

ARTICLES

Lethal Injection Chaos Post-*Baze*

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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 six years after Baze, legal challenges to lethal injection soared as states scrambled to quell litigation by modifying their lethal injection protocols. My 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 attempts include frequent drug switches that take place quickly, without oversight, and based purely on convenience and

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availability. The resulting unreliability and randomness heighten the risk that the execution process will violate the Eighth Amendment's Cruel and Unusual Punishment Clause. As that risk increases, so does the tendency for states to retreat into secrecy regarding their lethal injection protocols.

For a growing number of states, alternative protocols also incorporate the use of compounding pharmacies to produce lethal injection drugs. Traditionally, compounding pharmacies are non-FDA regulated, small-scale pharmacies that make customized drugs on an as-needed basis in response to individualized prescriptions. This trend toward using compounding pharmacies is highly problematic. For example, state regulations are paltry. They also 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. Evidence shows, however, that proposed and newly adopted federal legislation regulating 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*, a Kentucky case, to determine the future direction of lethal injection.³ In *Baze*, a 7-2 decision with a plurality opinion,⁴ the Court upheld the constitutionality of Kentucky’s lethal injection protocol under the Eighth Amendment’s Cruel and Unusual Punishment 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 chloride, a toxin

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, *Getting to Death: Are Executions Constitutional?*, 82 IOWA L. REV. 319, 373–400 (1997) [hereinafter Denno, *Getting to Death*]; 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) [hereinafter Denno, *When Legislatures Delegate*].

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. 553 U.S. at 40–41.

4. Chief Justice John Roberts announced the judgment of the Court and delivered an opinion in which Justices 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.

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. 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 definitive response to the issue of lethal injection's constitutionality.¹⁶ In fact, *Baze* was so splintered that none of its seven opinions garnered more than three votes,¹⁷ and the

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, *Challenges Remain for Lethal Injection*, *N.Y. TIMES*, Apr. 17, 2008, <http://www.nytimes.com/2008/04/17/washington/17lethal.html>.

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, <http://www.nytimes.com/2008/01/08/us/08scotus.html>.

16. *See infra* Part II.

17. *See supra* note 4 and accompanying text.

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 Thomas,²¹ and Alito²² expressed concern that the *Baze* decision would only lead to additional debate and litigation. Until now, however, criticisms and concerns regarding developments in lethal injection protocols after *Baze* have been largely predictive.

This Article provides facts where there has been only foresight. I present the results of a unique empirical study in which I collected and analyzed over 300 cases citing *Baze* in the first 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 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 the difficulties with injecting inmates whose drug-use histories diminish the availability of usable veins.²³ Despite states' efforts to improve their procedures, such deficiencies have led to some of the most glaring and gruesome failures ever documented in the history of lethal injection.²⁴

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

18. For an analysis of the different opinions in *Baze*, see generally 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 (Charles J. Ogletree, Jr. & Austin Sarat eds., 2009).

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

20. *Baze v. Rees*, 553 U.S. 35, 71 (2008) (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 105 (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 *infra* Part II.

24. See *infra* notes 159, 205, 311–12 and accompanying text.

as controversy over physician involvement. Combined with widely publicized botched executions, the lethal injection debate after *Baze* encompassed problems even worse and more varied than those that existed before the Court's intervention.²⁵ Yet no one—not even the more prescient 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 after *Baze* was decided.²⁶

As death-penalty states face the daunting reality of diminishing or depleted drug supplies and ever-increasing restrictions on drug importation, they are struggling to match their protocols to drug availability.²⁷ Some states have put lethal injection executions on hold until the drug situation is resolved,²⁸ while others have turned to the U.S. Department of Justice for help.²⁹ 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.³⁰ 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,³¹ compounding pharmacies (and pharmacies generally) are regulated relatively permissively by the states.³²

Over the past few decades, however, the FDA has discovered a disturbing trend in which compounding pharmacies capitalize on their ability to produce

25. See *infra* section II.B.

26. See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-14-194, DRUG SHORTAGES: PUBLIC HEALTH THREAT CONTINUES, DESPITE EFFORTS TO HELP ENSURE PRODUCT AVAILABILITY 14 fig.4, 21 (2014) (charting the number of active drug shortages from January 2007 through June 2013 and finding that the immediate cause of drug shortages is traceable to slow or halted production of drugs). Hospira, Inc. was among the manufacturers interviewed for the GAO report. *Id.* at 65.

27. See *infra* Parts III, IV.

28. See Kimberly Leonard, *Lethal Injection Drug Access Could Put Executions on Hold*, CENTER FOR PUB. INTEGRITY (July 11, 2012, 4:23 PM), <http://www.publicintegrity.org/2012/04/04/8589/lethal-injection-drug-access-could-put-executions-hold>.

29. See Bill Mears, *States Urge Feds to Help Import Lethal Injection Drugs*, CNN (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 fifteen states asking for help, noting that “[a]t the very core of the states’ police powers are their powers to enact laws to protect their citizens against violent crimes” and “[a]s state attorneys general, we are tasked with enforcing those laws, including in instances where capital punishment is authorized for the most heinous of crimes”).

30. See Meredith Clark, *US Execution Strategy Threatened by Drug Shortfall*, MSNBC (May 3, 2013, 11:20 AM), <http://www.msnbc.com/melissa-harris-perry/us-execution-strategy-threatened-drug-shor>.

31. See STAFF OF REP. EDWARD J. MARKEY, U.S. HOUSE OF REPRESENTATIVES, STATE OF DISARRAY: HOW STATES’ INABILITY TO OVERSEE COMPOUNDING PHARMACIES PUTS PUBLIC HEALTH AT RISK 6 (2013), available at <http://www.hsdl.org/?view&did=735130> (reporting the responses to an investigation which examined the state oversight of compounding pharmacies).

32. 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).

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.³³ This practice has had, at times, disastrous results.

For example, in early October 2012, a contaminated steroid produced by a compounding pharmacy in Massachusetts led to a fungal meningitis outbreak that has killed a total of sixty-four people and sickened hundreds more.³⁴ This tragedy led the FDA to inspect thirty-one compounding pharmacies over the next six months, whereby the FDA made a series of disturbing discoveries concerning the pharmacies' lack of safeguards.³⁵ Moreover, an April 2013 study released by the U.S. House of Representatives revealed that almost all states provide overall ineffective oversight and regulation of the compounding pharmacies within their borders. In response to these findings, legislation has been proposed that would require FDA approval of not only pharmacies engaged in interstate commerce, but also those involved in high-risk compounding.³⁶

As the FDA continues to explore ways to increase oversight of compounding pharmacies, state pharmacy boards have also been working on their own to increase their regulatory oversight in response to the negative focus on compounding pharmacies after the meningitis outbreak. Proposed state regulations include stricter requirements for both local compounding pharmacies and out-of-state pharmacies that cross state lines, clearer definitions of compounding, additional inspection protocols, and the installment or improvement of prescription-monitoring programs.³⁷

33. See OFFICE OF REP. EDWARD J. MARKEY, U.S. HOUSE OF REPRESENTATIVES, COMPOUNDING PHARMACIES: COMPOUNDING RISK 5 (2012), available at http://www.snmni.org/files/docs/Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL_0_1382017898361_1.pdf (addressing current regulatory oversight and gaps in legal authority over compounding pharmacies in response to the fungal meningitis outbreak in Boston); Editorial, *Fix 'Compounding Pharmacy' Oversight: Our View*, USA TODAY (Apr. 28, 2013, 6:27 PM), <http://www.usatoday.com/story/opinion/2013/04/28/compounding-pharmacy-fda-editorials-debates/2119621>.

34. See *Multi-State Meningitis Outbreak—Current Case Count*, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 23, 2013, 5:30 PM), <http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html>. For more information on the meningitis outbreak and the continually developing outcomes, see Scott Gottlieb, *Compounding a Crisis at FDA*, FORBES (May 24, 2013, 8:59 AM), <http://www.forbes.com/sites/scottgottlieb/2013/05/24/compounding-a-crisis-at-fda/>.

35. See Margaret A. Hamburg, *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/>; *Summary: 2013 FDA Pharmacy Inspection Assignment*, FDA, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm347722.htm> (last updated Jan. 9, 2014); see also *infra* notes 261–62 and accompanying text (listing the extent of the problems).

36. See STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 2–3.

37. See Andrew Pollack, *Checks Find Unsafe Practices at Compounding Pharmacies*, N.Y. TIMES, Apr. 12, 2013, at A12; see also Kara Nett Hinkley, *Compounding Interest*, ST. LEGISLATURES, June 2013, at 22, 23, available at http://www.ncsl.org/Portals/1/Documents/magazine/articles/2013/SL_0613-Compounding.pdf; *State Regulation of Compounding Pharmacies*, NAT'L CONF. OF ST. LEGISLATURES, <http://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx> (last updated Jan. 2014).

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. Finally, and perhaps most significantly, several of the proposed restrictions may effectively negate altogether the ability of compounding pharmacies to produce lethal injection drugs.

Thus, death-penalty states could 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 make increased regulation inevitable. Death-penalty states have an unsettling tendency to retreat into secrecy with respect to execution protocols and source materials when legal challenges appear threatening, yet currently proposed regulations may hinder such retreat.

In sum, *Baze v. Rees*—the Supreme Court’s only opinion on the constitutionality of lethal injection—failed to answer significant questions, and many of the issues that the Court did consider have been subsumed by new legal and practical challenges. The future of lethal injection remains unclear. This Article is intended to be a point-in-time snapshot of the rapidly changing factors affecting the use of lethal injection in the United States. Part I of this Article briefly describes the history of lethal injection methods and provides a foundation for the current debate regarding lethal injection drugs. Part II discusses the role of *Baze* as precedent, supporting the remarkable assertion that *Baze* has been rendered mostly irrelevant merely five years after its issuance. Part II also discusses legal challenges after *Baze* as well as states’ attempts to quell litigation by switching their lethal injection protocols from three-drug to one-drug procedures. Part III 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 IV reveals the dangers associated with states’ attempts to address those shortages by seeking compounded drugs from pharmacies that lack federal oversight and explains how new regulations may impede states’ increasingly frantic efforts to procure lethal injection drugs. Part V 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. Part V also emphasizes the likelihood that new compounding pharmacy regulations will promote such transparency. This Article concludes by condemning states’ efforts to retreat into secrecy regarding execu-

tion practices. Such efforts thwart any attempt to address problems with lethal injection and only further contribute to the chaos. Transparency regarding lethal injection procedures is 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,³⁸ 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.³⁹ 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.⁴⁰ The State of New York considered using one form of lethal injection (cyanide injection) as early as 1888,⁴¹ yet a state commission rejected that choice because the medical profession believed that the public would begin to link the practice of medicine to death.⁴² Of course, this concern about lethal injection remains today.⁴³

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.⁴⁴ 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.⁴⁵ In 1976, the United States started to examine the lethal injection issue more intently after the

38. See 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 the guardians of a moral order that, in part, bases its claims to superiority in its condemnation of killing").

39. For discussions of legislative changes in execution methods over time, see 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*]; Denno, *Getting to Death*, *supra* note 1, at 375–79; 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.

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

41. See REPORT OF THE COMMISSION TO INVESTIGATE AND REPORT THE MOST HUMANE AND PRACTICAL METHOD OF CARRYING INTO EFFECT THE SENTENCE OF DEATH IN CAPITAL CASES 78, 85 (Albany, The Argus Co. 1888).

42. See Denno, *Engineering of Death*, *supra* note 39, at 572–73.

43. See Denno, *Lethal Injection Quandary*, *supra* note 1, at 80–81.

44. See ROYAL COMMISSION ON CAPITAL PUNISHMENT, REPORT, 1949–1953, [Cmd.] 8932, at 258–61 (U.K.).

45. *Id.* at 258.

Supreme Court reinstated the death penalty in *Gregg v. Georgia*,⁴⁶ a case that marked the end of a nine-year pause in this country's executions.⁴⁷ Remarkably, no state legislature addressed the evidence gathered and conclusions reached on injection procedures either from the New York or British commissions.⁴⁸

Such disregard for past medical investigations was clear in May 1977, when Oklahoma became the first state to adopt lethal injection.⁴⁹ 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.⁵⁰ 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."⁵¹

With virtually no scientific study or relevant medical background, Dr. Chapman quickly concocted the three-drug formula formerly used by Kentucky.⁵² Yet, within days of the Oklahoma legislature adopting his method, Chapman warned the public of lethal injection's hazards.⁵³ In the *Daily Oklahoman*, for example, he noted that "if the death-dealing drug is not administered properly, the convict may not die and could be subjected to severe muscle pain."⁵⁴ Other news articles at the time stressed the tentative status of Oklahoma's protocol. A 1979 article in the *Daily Oklahoman* emphasized that "[o]fficials 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."⁵⁵ The article also noted that "[o]fficials feel that if and when they have to use the injection law, *new and better drugs may be available*."⁵⁶ 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.⁵⁷ At one point, the Oklahoma legislature considered requiring that injection could not supplant electrocution without being "ruled legal by the U.S. Supreme Court."⁵⁸ Legisla-

46. 428 U.S. 153, 207 (1976) (plurality opinion).

