Execution by . . . Heroin?: Why States Should Challenge the FDA's Ban on the Importation of Sodium Thiopental

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ABSTRACT: This Note traces the history of the lethal injection drug shortage and its impact on how states carry out the death penalty. Though this topic has received much attention in recent years, relatively little attention has been paid to the D.C. Circuit's decision in Cook v. FDA, *which exacerbated the shortage. In* Cook, *the D.C. Circuit enjoined the FDA from exercising its enforcement discretion to allow the importation of sodium thiopental, the primary anesthetic used by states in lethal injection executions. This decision is significant because it effectively required the FDA to ban the importation of sodium thiopental, forcing states to find other ways to carry out executions. Many states have turned to new drugs and manufacturers, while others have returned to past methods of execution. However, states' use of alternative drugs and manufacturers has had disastrous consequences, and the return to old methods of execution constitutes an unacceptable regression towards inhumane and barbaric punishment. Thus, this Note argues that states should make every effort to obtain sodium thiopental. Potential avenues to obtain the drug include adhering to the FDA's regulations or litigating against the FDA's regulations. Renewed access to sodium thiopental will resolve many of the problems plaguing the administration of lethal injection.*

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I. INTRODUCTION & BACKGROUND

"I've heard everything from using heroin to using nitrogen to going back to the electric chair. That's a debate that probably we need to have."[1]

A lethal injection drug shortage has crippled the "machinery of death."[2] In recent years sodium thiopental, one of the most reliable and effective anesthetics[3] used by states in lethal injection executions, has become unavailable in the United States.[4] The D.C. Circuit's decision in *Cook v. FDA* to enjoin the United States Food and Drug Administration ("FDA") from allowing the importation of sodium thiopental[5] has compounded the shortage, forcing states into what has been described by some as "an almost Wild West frenzy."[6] Now officials are exploring new and old frontiers such as alternative drugs, alternative manufacturers, and past methods of execution in an effort to find a solution to the shortage.[7] Such efforts have been largely unavailing, however, and have renewed the debate over whether the death

1. Karen Kasler, *Lethal Injection Drug Shortage Causes Lawmakers to Consider Changing Execution Method*, WXVU (Oct. 23, 2015), http://wvxu.org/post/lethal-injection-drug-shortage-causes-lawmakers-consider-changing-execution-method#stream/0.

2. Callins v. Collins, 510 U.S. 1141, 1145 (1994) (Blackmun, J., dissenting).

3. *See* Robert Lowes, *Anesthesiologists Ask FDA to Okay Importation of Sodium Thiopental*, MEDSCAPE (Feb. 11, 2011), http://www.medscape.com/viewarticle/737303 (discussing the American Society of Anesthesiologists' request to the FDA that it allow the importation of sodium thiopental because it "remains a mainstay of anesthesia induction medications" and, therefore, "[i]ts availability must be ensured").

4. Ty Alper, Opinion, *Why the Execution Drug Shortage Won't Go Away*, L.A. TIMES (Apr. 13, 2015, 11:22 PM), http://www.latimes.com/opinion/op-ed/la-oe-alper-lethal-injection-shortages-20150414-story.html.

5. Cook v. FDA, 733 F.3d 1, 3 (D.C. Cir. 2013).

6. Gregg Zoroya, *Death Penalty Spurs Wild West Scramble for Drugs*, USA TODAY (Mar. 17, 2014, 6:49 PM), http://www.usatoday.com/story/news/nation/2014/03/09/executions-lethal-injection-drugs-prisons-death-penalty/5866947.

