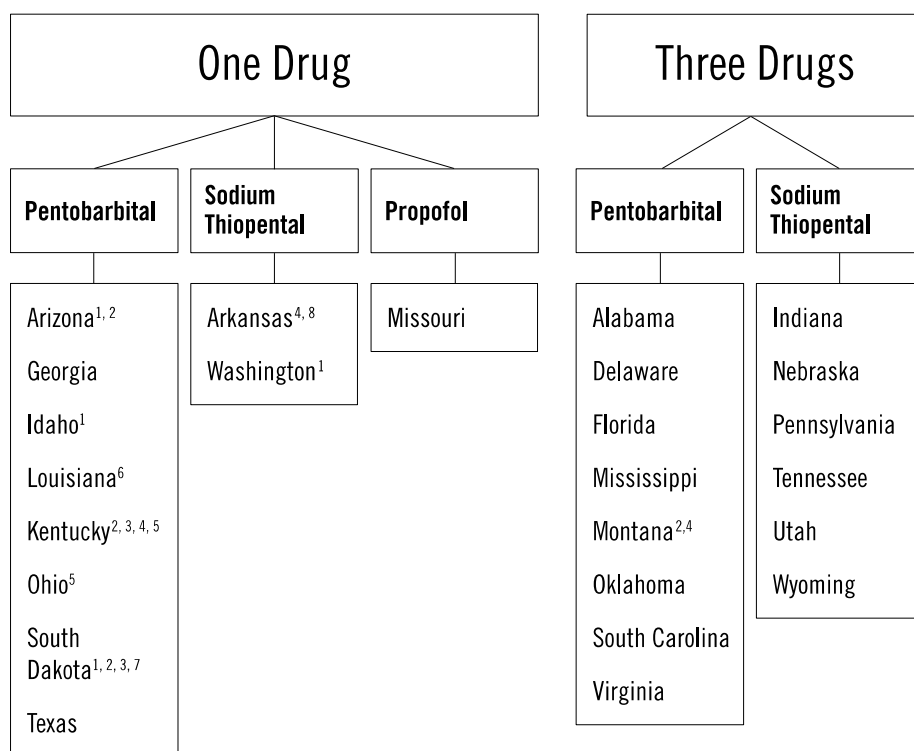
Changes in State Lethal Injection Protocols: 2010-2013*

| Year | Three Drugs to One Drug | Sodium Thiopental to Pentobarbital | Sodium Thiopental to Propofol |
|------|--|--|-------------------------------|
| 2009 | Ohio ⁵ | | |
| 2010 | Washington ¹ | Oklahoma | |
| 2011 | South Dakota ^{1, 2, 3, 7} | Alabama Arizona ^{1, 2} Delaware Florida Georgia Idaho ¹ Mississippi Montana ^{2, 4} Ohio ⁵ South Carolina South Dakota ^{1, 2, 3, 7} Texas Virginia | |
| 2012 | Arizona ^{1, 2} Georgia Idaho ¹ Missouri Texas | | Missouri |
| 2013 | Arkansas ^{4, 8} Kentucky ^{2, 3, 4, 5} Louisiana ⁶ | Kentucky ^{2, 3, 4, 5} Louisiana ⁶ | |

¹ Allows for either one or three drugs.² Allows either sodium thiopental or pentobarbital.³ Allows for either one or two drugs.⁴ Executions are on hold due to court challenges.⁵ Backup protocol uses two drugs.⁶ Execution stayed so judge can evaluate protocol.⁷ Allows for one, two, or three drugs.⁸ Considering other drugs.

*Information for this chart reflects trends up to Aug. 1, 2013, and comes from the following sources: DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org> (last visited Aug. 1, 2013); See also Death Penalty Clinic: UC Berkeley School of Law, *Execution Protocol Information*, LETHAL INJECTION.ORG, <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html> (last visited Aug. 1, 2013); <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html> (last visited Aug. 1, 2013).

Chart 2

Types of Anesthetic Used in Lethal Injection Protocols: 2013*

¹ Allows for either one or three drugs.

² Allows either sodium thiopental or pentobarbital.

³ Allows for either one or two drugs.

⁴ Executions are on hold due to court challenges.

⁵ Backup protocol uses two drugs.

⁶ Execution stayed so judge can evaluate protocol.

⁷ Allows for one, two, or three drugs.

⁸ Considering other drugs.

*Information for this chart reflects trends up to Aug. 1, 2013, and comes from the following sources: DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org> (last visited Aug. 1, 2013); See also Death Penalty Clinic: UC Berkeley School of Law, *Execution Protocol Information*, LETHAL INJECTION.ORG, <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html> (last visited Aug. 1, 2013); <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html> (last visited Aug. 1, 2013).