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

48. See Denno, *Lethal Injection Quandary*, *supra* note 1, at 65.

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

50. See Denno, *Lethal Injection Quandary*, *supra* note 1, at 66.

51. *Id.* (alteration in original) (quoting E-mail from A. Jay Chapman, Forensic Pathologist, Santa Rosa, Cal., to author (Jan. 18, 2006) (on file with author)).

52. See *id.* at 66–75.

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

54. *Id.*

55. See Jim Killackey, *Officials Draw Grim Execution Scene*, DAILY OKLAHOMAN, Nov. 12, 1979, at 1.

56. *Id.* (emphasis added).

57. 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 the Senate should study [the bill] more carefully").

58. See Mike Hammer, *Drug Death Bill Passes*, DAILY OKLAHOMAN, Apr. 21, 1977, at 65.

Chart 1

States Adopting Lethal Injection by Year: 1977–2014*

1977	Oklahoma • Texas
1978	Idaho
1979	New Mexico
1981	Washington
1982	Massachusetts
1983	Arkansas • Illinois • Montana • Nevada • New Jersey • North Carolina • Utah
1984	Mississippi • Oregon • South Dakota • Wyoming
1986	Delaware • New Hampshire
1988	Colorado • Missouri
1990	Louisiana • Pennsylvania
1992	Arizona • California
1993	Ohio ¹
1994	Kansas • Maryland • Virginia
1995	Connecticut • Indiana • New York • South Carolina
1998	Kentucky • Tennessee
2000	Florida • Georgia
2002	Alabama
2009	Nebraska

¹ In 2001, Ohio changed from a choice state to a single-method state.

* Information for this chart comes from the following sources: NEB. REV. STAT. § 83-964 (2010); 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, 188 (Charles J. Ogletree, Jr. & Austin Sarat eds., 2009).

tive 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.⁵⁹ As the trial court in *Baze v. Rees* concluded in 2005, “there is scant evidence that ensuing States’ adoption of lethal injection was supported by any additional medical or scientific studies Rather, it is this Court’s impression that the various States simply fell in line relying solely on Oklahoma’s protocol.”⁶⁰ Indeed, after Oklahoma adopted the method, state after state followed suit. As Chart 1 of this Article shows, thirty-nine states joined this movement between

59. See Denno, *Lethal Injection Quandary*, *supra* note 1, at 64–117.

60. *Baze v. Rees*, No. 04-CI-01094, 2005 WL 5797977, at *2 (Ky. Cir. Ct. July 8, 2005), *aff’d*, 217 S.W.3d 207 (Ky. 2006), *aff’d*, 553 U.S. 35 (2008).

1977 and 2009, switching to lethal injection like falling dominos. Many of these states simply copied the language of Oklahoma's lethal injection statute.⁶¹

The thirty-nine-state figure alone is remarkable. Even more extraordinary is that six states, including Oklahoma, made the switch by 1982,⁶² the year this country's first lethal injection execution took place.⁶³ Another seven states changed in 1983 alone.⁶⁴ 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.⁶⁵ In addition, twelve states enacted lethal injection in the nine-year stretch from 1994, when Kansas, Maryland, and Virginia adopted the method, to 2002, when Alabama did.⁶⁶ Nebraska was a lone wolf, switching to lethal injection in 2009, a year after the Nebraska Supreme Court finally declared electrocution unconstitutional.⁶⁷ By 2009, then, all death-penalty states in this country had switched to lethal injection, either entirely or as an option,⁶⁸ and nearly all states used a protocol consisting of the same three drugs.⁶⁹

Of the thirty-two death-penalty states that exist in mid-2014, lethal injection is the sole method of execution in twenty-one states, as shown in Chart 2 of this Article.⁷⁰ Three states—Utah, Kentucky, and Tennessee—have also adopted

61. See Denno, *Getting to Death*, *supra* note 1, at 375; Denno, *Lethal Injection Quandary*, *supra* note 1, at 78; Denno, *When Legislatures Delegate*, *supra* note 1, at 92, 95–100.

62. See *supra* Chart 1 (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).

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

64. See *supra* Chart 1 (showing that Arkansas, Illinois, Montana, Nevada, New Jersey, North Carolina, and Utah adopted lethal injection in 1983).

65. By the end of 1983, thirty-eight states had the death penalty. See BUREAU OF JUSTICE STATISTICS, U.S. DEP'T OF JUSTICE, CAPITAL PUNISHMENT 1983, at 6–7 (1986).

66. See *supra* Chart 1 (showing that a series of states adopted lethal injection between 1994 and 2002, starting with Kansas, Maryland, Virginia in 1994; Connecticut, Indiana, New York, and South Carolina in 1995; Kentucky and Tennessee in 1998; Florida and Georgia in 2000; and Alabama in 2002).

67. 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. NEB. REV. STAT. § 83-964 (2010).

68. See *supra* Chart 1.

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

70. See ARIZ. REV. STAT. ANN. § 13-757 (2010); ARK. CODE ANN. § 5-4-617 (Supp. 2013); COLO. REV. STAT. ANN. § 18-1.3-1202 (West 2013); DEL. CODE ANN. tit. 11, § 4209 (Supp. 2012); GA. CODE ANN. § 17-10-38 (2013); IDAHO CODE ANN. § 19-2716 (Supp. 2013); IND. CODE § 35-38-6-1 (2012); KAN. STAT. ANN. § 22-4001 (2007); LA. REV. STAT. ANN. § 15:569 (2012); MISS. CODE ANN. § 99-19-51 (West 2013); MONT. CODE ANN. § 46-19-103(3) (2013); NEB. REV. STAT. § 83-964 (Supp. 2010); NEV. REV. STAT. ANN. § 176.355 (LexisNexis Supp. 2013); N.C. GEN. STAT. § 15-187 (2013); OHIO REV. CODE ANN. § 2949.22 (LexisNexis 2006); OKLA. STAT. ANN. tit. 22, § 1014 (West Supp. 2014); OR. REV. STAT. § 137.473 (2013); 61 PA. CONS. STAT. ANN. § 4304 (West 2010); S.D. CODIFIED LAWS § 23A-27A-32 (Supp. 2013); TEX. CODE CRIM. PROC. ANN. art. 43.14 (West Supp. 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 Supp. 2013).

Chart 2

Execution Methods by State: 2014*

Single-Method States (24)
Arizona ● Arkansas ● Colorado ● Delaware ● Georgia ● Idaho ● Indiana ● Kansas ● Kentucky ● Louisiana ● Mississippi ● Montana ● Nebraska ● Nevada ● North Carolina ● Ohio ● Oklahoma ● Oregon ● Pennsylvania ● South Dakota ● Tennessee ● Texas ● Utah ● Wyoming
Choice States (11)
Lethal Injection or Hanging (2): New Hampshire ● Washington
Lethal Injection or Firing Squad (1): Utah
Lethal Injection or Electrocution (6): Alabama ● Florida ● Kentucky ● South Carolina ● Tennessee ● Virginia
Lethal Injection or Lethal Gas (2): California ● Missouri
States Without the Death Penalty (18)
Alaska ● Connecticut ● Hawaii ● Illinois ● Iowa ● Maine ● Maryland ● Massachusetts ● Michigan ● Minnesota ● New Jersey ● New Mexico ● New York ● North Dakota ● Rhode Island ● Vermont ● West Virginia ● Wisconsin Also—District of Columbia

* Kentucky, Tennessee, and Utah have provisions that are not retroactive and therefore allow choices for some inmates. These three states are listed in both the Single-Method States and Choice States categories.

lethal injection as their sole execution method but have done so with provisions that are not retroactive.⁷¹ Lethal injection is one of two possible methods of execution in eleven 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).⁷² 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.⁷³

71. See KY. REV. STAT. ANN. § 431.220 (West Supp. 2013); TENN. CODE ANN. § 40-23-114 (2012); UTAH CODE ANN. § 77-18-5.5 (LexisNexis 2012).

72. 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 § 15-18-82.1 (LexisNexis 2011); FLA. STAT. ANN. § 922.105 (West Supp. 2014); S.C. CODE ANN. § 24-3-530 (2007); VA. CODE ANN. § 53.1-234 (2013). New Hampshire and Washington also have hanging as a method. See N.H. REV. STAT. ANN. § 630:5 (2007); WASH. REV. CODE ANN. § 10.95.180 (West 2012). California and Missouri both have lethal gas as an alternative. See CAL. PENAL CODE § 3604 (West 2011); MO. REV. STAT. § 546.720 (Supp. 2012). 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.

73. The statutes for these eighteen states are listed in chronological order as follows beginning with the first state without the death penalty: Act of May 18, 1846, ch. 153, sec. 1, 1846 Mich. Pub. Acts 658 (fixing the punishment for first-degree murder at “solitary confinement at hard labor in the state prison

Statistics demonstrating lethal injection's dominance, however, ignore the effect that lethal injection challenges can have on capital punishment. Indeed, it was the dominance of lethal injection that imperiled all capital punishment when lethal injection faced legal challenges. 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 2008.⁷⁴ Numerous states and the federal government ceased executions entirely, often at least partly due to problems and legal challenges related to lethal injection.⁷⁵ Beginning on

for life"); Act of July 12, 1853, ch. 103, 1853 Wis. Sess. Laws 100; Act of Mar. 17, 1887, ch. 133, 1887 Me. Laws 104; Act of Apr. 22, 1911, ch. 387, 1911 Minn. Laws 572 (revising Minnesota's sentence for first-degree murder to "imprisonment for life"); Act of June 4, 1957, 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); Act of Mar. 30, 1957, ch. 132, 1957 Alaska Sess. Laws 262 (abolishing the death penalty "as punishment in Alaska for the commission of any crime," prior to Alaska gaining statehood); Act of Apr. 15, 1965, No. 30, 1965 Vt. Acts & Resolves 28 (codified as amended at VT. STAT. ANN. tit. 13, § 2303 (2009)); W. VA. CODE ANN. § 61-11-2 (LexisNexis 2013) (abolishing capital punishment in West Virginia); Act of May 14, 1965, ch. 436, sec. 3, 1965 Iowa Acts 828; Criminal Law Revision Act, ch. 116, §§ 31, 41, 1973 N.D. Laws 215, 286-88, 300 (repealing North Dakota's capital-punishment statute and creating new criminal sentencing guidelines); Act of Dec. 26, 1980, No. 3-307, 27 D.C. Reg. 5624 (repealing the death penalty and substituting it with life imprisonment instead); *Commonwealth v. Colon-Cruz*, 470 N.E.2d 116, 129 (Mass. 1984) (holding that Massachusetts's death-penalty statute violated the state constitution); Act of July 1, 1984, ch. 221, sec. 1, 1984 R.I. Pub. Laws 523 (removing the punishment of death from sentencing provisions for first-degree murder); *People v. LaValle*, 817 N.E.2d 341, 367 (N.Y. 2004) (holding the death-penalty statute in violation of the state constitution); *People v. Taylor*, 878 N.E.2d 969, 983-84 (N.Y. 2007) (applying the holding in *LaValle* to the last remaining person on death row in the state); Act of Dec. 17, 2007, ch. 204, 2007 N.J. Laws 1427 (eliminating the death penalty in New Jersey and allowing for life imprisonment without eligibility for parole); Act of Mar. 18, 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 of Mar. 9, 2011, No. 96-1543, 2011 Ill. Laws 7778 (creating a death-penalty-abolition fund and abolishing the death penalty in Illinois); Act of Apr. 25, 2012, No. 12-5, 2012 Conn. Acts 13 (Reg. Sess.) (providing for a definite sentence of imprisonment for capital felonies); Act of May 2, 2013, ch. 156, 2013 Md. Laws 2298 (repealing the death penalty and substituting it with life without the possibility of parole). Notably, the abolishment of the death penalty was retroactive in every state except for New Mexico, Connecticut, and Maryland, therefore leaving several people on each of the three states' death rows. See 2009 N.M. Laws 133; 2012 Conn. Acts 13 (Reg. Sess.); 2013 Md. Laws 2298.

74. See *Executions by Year Since 1976*, DEATH PENALTY INFO. CENTER, <http://deathpenaltyinfo.org/executions-year> (last updated May 6, 2014).

75. See DEATH PENALTY INFO. CTR., *THE DEATH PENALTY IN 2013: YEAR END REPORT 2-4* (2013), available at <http://deathpenaltyinfo.org/documents/YearEnd2013.pdf> (discussing the significant decline in executions in 2013 due to states either suspending executions or repealing capital punishment because of problems such as drug availability and constitutional challenges to their protocols); Manny Fernandez, *Executions Stall as States Seek Different Drugs*, N.Y. TIMES, Nov. 9, 2013, at A1 (reporting on the inability of several states to perform executions because of the unavailability of lethal injection drugs and noting that Texas, Florida, and Ohio have been scrambling to find alternative drugs); Clare Algar, *Big Pharma May Help End the Death Penalty*, NEW REPUBLIC (Oct. 22, 2013), <http://www.newrepublic.com/article/115284/big-pharma-may-end-death-penalty> ("Shortages of lethal injection drugs and attendant litigation have resulted in moratoria—an official halting of executions—in Arkansas, California, Kentucky, Louisiana, Maryland, Missouri, Montana, Nebraska, North Carolina, Oregon, and Tennessee."); Dustin Volz, *Death Penalty Opponents Are Winning . . . Almost Everywhere*, NAT'L J. (Dec. 19, 2013), <http://www.nationaljournal.com/technology/death-penalty-opponents-are-winning-almost-everywhere-20131219> ("The [Death Penalty Information Center's] end-year report cites an

September 26, 2007, the day the Court granted certiorari in *Baze*, no additional executions were conducted until May 6, 2008.⁷⁶ Although 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.⁷⁷ Historically, such a lengthy hiatus is rare.⁷⁸ After *Baze* was decided, those stays ended when the Justices denied the underlying appeals. Executions began again, but so did lethal injection litigation, and with a vengeance.