7. *See infra* Part III.

penalty is still a justifiable form of punishment.[8] As a result, it has become very difficult for states to carry out court ordered executions. The current situation has exasperated correctional officials, prompting Arkansas Attorney General Dustin McDaniel to remark: "I've done everything I can do to carry out the executions that have been ordered in my state, and if somebody has an idea of how we can do that, I'd like to hear it."[9]

This Note, divided into four parts, seeks to provide such an idea. Part I serves as an introduction and background. Part I.A briefly discusses the history of lethal injection and Part I.B traces development of the lethal injection drug shortage, paying particular attention to the events that led to the D.C. Circuit's decision in *Cook v. FDA*. Next, Part II provides a detailed analysis of *Cook* and argues that it was wrongly decided. Part III then examines the states' various responses to the *Cook* decision and questions the viability of these responses. Finally, Part IV offers the states two potential solutions to the *Cook* decision, ultimately recommending litigation as the best solution. To be clear, this Note does not seek to comment on whether the use of the death penalty as a form of criminal punishment is justifiable or constitutional. Rather, its purpose is to address the consequences of the D.C. Circuit's decision in *Cook*, which have combined to make the death penalty more inhumane.

A. *HISTORY OF LETHAL INJECTION AS A METHOD OF EXECUTION*

Lethal injection was first adopted as a method of execution by Oklahoma in 1977.[10] Dr. Jay Chapman, Oklahoma's chief medical examiner at the time, created the lethal injection protocol at the request of former Oklahoma state legislator Bill Wiseman.[11] Chapman's protocol called for the administration of three different drugs via a saline drip: (1) sodium thiopental, an anesthetic that induces deep unconsciousness; (2) pancuronium bromide, a muscle relaxant that causes paralysis and suffocation; and (3) potassium chloride, a chemical compound that triggers cardiac arrest.[12] Convinced that lethal injection was a more humane—not to mention cheaper—method of capital punishment compared to previous methods, Oklahoma legislators passed the first lethal injection statute codifying Chapman's protocol on May 10, 1977.[13]

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8. *See infra* Part III.

9. Zoroya, *supra* note 6.

10. Josh Sanburn, *Creator of Lethal Injection Method: "I Don't See Anything That Is More Humane"*, TIME (May 15, 2014), http://time.com/101143/lethal-injection-creator-jay-chapman-botched-executions.

11. *Id.* According to Mr. Wiseman, he originally supported the adoption of lethal injection as a method of execution because he hoped to "make executions more humane." Vince Beiser, *A Guilty Man*, MOTHER JONES (Sept.–Oct. 2005), http://www.motherjones.com/politics/2005/09/guilty-man?page=1. Prior to the adoption of lethal injection, Oklahoma executed prisoners by electric chair. *Id.*

12. Deborah W. Denno, *Lethal Injection Chaos Post-*Baze, 102 GEO. L.J. 1331, 1333–34 (2014).

13. Beiser, *supra* note 11. For a more detailed history of the development of Dr. Chapman's

As Wiseman recalled, lethal injection offered "the following benefits[:] . . . '[n]o pain, no spasms, no smells or sounds—just sleep, then death.'"[14]

The protocol quickly spread across the country. Texas adopted lethal injection by statute one day after Oklahoma did.[15] By 1982, Idaho, New Mexico, Washington, and Massachusetts had also adopted lethal injection.[16] On December 7, 1982, Texas performed the first execution by lethal injection, using Chapman's three-drug protocol to execute Charles Brooks, Jr.[17] In the two years following Texas's successful execution, 12 more states decided to carry out executions by lethal injection.[18] Over roughly the next two decades, an additional 22 states adopted lethal injection, with Nebraska being the last state to adopt it in 2009.[19] Thus, "[b]y 2009 . . . all death-penalty states in this country had switched to lethal injection, either entirely or as an option, and nearly all states used a protocol consisting of the same three drugs."[20]

In 2008, the United States Supreme Court considered, for the first time, the constitutionality of Chapman's protocol under the Eighth Amendment in *Baze v. Rees*.[21] In *Baze*, prisoners who had been sentenced to death in Kentucky state court challenged the constitutionality of Kentucky's lethal injection protocol, arguing that it was "unconstitutional under the Eighth Amendment's ban on 'cruel and unusual punishments,' because of the risk that the protocol's terms might not be properly followed, resulting in significant pain."[22] The Court held that to establish an Eighth Amendment violation, prisoners must: (1) show that the challenged method of execution poses "a 'substantial risk of serious harm;'" and (2) offer a "feasible, readily implemented" alternative that "in fact significantly reduce[s the] substantial risk of severe pain."[23] It then found that Kentucky's lethal injection protocol did not constitute cruel and unusual punishment because it did not pose a

protocol, see Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 FORDHAM L. REV. 49, 64–70 (2007); and Jamie Fellner & Sarah Tofte, *So Long as They Die: Lethal Injections in the United States*, HUM. RTS. WATCH (Apr. 23, 2006), https://www.hrw.org/report/2006/04/23/so-long-they-die/lethal-injections-united-states.