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.⁷⁹ That prediction was never realized; apart from a slight rise in 2009, executions have continued their downward trend.⁸⁰ The number of executions by year is as follows: thirty-seven in 2008, fifty-two in 2009, forty-six in 2010, forty-three in 2011, forty-three in 2012, and thirty-nine in 2013.⁸¹ One reason for this decline may be that the death penalty's popularity has weakened in recent years.⁸² Whether because of discoveries of innocence among death-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.⁸³ Yet, lethal injection challenges may have contributed to this skepticism. According to one death-penalty commentator, lethal injection challenges "have already held up more executions, and for a

ongoing shortage of lethal-injection drugs in several states for 2013's drop in executions. California, North Carolina, Arkansas, and Maryland have not required a death sentence in more than seven years 'because of their inability to settle on a lethal-injection protocol.'" (quoting DEATH PENALTY INFO. CTR., *supra*, at 4)).

76. See Shaila Dewan, *Executions Resume, as Do Questions of Fairness*, N.Y. TIMES, May 7, 2008, <http://www.nytimes.com/2008/05/07/us/07execute.html> (noting that an execution on May 6, 2008 "ended a seven-month national suspension").

77. See Linda Greenhouse, *Justices Uphold Lethal Injection in Kentucky Case*, N.Y. TIMES, Apr. 17, 2008, <http://www.nytimes.com/2008/04/17/washington/17scotus.html>.

78. See *supra* notes 44–47 and accompanying text.

79. See Liptak, *supra* note 13.

80. See DEATH PENALTY INFO. CTR., *THE DEATH PENALTY IN 2012: YEAR END REPORT 1* (2012), available at <http://deathpenaltyinfo.org/documents/2012YearEnd.pdf> (noting that the number of new death sentences in 2012 was the second lowest since the death penalty was reinstated in 1976, representing a near 75% decline since 1996 when there were 315 new death sentences).

81. See *Executions by Year Since 1976*, *supra* note 74.

82. A 2012 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. Likewise, 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 (Jan. 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.

83. See Ronald J. Tabak, *Capital Punishment*, in *THE STATE OF CRIMINAL JUSTICE 2013*, at 305, 305–24, 328–38, 343–45 (Myrna S. Raeder ed., 2013).

longer time than appeals involving such . . . issues as race, innocence, and mental competency.”⁸⁴

II. *BAZE* AS PRECEDENT

Given the narrowness and ineffectiveness of the *Baze* opinion, the Court’s decision has had minimal effect in the way that the *Baze* plurality intended.⁸⁵ Rather than offering guidance on the future direction of lethal injection, 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 since 2008, it can be argued that *Baze* has rendered itself moot.⁸⁶ Strikingly, even Kentucky itself—the “model” state at the heart of *Baze*—has switched to a single-drug protocol, such that it is no longer “substantially similar” to the procedure the *Baze* Court hailed as the standard for other states to follow.⁸⁷

Yet this is a remarkable conclusion to reach regarding a Supreme Court opinion merely six 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.⁸⁸ I base this assertion on two grounds. First, although *Baze* has not been entirely void of precedential force, my analysis of all cases that have cited *Baze*, which I discuss in section II.A, indicates that the case’s value as precedent has been limited. My study demonstrates that number of citations is not always indicative of an opinion’s efficacy. Second, citations to *Baze* have decreased substantially in the last three years.⁸⁹ As I explain in section II.B, this decline is 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.⁹⁰ 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,

84. Dieter, *supra* note 2, at 789.

85. *See id.* at 806.

86. *See infra* section II.B.

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

88. This six-decade demarcation was offered by the Court. *See id.* at 48–50 (plurality opinion) (discussing the Eighth Amendment precedents of *Wilkerson v. Utah*, 99 U.S. 130 (1879), *In re Kemmler*, 136 U.S. 436 (1890), and *Louisiana ex rel. Francis 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.

89. The distributions by year are as follows: fifty-three cases in 2008; seventy-five cases in 2009; eighty-one cases in 2010; sixty-three cases in 2011; fifty-three cases in 2012; twelve cases in 2013 (as of May 13, 2013). Deborah W. Denno, *Analyzing Precedent in Baze v. Rees: 2008–2013*, at 5 (Aug. 1, 2013) (unpublished manuscript) (on file with author).

90. *See infra* section II.B.

the use of foreign-sourced drugs being a particularly striking example.⁹¹ Indeed, lethal injection litigation after *Baze* is so prolific and variable that it seemingly dwarfs the extent to which *Baze* has been used to dismiss challenges. I conclude that *Baze*'s already constrained precedential force is barely applicable to recent litigation spurred by this country's unanticipated drug shortages.

A. BAZE'S LIMITED PRECEDENTIAL FORCE

Three hundred thirty-three cases have cited the *Baze* Court's plurality opinion (as well as the concurrences and dissent) from the time *Baze* was decided until May 30, 2013.⁹² I reviewed the nature of each case's citation and reference to *Baze* and then grouped the cases along several dimensions into one or more of the following categories: the substantial-risk standard; concurring and dissenting opinions; and the Eighth Amendment standard.⁹³ In the next three subsections, I will discuss each group in turn.

91. For more information on the use of foreign-sourced drugs, see *infra* Part III.

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. See Denno, *supra* note 89, at 3–4. Thus, the final 333 cases are not redundant. *Id.* All 406 cases, however, are categorized and documented in detail in a manuscript on file with the author. *Id.* at tbl.A.

93. See Denno, *supra* note 89, at 5–23. In total, fourteen 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 the Eighth Amendment. See, e.g., *Bethea v. Salazar*, No. EDCV 05-1168 DOC (FFM), 2008 WL 4381545, at *13 n.24 (C.D. Cal. Sept. 23, 2008) (citing *Baze* stating that the Eighth Amendment provides that excessive bail shall not be required, and excessive fines shall not be imposed); *State v. Cottrell*, 271 P.3d 1243, 1250 n.4 (Idaho Ct. App. 2012) (citing *Baze* 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 categories. Most of these cases mentioned *Baze* in a footnote or in combination with other cases to reinforce a briefly mentioned point. See *Zack v. Tucker*, 704 F.3d 917, 925 (11th Cir. 2013) (stating that the Supreme Court in *Baze* “observed that the purpose of the habeas statute of limitations is to end delays in criminal cases”); *Walker v. Epps*, 550 F.3d 407, 416 (5th Cir. 2008) (stating that *Baze* has permitted inmates to challenge the state's method of execution under 42 U.S.C. § 1983 and a constitutional standard); *Schwab v. Sec'y, Dep't of Corr.*, 284 F. App'x 643, 644 (11th Cir. 2008) (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*, his case would be dismissed” (citation omitted)); *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: “[S]peculation cannot substitute for evidence of irreparable harm” (alteration in original) (internal quotation marks omitted)); *Barrett v. United States*, No. 09-CIV-105-JHP, 2010 WL 774192, at *1 (E.D. Okla. Feb. 26, 2010) (stating that “[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” (footnote omitted) (quoting *Baze v. Rees*, 553 U.S. 35, 84 (2008) (Stevens, J., concurring))); *Wilson v. Strickland*, No. 2:09-cv-271, 2009 WL 1362511, at *3 (S.D. Ohio May 13, 2009) (stating that “*Baze* did not *establish* a new claim or constitutional right but simply made clear the expansive *scope* of the claim and right involved”); *State v. Jackson*, No. 92003717DI, 2008 WL 5048424, at *3 (Del. Super. Ct. 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*.”); *State v. Hartman*, No. 25055, 2010 WL 4867370, at *4 (Ohio Ct. 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”).

1. Substantial-Risk Standard

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

a. Execution Team Training. Twenty-nine cases cited *Baze* in discussions of execution-team or supervisor training levels and protocols and reached varying results.⁹⁷ All cases, with the exception of one that was remanded,⁹⁸ relied on *Baze* to question 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

b. Drug Type and Protocol Implementation. Most cases (216 cases or 87%) cited *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

94. *Baze*, 553 U.S. at 47–50 (plurality opinion). 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); 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. CONST. L. 1407, 1409–14 (2010); Denno, *supra* note 18, at 196–201.

95. *Baze*, 553 U.S. at 50 (quoting *Helling v. McKinney*, 509 U.S. 25, 33, 34–35 (1993)).

96. See Denno, *supra* note 89, at tbl.B.

97. *Id.* at 13–14.

98. See *Morales v. Cate*, 757 F. Supp. 2d 961, 969 (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” (citations omitted) (quoting *Morales v. Tilton*, 465 F. Supp. 2d 972, 979–80 (N.D. Cal. 2006))).

99. *Beaty 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 89, at 10.

argued that the protocol's implementation violates the Eighth Amendment,¹⁰¹ whereas others involved challenges to the type of drug being injected, such as the choice of pentobarbital in place of sodium thiopental, which was needed to rectify the issues presented by a shortage of the latter.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 216 cases concern challenges to a state protocol's method or procedure.¹⁰⁴ These cases include challenges to the type of method used—a one-drug¹⁰⁵ or three-drug¹⁰⁶ method—and the state protocol's lethal injection procedure in general.¹⁰⁷ As stated above, each court presented with a protocol challenge found that the plaintiffs in question could not establish that the protocol created a demonstrated risk of severe pain, as explicated in *Baze*, or that the risk was substantial compared to other known

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 cruel and unusual.” (quoting *Baze v. Rees*, 553 U.S. 35, 50 (2008)) (internal quotation marks omitted)); *Batiste v. State*, 121 So. 3d 808, 873 (Miss. 2013) (finding that Mississippi’s protocol was “substantially similar to Kentucky’s protocol” and thus that an Eighth Amendment challenge was unfounded (quoting *Chamberlin v. State*, 55 So. 3d 1046, 1056 (Miss. 2010))).

102. See *Pavatt v. Jones*, 627 F.3d 1336, 1339–40 (10th Cir. 2010) (upholding a district court’s 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 (“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.”); *Lucas v. Upton*, No. 5:09-CV-289 (CAR), 2011 WL 4526754, at *4 n.3 (M.D. Ga. Sept. 28, 2011) (“Since confiscation of its supply of sodium thiopental, Georgia, as well as several other states, has started to use pentobarbital as the first drug in the three-step lethal injection process.”); *State v. Santiago*, 49 A.3d 566, 698 (Conn. 2012) (noting that “in 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”); *State v. Rizzo*, 31 A.3d 1094, 1169 (Conn. 2011) (noting the shortage of thiopental sodium generally).

103. See *Denno*, *supra* note 89, at 11.

104. See *id.* at tbl.B.

105. See *Pardo v. Palmer*, 500 F. App’x 901, 902–05 (11th Cir. 2012) (upholding a one-drug lethal injection protocol); *Cooley v. Strickland*, 589 F.3d 210, 223–25 (6th Cir. 2009) (holding that the risk of improper implementation of Ohio’s one-drug protocol did not violate the Eighth Amendment).

106. See *Peterson v. State*, 2 So. 3d 146, 156–57 (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 *Grant v. Workman*, No. 05-CV-0167-TCK-TLW, 2010 WL 5069853, at *39 (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 the inmate suffering intense pain due to the fact that “there is no assurance that Oklahoma’s procedure will render him unconscious during the execution”); *State v. Odom*, No. W2008-02464-CCA-R3-DD, 2010 Tenn. Crim. App. LEXIS 223, at *103–07 (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).

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, 27 of the 216 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 the drug's 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

c. Foreign-Sourced Drugs. With the increasing scarcity of lethal injection drugs in this country, 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 thirteen 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

108. See *Harbison v. Little*, 571 F.3d 531, 535–39 (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, e.g., *Batiste v. State*, 121 So. 3d 808, 873 (Miss. 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 because it was found to be "substantially similar" to Kentucky's protocol); *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 "failed as a matter of law to demonstrate a substantial or objectively intolerable risk that he will receive an inadequate dose of thiopental"); *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" (quoting *Schwab v. State*, 995 So. 2d 922, 924–33 (Fla. 2008))).

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

111. See *Denno*, *supra* note 89, at tbl.B.

112. See *Jackson*, 656 F.3d at 164 (noting that "each court to consider this issue has uniformly held that the use of pentobarbital in lieu of sodium thiopental is constitutional"); *Creech v. Reinke*, No. 1:12-cv-00173-EJL, 2012 WL 1995085, at *16–24 (D. Idaho June 4, 2012) (upholding a one-drug lethal injection protocol using pentobarbital); *Beaty v. Brewer*, 791 F. Supp. 2d 678, 681–86 (D. Ariz. 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); *Valle v. State*, 70 So. 3d 530, 538–53 (Fla. 2011) (upholding the use of pentobarbital in the state's three-drug lethal injection method); see also *DeYoung v. Owens*, 646 F.3d 1319, 1327 (11th Cir. 2011) (holding that use of pentobarbital does not violate the Eighth Amendment); *Powell v. Thomas*, 641 F.3d 1255, 1257–58 (11th Cir. 2011) (approving the substitution of pentobarbital for sodium thiopental).