14. Denno, *supra* note 13, at 67.

15. Fellner & Tofte, *supra* note 13.

16. Denno, *supra* note 12, at 1342 chart 1.

17. Robert Reinhold, *Technician Executes Murderer in Texas by Lethal Injection*, N.Y. TIMES (Dec. 7, 1982), http://www.nytimes.com/1982/12/07/us/technician-executes-murderer-in-texas-by-lethal-injection.html.

18. Denno, *supra* note 12, at 1342 chart 1.

19. *Id.*

20. *Id.* at 1342 (footnote omitted).

21. Baze v. Rees, 553 U.S. 35 (2008) (plurality opinion).

22. *Id.* at 41. The prisoners acknowledged that, if performed properly, Kentucky's lethal injection protocol would not constitute cruel and unusual punishment. *Id.*

23. *Id.* at 52 (quoting Farmer v. Brennan, 511 U.S. 825, 842 (1994)).

substantial risk of serious harm as "compared to the known and available alternatives."[24]

B. DEVELOPMENT OF THE LETHAL INJECTION DRUG SHORTAGE

Kentucky's victory in *Baze* seemingly ensured the continued viability of Chapman's lethal injection protocol. In 2010, however, the supply of sodium thiopental—the first drug in the protocol used to induce deep unconsciousness—in the United States began to dwindle, forcing some states to delay executions.[25] Hospira, an Illinois pharmaceutical company and the sole manufacturer of sodium thiopental in the United States, "blamed the shortage on unspecified problems with its raw-material suppliers," but some questioned the veracity of Hospira's explanation.[26] On January 21, 2011, their suspicions were confirmed as Hospira, "after months of pressure by activists,"[27] issued a press release stating it was "exit[ing] the sodium thiopental market and [would] no longer attempt to resume production of [sodium thiopental]."[28]

Just a few months before losing access to Hospira, states had also lost access to many foreign producers. In November 2010, then-British Business Secretary Vincent Cable banned the exportation of sodium thiopental in response to "revelations . . . that British-manufactured sodium thiopental was being used as a painkiller in some US states prior to lethal injections."[29] With sources of sodium thiopental quickly drying up, states began to modify their lethal injection protocols, turning to other barbiturates like pentobarbital.[30] In 2010, Oklahoma became the first state to execute an inmate using pentobarbital instead of sodium thiopental.[31] The sole producer of

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24. *Id.* at 61. For an in-depth look at how other courts have applied *Baze* as precedent see Denno, *supra* note 12, at 1347–54.

25. Andrew Welsh-Huggins, *Some US Executions Held Up by Shortage of Drug*, CORRECTIONSONE (Sept. 28, 2010), http://www.correctionsone.com/jail-management/articles/2719784-Some-US-executions-held-up-by-shortage-of-drug.

26. *Id.*

27. Nathan Koppel, *Drug Halt Hinders Executions in the U.S.*, WALL STREET J. (Jan. 22, 2011, 12:01 AM), http://www.wsj.com/articles/SB10001424052748704754304576095980790129692.

28. Press Release, Hospira, Hospira Statement Regarding Pentothal (Sodium Thiopental) Market Exit (Jan. 21, 2011), http://phx.corporate-ir.net/phoenix.zhtml?c=175550&p=irol-newsArticle_print&ID=1518610. Hospira initially announced it would move its sodium thiopental production to Italy but the Italian government opposed the move. Koppel, *supra* note 27.