113. See *infra* notes 181–82 and accompanying text.

114. See *Denno*, *supra* note 89, at 8.

unconstitutional harm.¹¹⁵ By July 23, 2013, such determinations would no longer be viable. On that date, 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

d. Failure to Protect. Not surprisingly, courts have relied on *Baze* for challenges apart from problems associated with lethal injection. Altogether, thirty-three 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 violence, assault, or abuse; however, some cases discuss different settings in which a substantial risk first must be established.¹²¹ Although such a use of *Baze* is unsurprising 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

115. See *Towery v. Brewer*, No. CV-12-245-PHX-NVW, 2012 WL 592749, at *15 (D. Ariz. Feb. 23, 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); *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 a substantial risk of serious harm”).

116. See *Cook v. FDA*, 733 F.3d 1, 12 (D.C. Cir. 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 creates an unnecessary risk of improper anesthetization).

117. See *Denno*, *supra* note 89, at tbl.A.

118. *Wilson v. Ryker*, 451 F. App’x 588, 589 (7th Cir. 2011).

119. *Baze v. Rees*, 553 U.S. 35, 50 (2008) (quoting *Louisiana ex rel. Francis v. Resweber*, 329 U.S. 459, 463 (1947)) (internal quotation marks omitted).

120. See, e.g., *Porter v. Cash*, No. CV 11-10308-DMG (AGR), 2012 WL 5308369, at *3 (C.D. Cal. Sept. 20, 2012); *Mitchell v. Cnty. of San Bernardino*, No. CV 09-5531-SJO (AGR), 2011 WL 4801890, at *5 (C.D. Cal. June 13, 2011); *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, 252–61 (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.

2. Concurring and Dissenting Opinions

Over one-fifth of the 333 cases cited opinions other than the *Baze* plurality.¹²³ These seventy-two cases primarily included references to Justice Thomas's and Justice Stevens's concurrences as well as Justice Ginsburg's dissent, nearly in equal number.¹²⁴ In total, thirty-four cases cited to Justice Thomas's concurrence,¹²⁵ which argued that inmates should be required to show that a lethal injection protocol is "deliberately designed to inflict pain" to establish an Eighth Amendment violation.¹²⁶ 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's more rigorous intent-based standard.¹²⁷ A disproportionate number of these cases (sixteen in total) originated in Florida and frequently cited the following quote from the Florida Supreme Court:¹²⁸ "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)."¹²⁹ Although seemingly dicta, the repeated 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 (thirty-three in total) cited Justice Stevens's concurrence,¹³⁰ a particularly noteworthy opinion because it was the first time he voiced his general opposition to the death penalty.¹³¹ 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.¹³² In my study, some cases cited Justice Stevens's commentary

123. See Denno, *supra* note 89, at 18.

124. See *id.* at tbl.A.

125. See *id.*

126. *Baze v. Rees*, 553 U.S. 35, 94 (2008) (Thomas, J., concurring).

127. 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 which does not involve the *purposeful* infliction of 'pain and suffering beyond that necessary to cause death'" (emphasis added) (quoting *Baze*, 553 U.S. at 96 (Thomas, J., concurring))).

128. See Denno, *supra* note 89, at 18.

129. *Ventura v. State*, 2 So. 3d 194, 200 (Fla. 2009) (discussing the variety of opinions in *Baze* and noting that it believes Florida's protocol would meet all the risk-based standards mentioned by the *Baze* Court).

130. See Denno, *supra* note 89, at tbl.A.

131. See *Baze*, 553 U.S. at 78–86 (Stevens, J., concurring).

132. 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 an 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

regarding the risk of error in capital cases,¹³³ whereas other cases cited his reservations regarding the value of the death penalty.¹³⁴

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.¹³⁵ "[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."¹³⁶ The thirty-six cases in my study that cited to Justice Ginsburg's dissent stressed the safeguards that states had implemented in their lethal injection protocols.¹³⁷ The majority of states 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.¹³⁸

3. Eighth Amendment Standard

Altogether, fifty-four cases cited *Baze* in reference to the Eighth Amendment or to affirm the constitutionality of lethal injection by the Court's holding that injection does not constitute cruel and unusual punishment.¹³⁹ Some cases,

contributions to any discernible social or public purposes.'" *Id.* at 86 (quoting *Furman v. Georgia*, 408 U.S. 238, 312 (1972) (White, J., concurring)).

133. *See In re Noling*, 651 F.3d 573, 576 (6th Cir. 2011) ("In *Baze v. Rees*, Justice Stevens 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." (citation omitted)); *People v. Runge*, 917 N.E.2d 940, 998 (Ill. 2009) (Burke, J., dissenting) (noting that the "risk of error in capital cases may be greater than in other cases because the facts are often so disturbing" (quoting *Baze*, 553 U.S. at 84 (Stevens, J., concurring)) (internal quotation marks omitted)).

134. *See Jackson v. Danberg*, 594 F.3d 210, 218 (3d Cir. 2010) (noting 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" (quoting *Baze*, 553 U.S. at 86 (Stevens, J., concurring)) (internal quotation mark omitted)); *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's "general disagreement with . . . the death penalty").

135. *See Baze*, 553 U.S. at 119–21 (Ginsburg, J., dissenting).

136. *Id.* at 117.

137. *See Denno*, *supra* note 89, at tbl.A.

138. *See Henyard v. Sec'y, Dep't of Corr.*, 543 F.3d 644, 648 (11th Cir. 2008) (citing to the finding by Justice Ginsburg that revisions to Florida's lethal injection protocols provide additional safeguards in comparison to Kentucky's protocols); *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.").

139. *See Denno*, *supra* note 89, at tbl.A; *see, e.g., 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"); *Alba v. Quarterman*, 621 F. Supp. 2d 396, 432 (E.D. Tex. 2008) (citing *Baze* to state that lethal injection is a constitutionally permissible form of execution); *Fields v. Commonwealth*, 274 S.W.3d 375, 420 (Ky. 2008) (citing *Baze* to support the statement that "[l]ethal injection is not cruel

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.¹⁴⁰ Other cases focused more specifically on lethal injection. *Broom v. Strickland*, 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

B. POST-BAZE LITIGATION AND RISK

On June 10, 2008, less than two months after *Baze* was decided, an Ohio state court ruled in *State v. Rivera* 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.¹⁴² 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*.¹⁴³ 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."¹⁴⁴ This recognition prompted the court to hold that the state's lethal injection protocol should use only "a lethal injection of a single, anesthetic drug."¹⁴⁵

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.¹⁴⁶ The *Rivera* court also recognized "[c]ircumstantial evidence . . . that some condemned prisoners have

and unusual punishment"); see also *Thompson v. Bell*, 580 F.3d 423, 448 (6th Cir. 2009) (Suhrheinrich, J., concurring); *Scott v. Houk*, No. 4:07-CV-0753, 2011 WL 5838195, at *45–46 (N.D. Ohio Nov. 18, 2011); *Riley v. McDaniel*, No. 3:01-cv-0096-RCJ-VPC, 2010 WL 3786070, at *59 (D. Nev. Sept. 20, 2010).

140. See *Trinidad y Garcia v. Thomas*, 683 F.3d 952, 964 (9th Cir. 2012) (citing *Baze* in support of the statement that "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" (quoting *Neely v. Henkel*, 180 U.S. 109, 122–23 (1901))).

141. No. 2:09-cv-823, 2010 WL 3447741, at *2 (S.D. Ohio Aug. 27, 2010) (stating that "a series of abortive execution attempts could potentially indeed present an unconstitutional violation").

142. No. 04CR065940, 2008 WL 2784679, at *1, *9 (Ohio Ct. Com. Pl. June 10, 2008).

143. See *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*, 35 *FORDHAM URB. L.J.* 957, 958–59 (2008).

144. *Rivera*, 2008 WL 2784679, at *6.

145. *Id.* at *9.

146. See *id.* at *3–4.

suffered a painful death, due to a flawed lethal injection.”¹⁴⁷

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.”¹⁴⁸ In contrast, “the Kentucky lethal injection statute has no mandate that an execution be painless.”¹⁴⁹ 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 executions.”¹⁵⁰

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.¹⁵¹ 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.”¹⁵² With *Rivera*, the “uniqueness” claim from *Baze* would no longer be accurate. By breaking away from the three-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*¹⁵³ and earlier cases,¹⁵⁴ *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 administer.¹⁵⁵ This solution was aided by the *Rivera* court's focus on the constitutional

147. *Id.* at *4.

148. OHIO REV. CODE ANN. § 2949.22(A) (LexisNexis 2006). 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*, 2008 WL 2784679, 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 held that “the words, ‘or combination of drugs,’ may be severed” from the Ohio statute in light of the court's ruling that only one anesthetic drug be employed. *Id.* at *9.

149. *Rivera*, 2008 WL 2784679, at *7 (alteration in original).

150. *Id.* at *9 (quoting *Baze v. Rees*, 553 U.S. 35, 47 (2008) (plurality opinion)).

151. See Adam Liptak & Adam B. Ellick, *Judge Orders Ohio to Alter Its Method of Execution*, N.Y. TIMES, June 11, 2008, <http://www.nytimes.com/2008/06/11/us/11death.html>.

152. *Baze*, 553 U.S. at 41 (plurality opinion).

153. 415 F. Supp. 2d 1037 (N.D. Cal. 2006), *aff'd per curiam*, 438 F.3d 926 (9th Cir. 2006).

154. See Denno, *Lethal Injection Quandary*, *supra* note 1, at 102–17.

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

viability of the execution method itself and not on 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.¹⁵⁶ 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*.¹⁵⁷ *Baze* was supposed to be the Supreme Court's effort to end the lethal injection story, not push it full throttle.

The next chapter after *Baze* 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.¹⁵⁸ 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 egregious example.¹⁵⁹

Although the Ohio Facility was stung by its experiences with the three-drug

156. See Atul Gawande, *When Law and Ethics Collide—Why Physicians Participate in Executions*, 354 NEW ENG. J. MED. 1221, 1229 (2006).

157. See Denno, *supra* note 18, at 202–04.

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

159. 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. See *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. See *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, even though he would be the first inmate ever to survive a lethal injection procedure. See *id.* at *1, *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. 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. See *id.* 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. See *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. See *id.* Ultimately, the execution was halted, and Broom remains alive, awaiting the possibility of a second execution attempt. See Josh Sanburn, *Ohio's Grisly Execution History*, TIME (Jan. 17, 2014), <http://nation.time.com/2014/01/17/ohios-grisly-execution-history/>.

procedure, officials were concerned about implementing a one-drug procedure that had yet to be used on anyone, anywhere.¹⁶⁰ 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.¹⁶¹ 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.¹⁶²

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 of confusion, disorientation, and intense psychological anguish and torment. The nausea-evoking effect of hydromorphone could cause the prisoner to vomit, before or after drifting into unconsciousness.¹⁶³ Ohio officials warned journalists witnessing the execution that Biros could end up vomiting and convulsing if in fact the backup plan went into effect.¹⁶⁴ Although Ohio's own lethal injection statute requires that death be quick and painless, expert testimony suggests that Plan B is probably the slowest lethal injection method yet proposed in the United States.¹⁶⁵ Likewise, Plan B directly contravenes Ohio's veterinary euthanasia laws because the particular drugs and intramuscular method are all prohibited for animals (the Ohio statute forbids any euthanasia for animals by intravenous drugs other than pentobarbital).¹⁶⁶

Plan B still remains in effect in Ohio. Regardless, Kenneth Biros's 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.¹⁶⁷

Ohio's move to a single-drug protocol served as an impetus for other states to also make the switch, irrespective of Ohio's difficulties with Biros's execution and the state's unique statute. For over a century, states have closely followed

160. 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).

161. See *Cooley v. Strickland*, 604 F.3d 939, 942–43 (6th Cir. 2010).

162. See de Vogue & Powell, *supra* note 160.

163. See *Cooley*, 604 F.3d at 943.

164. See Deborah W. Denno, *Ohio's Perverse First Place*, HUFFINGTON POST (Dec. 9, 2009), http://www.huffingtonpost.com/deborah-w-denno/ohios-perverse-first-plac_b_385808.html; Andrew Welsh-Huggins, *States: Death-Penalty Drug Scramble, Higher Cost*, BLOOMBERG BUS. WEEK (July 9, 2011, 2:14 PM), <http://www.businessweek.com/ap/financialnews/D9OC9L100.htm>.

165. See *Cooley v. Strickland*, No. 2:04-cv-1156, 2009 U.S. Dist. LEXIS 122025, at *225–26 (S.D. Ohio Dec. 7, 2009) (testimony of Mark Heath, M.D.).

166. See OHIO REV. CODE ANN. § 4729.532 (LexisNexis 2013).

167. See Aaron Marshall, *Kenneth Biros Becomes First Inmate Executed Using Single-Drug Method*, CLEVELAND.COM (Dec. 8, 2009, 6:10 PM), http://blog.cleveland.com/metro/2009/12/biros_becomes_first_inmate_exe.html.

Chart 3

Changes in State Lethal Injection Protocols: 2009–2013*

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.

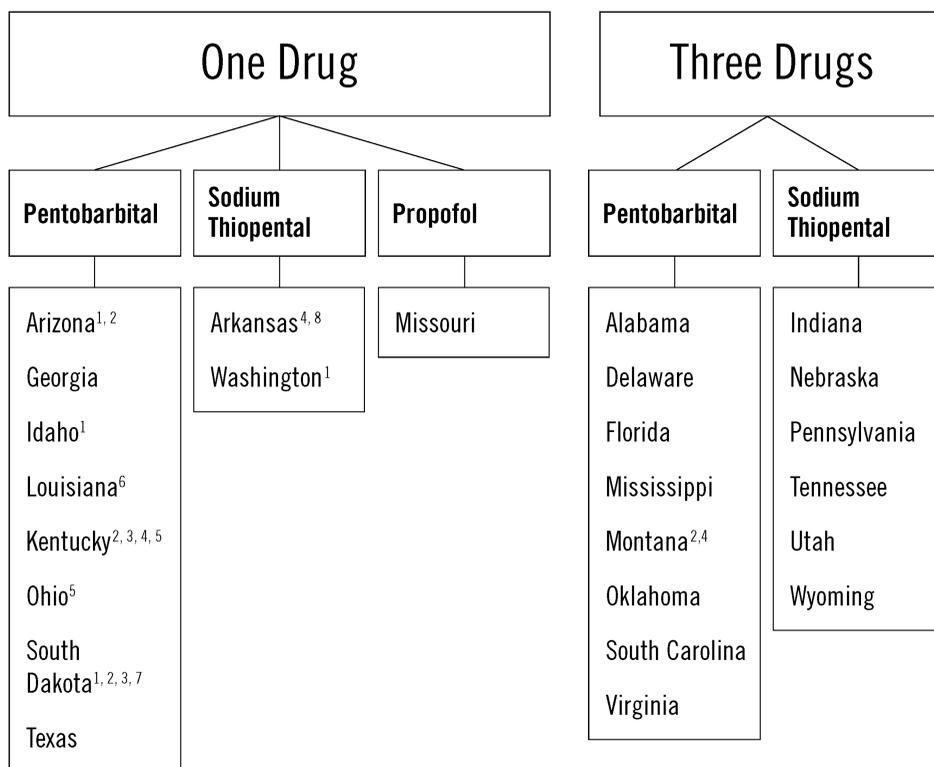
⁸ Considering other drugs.

* Information for this chart reflects trends up to August 1, 2013, and comes from the following sources: *State by State Lethal Injection*, DEATH PENALTY INFO. CENTER, <http://www.deathpenalty.org/state-lethal-injection> (last visited Jan. 31, 2014); Death Penalty Clinic, Univ. of Cal., Berkeley, Sch. of Law, *Execution Protocol Information*, LETHALINJECTION.ORG, <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html> (last visited Aug 1, 2013).

the execution strategies of other states,¹⁶⁸ and Ohio's change would be no exception. The key switch from the past was the greater rapidity and extent to

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

Chart 4

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 August 1, 2013 and comes from the following sources: *State by State Lethal Injection*, DEATH PENALTY INFO. CENTER, <http://www.deathpenalty.org/state-lethal-injection> (last visited Jan. 31, 2014); Death Penalty Clinic, Univ. of Cal., Berkeley, Sch. of Law, *Execution Protocol Information*, LETHALINJECTION.ORG, <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html> (last visited Aug. 1, 2013).

which states would follow Ohio's decision to use only sodium thiopental. As Charts 3 and 4 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 five years (2009–2013).¹⁶⁹ 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 in 2011 and then by five states in 2012 (Arizona, Georgia,

169. See *supra* Charts 3 & 4.

Idaho, Missouri, and Texas).¹⁷⁰ So far, three states have switched from three drugs to one in 2013 (Arkansas, Kentucky, and Louisiana).¹⁷¹

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*.¹⁷² 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).¹⁷³ At the same time, death by sodium thiopental alone typically takes longer, and the procedure is less predictable because it is far less known.¹⁷⁴ 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 its 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 2012.¹⁷⁵ Yet death-penalty states would soon encounter an obstacle that the switch from three drugs to one drug would not alleviate: a nationwide dearth of lethal injection drugs. More than any legal argument, this practical challenge—one that the *Baze* Court could not have anticipated—would threaten the continued use of lethal injection as this country's primary method of execution.

III. POST-BAZE DRUG SHORTAGES

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.¹⁷⁶ In late 2010, the British government announced plans to create an export restriction that would ban the export of sodium thiopental to the United States after learning that the drug would be solely used for executions.¹⁷⁷ 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

170. See *supra* Charts 3 & 4.

171. See *supra* Charts 3 & 4.

172. As Franklin Circuit Judge Phillip Shepherd postulated, by moving to a one-drug protocol in Kentucky, "any claims of cruel and unusual punishment by the inmates 'will be rendered moot.'" *Ky. to Change Execution Method from 3 Drugs*, FOX NEWS (June 1, 2012), <http://www.foxnews.com/us/2012/05/31/ky-to-change-execution-method-from-3-drugs/>.

173. See *supra* note 155.

174. See *supra* note 155.

175. *Compare Execution List 2013*, DEATH PENALTY INFO. CENTER, <http://www.deathpenaltyinfo.org/execution-list-2013> (last visited Feb. 17, 2014), with *Execution List 2012*, DEATH PENALTY INFO. CENTER, <http://www.deathpenaltyinfo.org/execution-list-2012> (last visited Feb. 17, 2014).

176. See *Cook v. FDA*, 733 F.3d 1, 4 (D.C. Cir. 2013) ("In 2009 the last domestic manufacturer of thiopental stopped making it."); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-14-194, *supra* note 26, at 14 fig.4, 21; Kevin Sack, *Shortage of Widely Used Anesthetics Is Delaying Executions in Some States*, N.Y. TIMES, Sept. 30, 2010, <http://www.nytimes.com/2010/09/30/us/30drug.html>.

177. See Dominic Casciani, *US Lethal Injection Drug Faces UK Export Restrictions*, BBC NEWS (Nov. 29, 2010, 13:47), <http://www.bbc.co.uk/news/uk-11865881>.

prevent the drug from “being diverted to departments of corrections for use in capital punishment procedures.”¹⁷⁸ Unwilling to risk potential liability, in January 2011, Hospira stopped manufacturing sodium thiopental entirely.¹⁷⁹ Europe’s prohibition of the death penalty had become an American problem.¹⁸⁰

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.¹⁸¹ Until recently, for example, the London wholesaler Dream Pharma Ltd. purchased sodium thiopental manufactured in Austria and then shipped it to various states in the United States for use in lethal injections.¹⁸² Such practices raised concerns that prisoners may be injected with drugs that are impure, expired, unsafe, or ineffective.¹⁸³ It bears reminding that if sodium thiopental is ineffective and does not render the inmate unconscious, that inmate is tortured by the injection of the second and third drugs.¹⁸⁴

Many death-penalty states experienced an onslaught of litigation challenging the use of foreign-sourced sodium thiopental in lethal injection proceedings.¹⁸⁵ 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 supplies.¹⁸⁶ But the most striking legal development occurred in

178. See Press Release, Hospira, Inc., Hospira Statement Regarding Pentothal™ (Sodium Thiopental) Market Exit (Jan. 21, 2011), available at <http://phx.corporate-ir.net/phoenix.zhtml?c=175550&p=irol-newsArticle&ID=1518610&highlight>.

179. See *id.*; Erik Eckholm & Katie Zezima, *States Face Shortage of Key Lethal Injection Drug*, N.Y. TIMES, Jan. 22, 2011, www.nytimes.com/2011/01/22/us/22lethal.html.

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

181. See “*Lethal Injection Scramble*” Map from ACLU of Northern California, DEATH PENALTY INFO. CENTER, <http://www.deathpenaltyinfo.org/lethal-injection-moratorium-executions-ends-after-supreme-court-decision> (follow “‘Lethal Injection Scramble’ map from ACLU of Northern California” hyperlink); see also Press Release, ACLU of N. Cal., CDCR Documents Reveal “Secret Mission” to Acquire Lethal Injection Drug (Dec. 10, 2010), available at <https://www.aclunc.org/news/cdcr-documents-reveal-secret-mission-acquire-lethal-injection-drug> (noting that documents from the California Department of Corrections and Rehabilitation revealed “a global search for [lethal injection] drugs in places as far-flung as Pakistan”).

182. See “*Lethal Injection Scramble*” Map from ACLU of Northern California, *supra* note 181.

183. See *Beaty v. FDA*, 853 F. Supp. 2d 30, 36–37 (D.D.C. 2012).

184. See *supra* note 10 and accompanying text.

185. See *Denno*, *supra* note 89, at tbl.B.

186. See *State by State Lethal Injection*, DEATH PENALTY INFO. CENTER, <http://www.deathpenaltyinfo.org/state-lethal-injection> (last visited Feb. 17, 2014). Arizona, Arkansas, California, Georgia, Nebraska, South Carolina, South Dakota, and Tennessee received letters from the FDA in April 2012 requesting the relinquishment of foreign-sourced sodium thiopental, in accordance with the U.S. district court’s ruling in *Beaty v. FDA*. See *id.* Alabama, Georgia, Kentucky, South Carolina, and Tennessee had foreign-sourced sodium thiopental seized by the DEA in March or April 2011. See *id.* Arkansas turned over its foreign-sourced sodium thiopental to the DEA in July 2011. See *id.* Both *Beaty* and *Cook* list Arizona, Arkansas, California, Georgia, South Carolina, and Tennessee as states that received ship-

March 2012. In *Beatty v. FDA*, the U.S. District Court for the District of Columbia ultimately banned the importation of sodium thiopental, finding that the 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.”¹⁸⁷ On July 23, 2013, the D.C. Circuit affirmed *Beatty* with an unambiguous holding in *Cook v. FDA*:

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.¹⁸⁸

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 a choice between the two drugs.¹⁸⁹ Indeed, in 2012 and 2013, pentobarbital was the primary drug employed in executions by lethal injection.¹⁹⁰ 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 2010¹⁹¹ and in a one-drug execution in Ohio the following year.¹⁹² As Charts 3 and 4 of this Article show, an unprecedented number of states—thirteen in total, including Ohio—switched from sodium thiopental to pentobarbital in 2011 alone.¹⁹³ Only Kentucky and Louisiana changed thereafter—both in 2013.¹⁹⁴

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.¹⁹⁵ Much of the

ments of sodium thiopental from the United Kingdom pharmaceutical company, Dream Pharma Ltd. See *Cook v. FDA*, 733 F.3d 1, 4 (D.C. Cir. 2013); *Beatty*, 853 F. Supp. 2d at 34–35. For further discussion of these cases, see *infra* notes 187–88 and accompanying text.

187. 853 F. Supp. 2d at 32, 37, 41–43.

188. 733 F.3d at 12. 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. See *id.*

189. See *supra* Charts 3 & 4.

190. See *Execution List 2012*, *supra* note 175; *Execution List 2013*, *supra* note 175.

191. See Robert Boczkiewicz, *Appeals Court Rejects Convicted Killer’s Challenge to Oklahoma Execution Method*, NEWSOK (Dec. 15, 2010), <http://newsok.com/court-rejects-convicted-killers-challenge-to-oklahoma-execution-method/article/3523770>.

192. See Mears, *supra* note 29; Rob Stein, *Ohio Executes Inmate Using New, Single-Drug Method for Death Penalty*, WASH. POST (March 11, 2011), http://www.washingtonpost.com/wp-dyn/content/article/2011/03/10/AR2011031006250_pf.html.

193. See *supra* Charts 3 & 4.

194. See *supra* Charts 3 & 4.

195. See, e.g., *Arthur v. Thomas*, 674 F.3d 1257, 1259 (11th Cir. 2012); *Jackson v. Danberg*, 656 F.3d 157, 162 (3d Cir. 2011); *DeYoung v. Owens*, 646 F.3d 1319, 1322 (11th Cir. 2011); *Powell v.*

litigation involves Eighth Amendment Cruel and Unusual Punishment challenges¹⁹⁶ and is based in part on the sparse data available regarding the drug's effects on humans.¹⁹⁷ Of the first eight documented pentobarbital challenges, seven focused on the lack of substantial data concerning the efficacy of pentobarbital as an execution drug—that is, whether or not it is actually successful in anesthetizing the prisoner.¹⁹⁸ 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 for reasons related to politics, if not efficacy.¹⁹⁹

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

Thomas, 643 F.3d 1300, 1301–02 (11th Cir. 2011); *Pavatt v. Jones*, 627 F.3d 1336, 1337–38 (10th Cir. 2010); *Valle v. State*, 70 So. 3d 530, 538 (Fla. 2011); Verified Complaint at 3, *Blankenship v. Owens*, No. 2011cv202236 (Ga. Super. Ct. June 20, 2011); *see also* cases cited *supra* note 112; David Beasley, *Georgia Executes Man for 1978 Rape and Murder*, REUTERS (June 23, 2011, 9:11 PM), <http://www.reuters.com/article/2011/06/24/us-execution-georgia-idUSTRE75N06P20110624> (“The Georgia Supreme Court late Thursday unanimously rejected Blankenship’s last-minute request for a stay, including his claim that using pentobarbital in the execution would cause undue pain and suffering.”).