29. Peter Walker, *Vince Cable Restricts Export of Drug Used in US Executions*, GUARDIAN (Nov. 29, 2010, 8:49 AM), http://www.theguardian.com/science/2010/nov/29/sodium-thiopental-export-restrictions.

30. Raymond Bonner, *A Prolonged Stay: The Reasons Behind the Slow Pace of Executions*, PROPUBLICA (May 22, 2013, 11:23 AM), http://www.propublica.org/article/a-prolonged-stay-the-reasons-behind-the-slow-pace-of-executions; *see also* James Gibson & Corinna Barrett Lain, *Death Penalty Drugs and the International Moral Marketplace*, 103 GEO. L.J. 1215, 1227 (2015) ("In 2011 alone, thirteen states changed their protocols, substituting pentobarbital for thiopental.").

31. David W. Freeman, *Pentobarbital, Euthanasia Drug, Used in Oklahoma Execution: Was It*

pentobarbital used in the United States is Lundbeck, a company headquartered in Denmark.[32] In July 2011, facing significant external pressures, Lundbeck took steps to prevent correctional facilities in the United States from acquiring pentobarbital.[33]

In December 2011, the European Union followed Britain's lead, deciding that the choice of whether to export drugs for lethal injection would no longer be left to pharmaceutical companies.[34] At that time, the European Commission, the executive arm of the European Union, "expanded its Regulation on Products used for Capital Punishment and Torture to include 'products which could be used for the execution of human beings by means of lethal injection,' including 'short and intermediate acting barbiturate anaesthetic agents,'" thereby effectively banning the exportation of sodium thiopental and pentobarbital from Europe.[35] The new regulations were described as furthering the European Union's wider goal of abolishing capital punishment around the world.[36]

The European Union is not the only government entity that has significantly affected the supply of lethal injection drugs in the United States. From July 2010 to January 2011, the FDA detained multiple shipments of sodium thiopental that had been shipped from Dream Pharma ("Dream"), a wholesale pharmaceutical distributor based in London.[37] Upon discovering that the shipments had been headed to correctional facilities in several states, including Georgia, Arkansas, Arizona, Tennessee, and California, the FDA

Inhumane?, CBS NEWS (Dec. 17, 2010, 10:32 AM), http://www.cbsnews.com/news/pentobarbital-euthanasia-drug-used-in-oklahoma-execution-was-it-inhumane.

32. *See* Mary D. Fan, *The Supply-Side Attack on Lethal Injection and the Rise of Execution Secrecy*, 95 B.U. L. REV. 427, 440 (2015); Teri Schultz, *Europe Fights the Death Penalty—With Drugs*, PUB. RADIO INT'L: GLOBALPOST (May 13, 2011, 10:03 AM), http://www.pri.org/stories/2011-05-13/europe-fights-death-penalty-drugs.

33. Fan, *supra* note 32, at 440.

34. Ed Pilkington, *Europe Moves to Block Trade in Medical Drugs Used in US Executions*, GUARDIAN (Dec. 20, 2011, 1:27 PM), http://www.theguardian.com/world/2011/dec/20/death-penalty-drugs-european-commission.

35. Matt Ford, *Can Europe End the Death Penalty in America?*, ATLANTIC (Feb. 18, 2014), http://www.theatlantic.com/international/archive/2014/02/can-europe-end-the-death-penalty-in-america/283790 (quoting Commission Implementing Regulation 1352/2011, 2011 O.J. (L 338) 31, 34 (EU)).

36. Pilkington, *supra* note 34. The European Union's influence on death penalty policy in the United States extends beyond the export ban. Ford, *supra* note 35 ("The European Union . . . makes no secret of its death-penalty stance. EU guidelines call for its 'universal abolition' and declare that doing so would '[contribute] to the enhancement of human dignity and the progressive development of human rights.' EU diplomats and leaders frequently petition U.S. governors and state parole boards to halt forthcoming executions. Sometimes, the supranational organization even works in more subtle ways: EU agencies contributed over $4.8 million in donations to U.S. anti-death-penalty organizations between 2009 and 2013." (alteration in original)).

37. Beaty v. FDA, 853 F. Supp. 2d 34–35 (D.D.C. 2012), *aff'd in part*, *vacated in part sub nom.* Cook v. FDA, 733 F.3d 1 (D.C. Cir. 2013).

immediately released the shipments.[38] In January 2011, the FDA issued a statement to the *Wall Street Journal* indicating that it would "defer to law enforcement and permit the importation of thiopental sodium."[39] The statement read in part: "The FDA 'is charged by Congress with protecting the public health . . . . Reviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role.'"[40]

On January 25, 2011, 13 states that were anticipating shortages sent a letter to Attorney General Eric Holder, the head of the Department of Justice ("DOJ") at the time, asking for "assistance in either identifying an appropriate source for sodium thiopental or making supplies held by the Federal Government available."[41] Holder responded that the federal government was also having trouble procuring sodium thiopental but was "looking at all applicable options to determine the best course of action for effectively discharging our legal responsibilities."[42] However, in the following months, the Drug Enforcement Agency ("DEA"), which is overseen by the DOJ, seized all of the shipments of sodium thiopental that the FDA had released in 2010 to Georgia, Arkansas, Arizona and Tennessee, citing concerns about the legality of the methods used to import the drugs.[43] The DEA never seized the shipment of sodium thiopental obtained by California.[44]

The questions surrounding the quality of the sodium thiopental sold by Dream and the legality of the methods by which it was imported prompted death row prisoners in Arizona, California, and Tennessee to file suit in the United States District Court for the District of Columbia against the FDA,

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38. *Beaty*, 853 F. Supp. 2d at 35.

39. Nathan Koppel, *FDA Takes Stance on the Importation of Lethal-Injection Drugs*, WALL STREET J.: L. BLOG (Jan. 4, 2011, 4:40 PM), http://blogs.wsj.com/law/2011/01/04/the-fda-takes-public-stance-on-the-importation-of-lethal-injection-drugs.

40. *Id.* The FDA also made clear "that while it will permit thiopental imports it . . . will not vet or vouch for the 'safety, effectiveness, purity, or any other characteristics' of thiopental shipments." *Id.*

41. Letter from John Kroger, Or. Att'y Gen., et al. to Att'y Gen. Eric Holder (Jan. 25, 2011), http://www.deathpenaltyinfo.org/documents/StateAGLetter.pdf.

42. Letter from Eric H. Holder, Att'y Gen., to James McPherson, Exec. Dir., Nat'l Ass'n of Att'ys Gen. (March 4, 2011), http://www.scribd.com/doc/50471723/Attorneys-General-Letter-DOJ-Response.

43. Jeannie Nuss, *Arkansas Latest State to Turn Over Execution Drug*, CNS NEWS (July 22, 2011, 3:15 AM), http://cnsnews.com/news/article/arkansas-latest-state-turn-over-execution-drug; Ariane de Vogue, *DOJ Tells Arizona It Illegally Obtained Death Penalty Drug*, ABC NEWS (May 25, 2011), http://abcnews.go.com/Politics/Controversial-arizona-execution-set/story?id=13679827.

44. Judson Berger, *Justice Department Pursues 'Strange' Probe of Execution Drug*, FOX NEWS (May 8, 2011), http://www.foxnews.com/politics/2011/05/08/justice-department-pursues-strange-probe-execution-drug. It is unclear why California's sodium thiopental shipment was never seized. Some commentators argue that the DOJ's purpose in seizing the imported sodium thiopental was to "slow the pace of executions," a purpose which was not served by seizing California's shipment because California "had executions on hold anyway and just announced it was delaying executions for at least another year." *Id.*

Department of Health and Human Services, and various government officials.[45] In *Beaty v. FDA*, the prisoners alleged that the FDA, in releasing Dream's shipments of sodium thiopental, had improperly allowed the importation "of a misbranded and unapproved new drug" thereby violating several provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and requiring refusal of admission.[46] The FDA argued it had discretion over whether to reject misbranded and unapproved sodium thiopental, but the court disagreed and found that the language of the FDCA required the FDA to reject such drugs.[47] The court then permanently enjoined the FDA from permitting the importation of "apparently misbranded or unapproved" sodium thiopental.[48]