196. *See, e.g., Arthur*, 674 F.3d at 1259 (noting plaintiff’s allegations 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).

197. *See id.* at 1266–67 (Hull, J., dissenting) (quoting anesthesiologists’ declarations that pentobarbital “is not approved by the FDA as an anesthesia induction agent,” that “there is no scientific literature establishing the anesthetic dose of pentobarbital,” and that “[t]he switch to pentobarbital, for which there is no clinical knowledge regarding its effects on human beings when rapidly administered in high dosages to a conscious person, combined with the use of pancuronium bromide and potassium chloride, confers a substantial risk of an excruciating and agonizing death process” (alteration in original) (internal quotation marks omitted)).

198. *See Arthur*, 674 F.3d at 1259 (“Arthur alleges 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.”); *Jackson*, 656 F.3d at 162–63 (finding that the district court “did not abuse its discretion in denying Plaintiffs’ motion for a stay” based on Plaintiffs’ allegations that the use of pentobarbital violates the Eighth Amendment); *DeYoung*, 646 F.3d at 1327 (“DeYoung has wholly failed to show that pentobarbital, once fully administered and allowed to act, is ineffective as an anesthetic.”); *Powell*, 643 F.3d at 1304 (rejecting plaintiff’s argument that the “change from sodium thiopental to pentobarbital[] is a substantial or significant change in the lethal injection protocol”); *Pavatt*, 627 F.3d at 1339–40 (upholding the district court’s denial of a stay of execution based on inmate’s failure to “establish a substantial likelihood of success on the merits of his Eighth Amendment challenge to the . . . revised protocol” calling for the use of pentobarbital); *Valle*, 70 So. 3d at 538 (rejecting plaintiff’s argument that the “use [of] pentobarbital constitutes cruel and unusual punishment because as a result of the substitution, he may remain conscious after being injected with pentobarbital, thereby subjecting him to significant pain during the administration of the final two drugs”); Verified Complaint, *supra* note 195, at 3 (“The administration of these drugs, particularly including Pentobarbital, a drug which has not been tested for induction of anesthetic coma in humans, by unqualified and untrained individuals creates a substantial risk of a botched and inhumane execution.” (footnote omitted)).

199. *See Valle*, 70 So. 3d at 542.

Danish manufacturer H. Lundbeck A/S (Lundbeck) worked vehemently to prevent the use of its pentobarbital—which it sold for treatment of seizures—in executions.²⁰⁰ 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.”²⁰¹ In December 2011, Lundbeck sold its pentobarbital rights to the Illinois pharmaceutical company Akorn, Inc. but first insisted upon an agreement that the drug would not be sold for the purpose of executing inmates.²⁰² Although it is not entirely clear how much pentobarbital is still available, ultimately it will either run out or expire.²⁰³

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.²⁰⁴ Regardless, the first three-drug execution using pentobarbital in Georgia—that of Roy Blankenship—was so seriously botched²⁰⁵ that the next pentobarbital execution in Georgia—that of Andrew Grant DeYoung—was videotaped as a safeguard.²⁰⁶ Notably, the only other videotaped execution in this 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.²⁰⁷

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 host of new

200. See Press Release, H. Lundbeck A/S, Lundbeck Overhauls Pentobarbital Distribution Program to Restrict Misuse (July 1, 2011), available at <http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=605775>; Letter from Staffan Schüberg, President, H. Lundbeck A/S, to Gary C. Mohr, Dir., Dep’t of Rehab. and Corr., Columbus, Ohio (Jan. 26, 2011), available at <http://www.deathpenaltyinfo.org/documents/LundbeckLethInj.pdf>; *Activities: Human Rights*, LUNDBECK, <http://www.lundbeck.com/global/corporate-responsib/report/activities/human-rights> (last updated Feb. 6, 2014).

201. Kitamura & Narayan, *supra* note 180; see David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions*, N.Y. TIMES (July 1, 2011), <http://www.nytimes.com/2011/07/02/world/europe/02execute.html>; Press Release, H. Lundbeck A/S, *supra* note 200.

202. See Leonard, *supra* note 28; *Lethal Injection*, DEATH PENALTY INFO. CENTER, <http://www.deathpenaltyinfo.org/lethal-injection-moratorium-executions-ends-after-supreme-court-decision> (last visited Feb. 18, 2014).

203. See Leonard, *supra* note 28 (“[T]hough some states may soon run out [of pentobarbital], . . . the drug could expire. Like most pharmaceuticals, pentobarbital has an expiration date of about 18 months.”).

204. See *supra* notes 195–99 and accompanying text.

205. 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, 10:53 EST), <http://www.dailymail.co.uk/news/article-2009873/He-suffered-greatly-Medical-expert-describes-prisoner-thrashed-desperately-botched-execution-new-drug.html>.

206. See Rhonda Cook, *DeYoung Executed with Videographer Documenting His Death*, ATLANTA J. CONST. (July 22, 2011, 7:46 AM), <http://www.ajc.com/news/news/local/deyoung-executed-with-videographer-documenting-his/nQJq5/>; see also Deborah W. Denno, *Should Executions Be Televised?*, ENCYCLOPAEDIA BRITANNICA BLOG (Aug. 16, 2011), <http://www.britannica.com/blogs/2011/08/should-executions-be-televised/> (discussing the history of televised executions).

207. See Dan Morain, *Witness to the Execution: A Macabre, Surreal Event*, L.A. TIMES (Apr. 22, 1992), http://articles.latimes.com/1992-04-22/news/mn-509_1_gas-chamber.

problems. In May 2012, for example, Missouri amended its lethal injection protocol to permit the use of propofol in one-drug executions.²⁰⁸ Less than a month after the drug's adoption, concerns were raised about its implementation²⁰⁹ and on July 11, 2012, the United Kingdom announced its ban on the exportation of propofol for execution purposes.²¹⁰ 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,²¹¹ thereby following in the footsteps of restrictions on the sale of thiopental and pentobarbital.²¹² Despite the drug's unavailability, Missouri's lethal injection protocol included the use of propofol until October 2013, although it was never used in a lethal injection procedure.²¹³ No state other than Missouri has indicated plans to adopt the drug.

Meanwhile, in May 2013, yet another drug company withdrew from the lethal injection market. Hikma, a British 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 after Arkansas declared its intent to be the first state to employ phenobarbital for lethal injections²¹⁴ in lieu of the other two execution drugs, pentobarbital or sodium thiopental, which most states currently use.

Phenobarbital has been prescribed to treat seizures but presumably has never been used for executions in the United States, and some experts have expressed their concern that it could have dire and unpredictable effects on inmates.²¹⁵ According to the Arkansas Department of Corrections, it selected phenobarbital after attorneys for several death-row inmates mentioned in a lawsuit that it

208. See *Lethal Injection: Missouri Intends to Use Propofol in One-Drug Lethal Injection*, DEATH PENALTY INFO. CENTER, <http://www.deathpenaltyinfo.org/lethal-injection-missouri-intends-use-propofol-one-drug-lethal-injection> (last visited Feb. 18, 2014).

209. See Jim Salter, *Missouri Opts for Untested Drug for Executions*, ASSOCIATED PRESS, May 24, 2012, available at <http://bigstory.ap.org/content/missouri-opts-untested-drug-executions-1> ("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.").

210. See Juliette Jowit, *UK to Ban Export of Drug Approved for Use in US Executions*, GUARDIAN (July 10, 2012, 15:00 EDT), <http://www.guardian.co.uk/world/2012/jul/10/uk-ban-export-drug-us-executions>.

211. See Letter from Scott Meacham, Exec. Vice President & Chief Commercial Officer, Fresenius Kabi USA, LLC, to Healthcare Provider (Aug. 28, 2012), available at <http://deathpenaltyinfo.org/documents/FreseniusPropofolStatement.pdf>; *Another Manufacturer Blocks Propofol for Execution Use*, USA TODAY (Sept. 27, 2012, 3:53 PM), <http://www.usatoday.com/story/money/business/2012/09/27/manufacturer-blocks-propofol-execution-use/1598109/>.

212. See *supra* notes 177–80 and accompanying text.

213. See *State by State Lethal Injection*, *supra* note 186.

214. See Press Release, Hikma Pharm. PLC, Hikma Pharmaceuticals Strongly Objects to the Use of Its Products in Capital Punishment (May 15, 2013), available at <http://www.hikma.com/en/media-center/news-and-press-releases/all-news/2013/15-05-2013.aspx>; Jeannie Nuss, *Arkansas Turns to Different Lethal Injection Drug*, YAHOO NEWS (Apr. 19, 2013, 7:18 PM), <http://news.yahoo.com/arkansas-turns-different-lethal-injection-drug-214639034.html>.

215. See Press Release, Hikma Pharm. PLC, *supra* note 214.

might be an available drug.²¹⁶ The Department has revealed little other information about the drug selection process apart from explaining that the agency also consulted other medical sources, which it did not identify.²¹⁷ In July 2013, Arkansas still did not have a valid execution statute,²¹⁸ and the Department of Corrections had changed its mind about incorporating phenobarbital because it could no longer acquire sufficient quantities of the drug.²¹⁹ Indeed, death-penalty states are becoming increasingly desperate in their efforts to procure lethal injection drugs, and this practical challenge has subsumed many of the issues addressed by the *Baze* Court.²²⁰

IV. THE HIGH-RISK ROLE OF COMPOUNDING PHARMACIES

Given the impact of drug shortages on lethal injection procedures,²²¹ it should come as no surprise that states are seeking help internally from local compounding pharmacies for the production of lethal injection drugs.²²² Yet recent discoveries of subpar conditions and contaminated drugs demonstrate the risk posed by compounding pharmacies. This risk provides states with an incentive to keep their lethal injection protocols secret because of the foreseeable challenges that they will face should it become known that the drugs are coming from pharmacies of this kind. However, the nondisclosure of a lethal injection protocol renders *Baze* moot because it becomes impossible to subject that protocol to all of the requirements of *Baze*. Further, compounding pharmacies by their very nature run counter to the requirements of *Baze* because the practices they engage in already pose a substantial risk.

Because of the heightened risk posed by compounding pharmacies, states face a quandary: states use compounded drugs because they could not carry out executions otherwise; yet they also recognize the risks associated with these drugs, as well as the potential for legal challenges. As a result, states default to secrecy regarding their protocols.

Yet there are also a number of reasons why states may view compounding pharmacies as better suited than large-scale drug manufacturers for the job of executing inmates. Most apparent is the reason discussed in Part III: large-scale

216. See Nuss, *supra* note 214.

217. See *id.*

218. See Death Penalty Clinic, Univ. of Cal., Berkeley, Sch. of Law, *Execution Protocol Information*, LETHALINJECTION.ORG, <https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/Litigators/li/protocol.html> (last visited Aug. 1, 2013).

219. See Jeannie Nuss, *Dustin McDaniel: Options 'Limited' for Future of Arkansas Death Penalty*, ARK. BUS. (July 25, 2013, 7:13 AM), <http://www.arkansasbusiness.com/article/93707/dustin-mcdaniel-options-limited-for-future-of-arkansas-death-penalty?page=all>.

220. See *supra* Part III.

221. See Tim Hoover, *Wanted: Execution Drug*, DENVER POST, Mar. 13, 2013, at A4; Ariane de Vogue, *Drug Shortage Disrupts Lethal-Injection Mix*, ABC NEWS (Mar. 16, 2011), <http://abcnews.go.com/Politics/death-penalty-drug-shortage-disrupts-execution-lethal-injection/story?id=13148874>; *State by State Lethal Injection*, *supra* note 186.

222. See *supra* notes 30–33 and accompanying text.

companies that are based in Europe but have subsidiaries in the United States have been strictly prohibited from facilitating the death penalty in the United States in any way.²²³ Even if they were permitted to do so, big pharmaceutical companies would have a much larger reputation at stake when they considered 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.²²⁴ The latter are governed by strict FDA regulations, whereas compounding pharmacies fall under the relatively lax authority of the states. In addition, 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.²²⁵ Yet recent events suggest that this perspective may be outdated. The remainder of Part IV 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.²²⁶ Physicians usually prescribe compounded medications when commercial drugs are unavailable or if the use of existing commercial alternatives is inhibited by allergies.²²⁷ When compounding pharmacies were first conceived in the 1800s, they typically served as the only source of prescription medication.²²⁸ Their prevalence was somewhat diminished during the Industrial Revolution when mass drug-manufacturing companies emerged with a superior capacity to produce generic drugs,²²⁹ but those companies did not dominate the market until around 1950.²³⁰ Today, there are about 56,000 compounding pharmacies in the United States.²³¹ Recent estimates show that approximately “3,000 facilities practice sterile compounding and supply most of the injectable drugs in the United States.”²³²

Compounded drugs are prepared by licensed pharmacists who practice in a licensed compounding pharmacy.²³³ Pharmacist licensure requirements are regu-

223. *See supra* Part III.

224. *See supra* notes 31–33 and accompanying text.

225. *See* Boodoo, *supra* note 32, at 232–34.

226. *See The Special Risks of Pharmacy Compounding*, FDA 1 (Dec. 2012), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM107839.pdf>.

227. *See id.*

228. *See* DAVID L. COWEN & WILLIAM H. HELFAND, *PHARMACY: AN ILLUSTRATED HISTORY* 186 (1990).

229. *See id.*

230. *See* Boodoo, *supra* note 32, at 222.

231. Hinkley, *supra* note 37, at 23.

232. *Id.*

233. *See supra* note 226; *Pharmacy Compounding and the FDA: Questions and Answers*, FDA, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/>

lated by state pharmacy boards²³⁴ and therefore vary by state.²³⁵ However, all pharmacists are required to pass a national, standardized licensure exam, and all states require pharmacists to pass an examination on compounding.²³⁶

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.²³⁷ 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 medications and procedures not approved by the FDA.²³⁸ The lack of FDA regulation is in fact the very root of physician liability. Because compounding pharmacies are not regulated by the FDA,²³⁹ they are “less legally secure than alternatives,” such as regular pharmacies and regulated medications.²⁴⁰ Doctors are required to know whether a given compounding pharmacy meets applicable safety standards.²⁴¹

B. REGULATORY OVERSIGHT OF COMPOUNDING PHARMACIES

In the early 1990s, the FDA became aware of compounding pharmacies whose practices did not align with the traditional individualized, prescription-based schema.²⁴² In response to this discovery, the FDA issued a compliance

ucm339764 (last updated Dec. 2, 2013); see also *Accreditation Council for Pharmacy Educ., Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*, ACCREDITATION COUNCIL FOR PHARMACY EDUCATION app. D, at xxii (2011), <https://www.acpe-accredit.org/pdf/finals2007Guidelines2.0.pdf> (listing compounding as a competency that pharmacy students should achieve before entering advanced pharmacy practice experiences).

234. See *State Regulation of Compounding Pharmacies*, *supra* note 37.

235. See *Licensure Transfer*, NAT'L ASS'N BOARDS PHARMACY, <http://www.nabp.net/programs/licensure/licensure-transfer> (last visited Feb. 18, 2014) (noting that each state board of pharmacy provides its 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).

236. See SCOTT GIBERSON ET AL., *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 in which the pharmacist must complete written math compounding components as well as hands-on drug compounding components. See *License Requirements*, N.Y. ST. EDUC. DEP'T, <http://www.op.nysed.gov/prof/pharm/pharmlic.htm#exam> (last visited July 15, 2013).

237. See Alicia Gallegos, *Physicians Entangled in Tainted Drugs Lawsuits*, AM. MED. NEWS (Feb. 11, 2013), <http://www.amednews.com/article/20130211/profession/130219977/2>.

238. See Jennifer Gudeman et al., *Potential Risks of Pharmacy Compounding*, 13 *DRUGS R&D* 1, 6 (2012), available at <http://link.springer.com/article/10.1007%2Fs40268-013-0005-9>.

239. See *Pharmacy Compounding and the FDA: Questions and Answers*, *supra* note 233 (“Compounded drugs are not FDA-approved. This means that FDA does not verify the quality, safety and effectiveness of compounded drugs.”).

240. Gallegos, *supra* note 237.

241. See *id.*

242. See OFFICE OF REP. EDWARD J. MARKEY, *supra* note 33, at 5.

guide in 1992,²⁴³ 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.²⁴⁴ Five years later, however, the FDA acknowledged continued confusion regarding the actual scope of that authority and worked with the Senate Committee on Labor and Human Resources to design legislation to clarify the matter.²⁴⁵

In 1997, section 127 of the Federal Food and Drug Administration Modernization Act (FDAMA)²⁴⁶ represented the first time that specific federal law governed the practices of compounding pharmacies. With unprecedented clarity, the FDAMA distinguished drug manufacturers from compounding pharmacies and listed nine requirements for classification as a true compounding pharmacy.²⁴⁷ 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 product[s]."²⁴⁸ Pharmacies that met these requirements fell within the scope of regulatory exemptions that the FDA had created for true compounding pharmacies²⁴⁹ and would not be required to register with the FDA, obtain its approval, or comply with any manufacturing practices or safety and efficacy standards.²⁵⁰ 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.²⁵¹

Since the passage of the FDAMA, several lawsuits and FDA actions have triggered reexamination of the legislation but, rather remarkably, no substantial changes have been made.²⁵² Beginning in the early 2000s, however, the FDA sent seventy-five publicly available warning letters to compounding pharmacies in twenty-eight 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 disturb-

243. See FDA, COMPLIANCE POLICY GUIDES MANUAL § 460.200 (2002) (reissuing the compliance guide concerning pharmacy compounding, which was originally issued in 1992).

244. See OFFICE OF REP. EDWARD J. MARKEY, *supra* note 33, at 5.

245. See S. REP. NO. 105-43, at 67 (1997).

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

247. See *id.*

248. *Id.* at 2328-29.

249. See *id.* at 2328-30.

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

251. See H.R. REP. NO. 105-399, at 94 (1997) (Conf. Rep.).

252. See STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 7.

ing issues.²⁵³ As concern grew that some pharmacies were exceeding the scope of traditional compounding practices,²⁵⁴ the FDA issued reports in 2003²⁵⁵ and 2006²⁵⁶ 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.²⁵⁷ 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 pharmacy boards were better equipped to regulate compounding pharmacies than the FDA.²⁵⁸

By October 2012, however, sentiments had shifted. 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 64 people and sickened 751 others across the nation.²⁵⁹ The facility that had compounded the contaminated drug was alleged to be a prime example of a compounding pharmacy operating like a drug-manufacturing company on a larger-than-permissible scale, and the tragic public-health consequences triggered a new receptiveness to increased oversight of compounding pharmacies.²⁶⁰

The FDA inspected thirty-one compounding pharmacies over the next six months and made a series of disquieting discoveries:²⁶¹ “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

253. See *FDA's Electronic Reading Room—Warning Letters*, FDA, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> (search “To find specific Warning Letters” for “Compounding Pharmacy”) (last visited July 19, 2013) (listing states that have received warning letters, including Alabama, Arizona, Arkansas, California, Connecticut, Florida, Idaho, Illinois, Indiana, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, Utah, Virginia, and Wyoming); see also OFFICE OF REP. EDWARD J. MARKEY, *supra* note 33, app. A, at 19 (listing a detailed timeline of media reports and FDA enforcement actions on compounding pharmacies).

254. See JANET HEINRICH, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-04-195T, *PRESCRIPTION DRUGS: STATE AND FEDERAL OVERSIGHT OF DRUG COMPOUNDING BY PHARMACIES* 5 (2003).

255. See *Report: Limited FDA Survey of Compounded Drug Products*, FDA, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155725.htm> (last visited July 19, 2013).

256. See *2006 Limited FDA Survey of Compounded Drug Products*, FDA, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm204237.htm> (last visited July 19, 2013).

257. See STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 8.

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

259. *Multi-State Meningitis Outbreak—Current Case Count*, *supra* note 34. For more information on the meningitis outbreak and the continually developing outcomes, see Gottlieb, *Compounding a Crisis at FDA*, *supra* note 34.

260. See STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 10; see also *supra* note 34 and accompanying text.

261. *Summary: 2013 FDA Pharmacy Inspection Assignment*, *supra* note 35.

non-sterile lab coats.”²⁶² Furthermore, a study released in April 2013 by the U.S. 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.²⁶³ In response to these findings, legislation has been proposed that would require FDA approval of 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,²⁶⁴ state pharmacy boards are working hastily to improve their regulatory systems in response to the negative attention. Proposed state regulations include the following: 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.²⁶⁵

C. PROPOSED BILLS AND NEWLY ADOPTED LEGISLATION

Following the October 2012 fungal meningitis outbreak in Massachusetts, several bills were proposed regarding the regulation of compounding pharmacies.²⁶⁶ 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 definitions of “compounding,” “sterile,” and “non-sterile” practices; guidelines for the frequency, funding, and performance of inspections; and the scope of transparency.²⁶⁷ The bills also create three separate categories of pharmacies, distinguishing among those that

262. Hamburg, *supra* note 35. In her post, Dr. Margaret A. Hamburg, the commissioner of the U.S. Food and Drug Administration (FDA), linked the summary of the 2013 FDA pharmacy inspection assignment to reference the inspections conducted. *See id.* 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.” *Summary: 2013 FDA Pharmacy Inspection Assignment, supra* note 35. 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. *See id.*

263. *See* STAFF OF REP. EDWARD J. MARKEY, *supra* note 31, at 2–3.

264. *See* Pollack, *supra* note 37.

265. *See* Hinkley, *supra* note 37, at 22, 23; *State Regulation of Compounding Pharmacies, supra* note 37.

266. *See State Regulation of Compounding Pharmacies, supra* note 37.

267. *Id.*; *see also* Hinkley, *supra* note 37.

engage in basic compounding and those that engage in high-risk sterile compounding.²⁶⁸

In May 2013, the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP Committee) 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.²⁶⁹ 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.²⁷⁰ The bill then categorizes these large-scale businesses as manufacturers, eliminating their pharmacy status altogether and removing their ability to be licensed as such.²⁷¹ If 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.²⁷² Under this bill, however, compounding manufacturers still would not be subject to the same kinds of regulations as traditional drug manufacturers under FDA authority because, for example, drugs produced by these kinds of manufacturers are by their very nature compounded rather than approved by the FDA.²⁷³ The HELP Committee continues to urge the Senate to bring this legislation to the floor for a vote in order to “prevent further tragedies.”²⁷⁴

On May 23, 2013, a House bill was proposed that also appears to close the gap in FDA authority.²⁷⁵ The Verifying Authority and Legality in Drug Com-

268. 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. See HEINRICH, *supra* note 254, at 3. “[S]terile compounding requires cleaner facilities than nonsterile compounding, as well as specific training for pharmacy personnel and testing of the compounded drug for sterility.” *Id.* 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.

269. See S. 959, 113th Cong. (2013).

270. *Id.* § 2.

271. See Memorandum from the House Comm. on Energy & Commerce Democratic Staff to the House Comm. on Energy & Commerce Democratic Members & Staff, Subcomm. on Health (July 15, 2013) [hereinafter Memorandum from the House Comm.], available at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Memo-Health-Drug-Compounding-Reform-2013-7-15-pdf>.

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

273. See Dye, *supra* note 250; Press Release, U.S. Senate Comm. on Health, Educ., Labor, & Pensions, *supra* note 272.

274. Press Release, Senate Comm. on Health, Educ., Labor, & Pensions, Health Committee Leaders Urge Senate Vote on Compounding Legislation “to Prevent Further Tragedies” (June 9, 2013), available at <http://www.help.senate.gov/newsroom/press/release/?id=c57674f7-e3cf-4d1c-a119-7d3cabd78013>.

275. See Verifying Authority and Legality in Drug (VALID) Compounding Act of 2013, H.R. 2186, 113th Cong. (2013).

pounding Act of 2013 (VALID Compounding Act) 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.²⁷⁶ However, the VALID Compounding Act still acknowledges large-scale compounders as pharmacies, in contrast to the Senate bill.²⁷⁷ 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,”²⁷⁸ whereas other compounding pharmacies must follow different FDA regulations in addition to state regulations.²⁷⁹ Compounding pharmacies would be subject to inspections, reporting, and labeling requirements.²⁸⁰ The VALID Compounding 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 wellbeing.”²⁸¹

The House also proposed a second bill, the Compounding Clarity Act of 2013 (Clarity Act), which is a discussion draft authored by Representative Morgan Griffith.²⁸² Like both the Senate bill and the VALID Compounding 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.²⁸³ Similar to the other bills, the Clarity Act creates a new category for nontraditional compounding pharmacies that do not operate like a traditional, small-scale compounding pharmacy.²⁸⁴

The Clarity Act, however, differs from the other bills regarding 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, whereas the Senate bill has a similar but much more limited provision, particularly with respect to the unlimited-

276. *Id.*

277. See Memorandum from the House Comm., *supra* note 271.

278. As defined by the VALID Compounding Act, “high-risk sterile compounding” means compounding sterile drug products using nonsterile ingredients, nonsterile devices, or nonsterile components.” H.R. 2186 § 2.

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

280. See H.R. 2186.

281. *Id.* § 2.

282. See Compounding Clarity Act, H.R. 3089, 113th Cong. (2013), available at <http://www.gpo.gov/fdsys/pkg/BILLS-113hr3089ih/pdf/BILLS-113hr3089ih.pdf>.

283. See *id.*

284. See *id.*

quantities portion.²⁸⁵ In even sharper contrast, the VALID Compounding Act strictly requires that a drug only be compounded pursuant to a valid and existent prescription, without exception.²⁸⁶ 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 manufacturing compounders must follow.²⁸⁷

On July 16, 2013, the Subcommittee on Health of the U.S. House Energy and Commerce Committee held a hearing to discuss all three proposed bills and examine their differences as well as the general need for stricter compounding regulation.²⁸⁸ At the hearing, a representative from the National Association of Boards of Pharmacy (NABP) testified regarding the proposed compounding regulatory bills.²⁸⁹ 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.²⁹⁰ 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.²⁹¹

Irrespective of these efforts, it was not until November 2013 that the final piece of proposed legislation—the “Drug Quality and Security Act”—was passed by both the House and the Senate.²⁹² Introduced at the end of September, the Act clarifies current federal law about pharmacy compounding so that a uniform, nationwide standard may be applied to compounding pharmacies.²⁹³ Although other bills had proposed it, the Drug Quality and Security Act marks the first piece of passed legislation that separates regulation of traditional small-scale compounding pharmacies from large-scale compounders that operate more like pharmaceutical manufacturers. The Act leaves regulation over traditional compounding pharmacies in the hands of the states, subject to the same FDA Compliance Policy guidance that they have adhered to since 2002. The Act refers to these large-scale compounding manufacturers as outsourcing facilities and provides voluntary federal registration for outsourcing facilities, set to begin in fiscal year 2015. These facilities will be permitted to compound

285. See Memorandum from the House Comm., *supra* note 271.

286. See H.R. 2186.

287. See Memorandum from the House Comm., *supra* note 271.

288. See *Reforming the Drug Compounding Regulatory Framework: Hearing on H.R. 2186, H.R. 3089, and S. 959 Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 113th Cong. (2013).