On May 21, 2012, the Attorneys General of 15 states sent a letter to Holder requesting that the FDA appeal the *Beaty* decision.[49] The letter described the *Beaty* decision as "flawed" and argued that:

> At the very core of the States' police powers are their powers to enact laws to protect their citizens against violent crimes. As state Attorneys Generals [sic], we are tasked with enforcing those laws, including in instances where capital punishment is authorized for the most heinous of crimes. Implicit in that obligation to our citizens is the need for the means by which to carry out executions.[50]

The Attorneys General also threatened that "[i]f the *Beaty* decision is not overturned, we as state Attorneys General will be forced to take actions to ensure execution by lethal injection remains a viable option."[51] Ultimately, the FDA did appeal the *Beaty* decision but the D.C. Circuit affirmed the ruling of the district court in *Cook v. FDA*.[52] That decision is the subject of Part II.

II. ASSESSMENT OF THE D.C. CIRCUIT'S DECISION IN *COOK V. FDA*

This Part explores the D.C. Circuit's decision in *Cook v. FDA* in greater depth. Part II.A discusses the Supreme Court's decision in *Heckler v. Chaney*,

45. Beaty v. FDA, 853 F. Supp. 2d 30, 32 (D.D.C. 2012), *aff'd in part*, *vacated in part sub nom.* Cook v. FDA, 733 F.3d 1 (D.C. Cir. 2013). Notably, Arizona, California, and Tennessee were not named as parties in the suit, meaning their interests were not represented in either *Beaty* or *Cook*.

46. *Id.* at 37.

47. *Id.* at 40.

48. Cook v. FDA, 733 F.3d 1, 3 (D.C. Cir. 2013).

49. Letter from E. Scott Pruitt, Okla. Att'y Gen., et al. to Eric H. Holder, Att'y Gen. (May 21, 2012), https://www.oag.ok.gov/oagweb.nsf/0/585879208 9a49b4086257a05006da605/$FILE/Sign-on%20Letter%20-%20Beaty.pdf. Only the FDA could appeal the decision because Arizona, California, and Tennessee were not named as parties in *Beaty*.

50. *Id.*

51. *Id.*

52. *Cook*, 733 F.3d at 12 (holding that "[t]he 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").

which provides background and exposition on the governing law utilized in *Cook*. Part II.B then analyzes the *Cook* decision. Finally, Part II.C argues that, in light of the Supreme Court's ruling in *Heckler v. Chaney*, *Cook v. FDA* was wrongly decided.

A. EXPLANATION OF THE SUPREME COURT'S DECISION IN HECKLER V. CHANEY

In *Heckler v. Chaney*, the United States Supreme Court considered "the extent to which a decision of an administrative agency to exercise its 'discretion' not to undertake certain enforcement actions is subject to judicial review."[53] Prisoners facing execution by lethal injection in Texas and Oklahoma argued that under the FDCA, the use of sodium thiopental for executions made it a "misbrand[ed]" and "new" drug pursuant to sections 352 and 355 respectively.[54] They further argued that the sodium thiopental required FDA approval "as 'safe and effective' for human execution."[55] Previously, the FDA had declined to take such action, arguing its jurisdiction to interfere with the states' criminal justice systems was questionable.[56] The FDA also argued that the alleged dangers to the inmates did not constitute "a serious danger to the public health or a blatant scheme to defraud," so its exercise of enforcement discretion was proper.[57] The Court, after declining to "address the thorny question of the FDA's jurisdiction,"[58] held that the decision was unreviewable because, in the FDCA, Congress "commit[ted] complete discretion to the [FDA] to decide how and when [enforcement provisions] should be exercised."[59]

The Court premised its holding in *Heckler* on the FDCA's general enforcement provision, which is contained in section 372.[60] Section 372 provides that "[t]he [FDA] is authorized to conduct examinations and investigations."[61] With no other "law to apply," i.e., provisions that "withdr[a]w discretion from the agency and provide[] guidelines for exercise of its enforcement power," the Court found that the language of section 372 clearly

53. Heckler v. Chaney, 470 U.S. 821, 823 (1985) (quoting 21 U.S.C. § 355(i)(1) (2012)).

54. *Id.* at 823–24 (quoting 21 U.S.C. §§ 352, 355).