289. See *id.* (statement of Carmen Catizone, Executive Director, National Association of Boards of Pharmacy).

290. See *id.* at 2, 4.

291. See *id.* at 3.

292. Drug Quality and Security Act of 2013, H.R. 3204, 113th Cong. (2013).

293. See *id.*

bulk quantities of drugs on the FDA's drug shortage list, in addition to other drugs that are on a "clinical need" list to be established by the FDA, without a prescription, as well as distribute these formulations out of state without limitation."²⁹⁴ Registered outsourcing facilities will be subject to FDA oversight similar to that of regular pharmaceutical manufacturers in the United States.²⁹⁵ Under the Act, outsourcing facilities will have to identify themselves for the FDA, enabling the FDA to know what kinds of pharmaceuticals each outsourcing facility is making and to receive event reports about all of the compounded drugs.²⁹⁶ The FDA's regulation powers will also grant them the authority to conduct risk-based inspections.²⁹⁷ Further, certain drugs will be listed as prohibited from being compounded at these facilities.²⁹⁸ The Act has been widely endorsed by many national health organizations²⁹⁹ and by President Obama.³⁰⁰

D. IMPLICATIONS FOR DEATH-PENALTY STATES

Heightened regulation of compounding pharmacies seems inevitable under both state and federal law. This regulation is unlikely to further the goals of death-penalty states for a number of reasons. For example, the proposed VALID Compounding Act prohibits even small, state-regulated pharmacies from producing copies or effective copies of commercial drugs, no matter the quantity and with few exceptions.³⁰¹ This limitation would be problematic for states seeking lethal injection drugs, given that many such drugs are simply high doses of commercially available medication.³⁰² Another notable aspect of general compounding regulation is its strict prescription requirements, which should prohibit a compounding pharmacy from issuing a supply of lethal injection drugs.³⁰³ Instead, a physician must specifically order a prescription for an identified, 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.³⁰⁴ As previously discussed, physicians who write compounded

294. Press Release, Imprimis Pharmaceuticals Inc., Imprimis Optimistic After Congressional Passage of the Drug Quality and Security Act (Nov. 19, 2013), available at <http://online.wsj.com/article/PR-CO-20131119-905263.html?dsk=y>.

295. See H.R. 3204.

296. See *id.*

297. See *id.*

298. See *id.*

299. See Press Release, Ranking Member Lamar Alexander, Senate Comm. on Health, Educ., Labor, and Pensions, HELP Committee Members Call for Senate Passage of Drug Quality and Security Act (Sept. 28, 2013), available at <http://www.help.senate.gov/newsroom/press/release/?id=cce67150-6a23-454e-a60c-09643348c6e0>; Sabrina Tavernise, *Bill on Drug Compounding Clears Congress a Year After a Meningitis Outbreak*, N.Y. TIMES, Nov. 19, 2013, at A15.

300. See Kevin Outterson, *The Drug Quality and Security Act—Mind the Gaps*, 370 NEW ENG. J. MED. 97, 97 (2014).

301. See H.R. 2186.

302. See *State by State Lethal Injection*, *supra* note 186.

303. See *id.*

304. See *supra* note 237 and accompanying text.

drug prescriptions are already placing themselves at considerable risk for liability.³⁰⁵ Physicians who participate in executions also face a broad range of potential repercussions, a topic discussed in depth elsewhere.³⁰⁶ Presumably, writing a prescription would qualify as participation.

Whether under state or federal oversight, compounding pharmacies may soon also face 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.³⁰⁷ Additional complications associated with producing lethal injection drugs, such as the Drug Quality and Security Act's extensive requirements for tracking and tracing drug products, 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. Although the exact specifications are yet to be established by the Secretary of Health and Human Services, it seems that it would be challenging for a correctional facility to maintain the secrecy of its pharmaceutical supplier because it would be up to the pharmacy itself to disclose all of its transaction history. Death-penalty states have a history of gravitating toward secrecy when their execution methods are questioned,³⁰⁸ yet these regulations may hinder them from doing so.

V. POST-BAZE SECRECY

As states hone in on local compounding pharmacies as potential sources 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.³⁰⁹ Alarming, the compounded drug was contaminated with fungus³¹⁰—a discovery that was made only because the drug was analyzed after the inmate began snoring and then

305. See *supra* notes 237–41 and accompanying text.

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

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

308. See Denno, *Getting to Death*, *supra* note 1, at 352–54, 385–86; Denno, *Lethal Injection Quandary*, *supra* note 1, at 94–95; Denno, *When Legislatures Delegate*, *supra* note 1, at 64 n.2.

309. See 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 186.

310. See Press Release, Reprieve, South Dakota Covers Up Source of ‘DIY’ Death Penalty Drugs Ahead of Execution (Oct. 30, 2012), *available at* http://www.reprieve.org.uk/press/2012_10_30_South_Dakota_execution_drugs/ (providing a link to the certificate of analysis “showing that the ingredients used to make South Dakota’s execution drugs were contaminated”).

remained open-eyed as he was executed.³¹¹ 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.³¹² 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.³¹³ 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.³¹⁴ 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 one hundred local compounding pharmacies seeking to “acquire sodium thiopental or other equally or more effective substance to cause death” in accordance with state law.³¹⁵ 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.³¹⁶ When the Georgia Department 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.³¹⁷ 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.³¹⁸ According to the Act's provisions, this information is considered a “state secret.”³¹⁹ Several states have proposed or passed new regulations that exclude the death-penalty protocol from required

311. See *South Dakota Murderer Executed by Lethal Injection for Beating to Death Prison Guard with Pipe During Botched Escape*, DAILY MAIL (Oct. 15, 2012, 23:49 EST), <http://www.dailymail.co.uk/news/article-2218181>.

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

313. See *id.*

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

315. Hoover, *supra* note 221.

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

317. See *id.*

318. See H.B. 122, 152d Gen. Assemb., Reg. Sess. (Ga. 2013).

319. *Id.*

disclosure, thereby keeping both the method itself as well as the source pharmacy, compounding or otherwise, completely confidential.³²⁰

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.³²¹ 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.³²² 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.³²³

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.³²⁴ States profess crucial reasons to shield the identities of all parties who are involved in the lethal injection process, including doctors, pharmacists, drug providers, wholesalers, retailers, or manufacturers.³²⁵ Currently the American Medical Association, American Nurses' Association, American Society of Anesthesiologists, and National Commission on Correctional Health Care all have ethical rules and guidelines opposing participation in lethal injections.³²⁶ 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.³²⁷ Yet these fears are carryovers from past methods of execution, which employed a substantially smaller execution team. In contrast, lethal injections involve multiple participants,³²⁸ none of whom presumably is wholly responsible for the execution, including the producer of the lethal injection

320. See *infra* notes 321–23 and accompanying text.

321. See S. 237, 89th Gen. Assemb., Reg. Sess. (Ark. 2013).

322. See S. 154, 108th Gen. Assemb., Reg. Sess. (Tenn. 2013).

323. S. 36, 88th Leg. Assemb., Reg. Sess. (S.D. 2013).

324. See Ellyde Roko, *Executioner Identities: Toward Recognizing a Right to Know Who Is Hiding Beneath the Hood*, 75 *FORDHAM L. REV.* 2791, 2796 n.39 (2007).

325. See *id.* at 2799–2800.

326. See Denno, *Lethal Injection Quandary*, *supra* note 1, at 53–59, 77–91.

327. See Roko, *supra* note 324, at 2809–12; see also *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> (noting state attorneys' contention that "a new state law barring the release of information about where Georgia obtains its execution drug. . . [is] necessary to discourage retaliation against those who take part in executions").

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

drugs.³²⁹

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.³³⁰

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.³³¹ Four years later, in 2005, I conducted 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 prior to the onslaught of lethal injection challenges starting in 2006.³³²

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

329. 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 compounding pharmacies have been found to encounter serious dosage errors, delivering drugs with up to 450% of the prescribed dosage. See Gilliland, *supra* note 312. 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. See Hamburg, *supra* note 35.

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

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

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

evaluation of their protocols, either because the information is confidential or nonexistent.³³³

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.³³⁴ By 2013, however, there is a hodgepodge of protocols among states that has no parallel prior to *Baze*, whether that comparison is being made relative to 2008 or 1977 or as far back as 1890.³³⁵ 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. In 2011, the Chief Deputy Attorney General of Delaware ordered that the state Department of Corrections violated the Freedom of Information Act³³⁶ by denying a request from a reporter for access to all information regarding its purchase and inventory of pentobarbital and sodium thiopental.³³⁷ 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 amount of a specific lethal injection drug in the Department's possession as well as information about the lethal injection protocol.³³⁸ He acknowledged that such information is not considered confidential under the state code in conjunction with a physical safety exception recognized by the Texas Supreme Court one year earlier³³⁹ 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.³⁴⁰ Most recently, an Atlanta circuit judge granted injunctive relief to a death-row inmate who challenged Georgia's Lethal Injection Secrecy Act as a violation of

333. *Id.* at 96–101.

334. *See supra* note 1 and accompanying text.

335. *See supra* notes 1, 39 and accompanying text.

336. DEL. CODE ANN. tit. 29, ch. 100 (2003).

337. *See* Freedom of Information Act Appeal Concerning Department of Correction, Del. Op. Att'y Gen. 11-IIB14 (2011), 2011 WL 4062225.

338. *See* Tex. Att'y Gen. Op. OR2012-07088 (2012), 2012 WL 1821071.

339. *Id.* “[F]reedom from physical harm is an independent interest protected under law, untethered to the right of privacy.” *Id.* (quoting Tex. Dep't of Pub. Safety v. Cox Tex. Newspapers, L.P., 343 S.W.3d 112, 117 (Tex. 2011) (internal quotation marks omitted)).

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

his due process rights in a potential Eighth Amendment claim.³⁴¹ 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.³⁴²

In May 2013, the American Civil Liberties Union (ACLU) 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.³⁴³ 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.³⁴⁴ However, the judge decided that details about the drug supplier should be part of the redacted information.³⁴⁵ 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.³⁴⁶ 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

Lethal injection is this country’s primary method of execution, yet its implementation is chaotic and its future is unclear. This Article’s point-in-time snapshot provides an overview of the multiple factors that have contributed to the prevailing state of confusion. The Supreme Court has done little to clarify matters—the *Baze* Court left key questions regarding lethal injection unanswered, and the issues that the Court did address have been rendered moot by

341. See *Hill v. Owens*, No. 2013-CV-233771, slip op. at 7 (Ga. Super. Ct. filed July 18, 2013), available at <http://www.deathpenaltyinfo.org/documents/HillStayOrder.pdf>.

342. See *id.* at 2–4. The state had filed an appeal to the Georgia Supreme Court seeking to overturn the lower court decision. See *State Appeals Stay of Execution in Hill Case*, *supra* note 327. On February 17, 2014, the Georgia Supreme Court heard oral arguments on the state’s appeal; a ruling is expected sometime in summer 2014. See Max Blau, *Georgia’s Supreme Court Hears Oral Arguments in Warren Hill Appeal*, CREATIVE LOAFING (Feb. 17, 2014, 3:30 PM), <http://www.clatl.com/freshloaf/archives/2014/02/17/georgias-supreme-court-hears-oral-arguments-in-warren-hill-appeal>.

343. See Karen Augé, *ACLU Suit: Public Is Entitled to Know How Nathan Dunlap Will Be Killed*, DENVER POST (May 21, 2013, 12:21 PM), http://www.denverpost.com/breakingnews/ci_23291066/aclu-suit-public-is-entitled-know-how-nathan.

344. See *ACLU of Colo. v. Colo. Dep’t of Corr.*, No. 13CV32325 (Dist. Ct., City & Cnty. of Denver, Colo. filed Aug. 1, 2013), available at <http://aclu-co.org/case/aclu-v-colorado-department-of-corrections>.

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

346. See *ACLU of Colo.*, No. 13CV32325.

unanticipated obstacles such as the shortage of lethal injection drugs. More than any legal argument, this practical impediment jeopardizes the use of lethal injection as a method of execution. As death-penalty states turn to increasingly nontraditional sources of drugs, such as compounding pharmacies, they face overwhelming criticism and legal challenges. In response, they have intensified their efforts to obscure information regarding the development and implementation of their lethal injection protocols.

Indeed, as risk and confusion surround lethal injection procedures, the only overarching constant appears to be states' desire for secrecy regarding execution practices. Amidst the chaos of drug shortages, changing protocols, legal challenges, and botched executions, states are unwavering in their desire to conceal this disturbing reality from the public. In fact, 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.