55. *Id.* at 824 (quoting 21 U.S.C. § 355).

56. *Id.* at 824–25 ("Were FDA clearly to have jurisdiction in the area, moreover, we believe we would be authorized to decline to exercise it under our inherent discretion to decline to pursue certain enforcement matters. The unapproved use of approved drugs is an area in which the case law is far from uniform. Generally, enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under [s]tate lethal injection laws, which are duly authorized statutory enactments in furtherance of proper [s]tate functions. . . .").

57. *Id.*

58. *Id.* at 828.

59. *Id.* at 835.

60. *Id.*

61. 21 U.S.C. § 372(a) (2012).

evinced Congress's intent to grant the FDA enforcement discretion.[62] Significantly, the Court did not consider "the [FDCA's] substantive prohibitions of 'misbranding' and the introduction of 'new drugs' absent agency approval" to constitute "law to apply."[63] Instead, it found the provisions to be "simply irrelevant to the agency's discretion to refuse to initiate proceedings."[64] The Court came to this conclusion despite the fact that both provisions use the word "shall," with section 352 stating "[a] drug . . . *shall* be deemed to be misbranded,"[65] and section 355 stating "no person *shall* introduce . . . into interstate commerce any new drug."[66] It is also important to note that at the end of its decision the Court declared: "The fact that the drugs involved in this case are ultimately to be used in imposing the death penalty must not lead this Court or other courts to import profound differences of opinion over the meaning of the Eighth Amendment . . . into the domain of administrative law."[67]

B. ANALYSIS OF THE D.C. CIRCUIT'S DECISION IN COOK V. FDA

In *Cook v. FDA*, the Court of Appeals for the District of Columbia Circuit considered whether the FDA's decision "to invoke [section 381(a)] [of the FDCA] and refuse admission to any particular drug offered for import is . . . subject to judicial review."[68] Section 381(a), the FDCA's import provision, provides that the FDA "*shall* request that if any drugs, devices, or tobacco products manufactured . . . in an establishment not so registered are imported or offered for import . . . , samples of such drugs . . . be delivered to the [FDA]."[69] It further states that "[i]f it appears from the examination of such samples" that the drugs (1) have been "manufactured . . . under insanitary conditions"; (2) are forbidden in the country from which they were exported; or (3) are "adulterated, misbranded, or in violation of section 355," then such drugs "*shall* be refused admission."[70] The court that found that Congress's use of the word "shall" "left the agency with no discretion to make an exception, no matter how sensible making a particular exception might be."[71] Thus, the court held the decision was reviewable and found that: "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 . . . examine foreign shipments of the

62. *Heckler*, 823 U.S. at 834–37.
63. *Id.* at 835–36.
64. *Id.* at 836.
65. 21 U.S.C. § 352(a) (emphasis added).
66. *Id.* § 355(a) (emphasis added).
67. *Heckler*, 823 U.S. at 838.
68. Cook v. FDA, 733 F.3d 1, 5 (D.C. Cir. 2013) (first alteration in original).
69. 21 U.S.C. § 381(a) (emphasis added).
70. *Id.* (emphasis added).
71. *Cook*, 733 F.3d at 8.

drug despite knowing they may have been prepared in an unregistered establishment."[72]

In its brief, the FDA made several policy-based objections, arguing primarily that "it must have discretion not to enforce [section] 381(a) in order to combat domestic shortages of medically necessary drugs."[73] The court quickly dismissed this objection, however, citing a 2011 report that showed the FDA most often uses the following methods to address drug shortages: "'Asking other firms to increase production (31%),' 'Working with manufacturers' to mitigate quality problems (28%), and 'Expediting review of regulatory submissions (26%).'"[74] The report also stated that the FDA resorted to importing unapproved drugs in only five percent of drug shortage cases, so the court reasoned that even if its holding "deprives the FDA of one possible response to five percent of all drug shortages, that is hardly an absurd result."[75] The FDA did not raise a jurisdictional question as to whether it could interfere with state law enforcement functions and the court did not address the issue despite the fact that it was implicitly raised by the FDA's 2011 policy statement that "in '*defer[ence] to law enforcement' agencies*, henceforth it would exercise its 'enforcement discretion not to review these shipments [of sodium thiopental].'"[76]

C. WHY COOK V. FDA *WAS WRONGLY DECIDED*

The D.C. Circuit's decision in *Cook* controverts the Supreme Court's holding in *Heckler*. In *Heckler*, the Supreme Court determined that substantive provisions of the FDCA containing the word "shall," like sections 352 and 355, were "simply irrelevant" in defining the scope of the FDA's enforcement discretion because they were subordinate to section 372, the general enforcement provision that the Court determined granted the FDA enforcement discretion.[77] The D.C. Circuit's determination that the word "shall" in section 381(a) indicated Congress's intent to limit the FDA's enforcement discretion and require rejection of drugs that violate the statutory requirements directly contradicts the Supreme Court's interpretation of the FDCA. Section 381(a), like sections 352 and 355, is a substantive provision, which, as noted, is "simply irrelevant" in determining the scope of the FDA's enforcement discretion.[78]

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72. *Id.* at 12.

73. *Id.* at 9.

74. *Id.* (quoting *Executive Summary: A Review of FDA's Approach to Medical Product Shortages*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm277744.htm (last updated Nov. 3, 2012)).

75. *Id.* at 10.

76. *Id.* at 4 (first alteration in original) (emphasis added).

77. *See supra* notes 62–64 and accompanying text.

78. *See supra* notes 63–64 and accompanying text.

In addition, even if the FDA does not have enforcement discretion to collect drugs and refuse admission if they are found to violate section 381(a), it is unclear whether this also means the FDA does not have enforcement discretion to determine whether a drug actually violates section 381(a) in the first place. The D.C. Circuit held that "[t]he clear implication [of its ruling] is the FDA must examine the samples that it must request *and determine* whether they appear to violate [section 381(a)]."[79] The D.C. Circuit justified this inference arguing that "it would make no sense for the Congress to mandate the collection, but not the examination, of samples of drugs."[80] Thus, the D.C. Circuit concluded that if the FDA is given drug samples it must, pursuant to section 381(a), determine if they are misbranded according to section 355 and refuse admission accordingly.[81] This conclusion, however, also contradicts the Supreme Court's interpretation of the FDCA because in *Heckler* the Court expressly noted that the FDA has enforcement discretion under section 372 to determine whether a drug is misbranded under section 355.[82]

Finally, the D.C. Circuit failed to adequately consider the consequences of its decision. In its brief consideration of the policy implications, the D.C. Circuit summarily dismissed the FDA's concerns about its ability to combat drug shortages, arguing that the FDA can employ a variety of methods other than importing unapproved drugs to address drug shortages.[83] However, none of the alternative methods the D.C. Circuit suggested—requesting a production increase, reducing quality problems, or expediting review—can be used to address the shortage of sodium thiopental in the United States because, as the court noted in the very beginning of its opinion, "[i]n 2009 the last domestic manufacturer of thiopental stopped making it."[84] Consequently, the FDA has been unable to provide any assistance to states seeking sodium thiopental and states have been forced to turn less desirable drugs, manufacturers, and methods as discussed in Part III. Thus, it is clear the D.C. Circuit erred in limiting the FDA's discretion to enforce section 381(a) of the FDCA.

III. RESPONSES TO THE D.C. CIRCUIT'S DECISION IN *COOK V. FDA*

This Part discusses and critiques the various ways in which states have responded to the *Cook* decision. Part III.A examines states' experimentation with alternative drugs, focusing on the recent use of midazolam. Next, Part III.B looks at states' engagement with compounding pharmacies to produce

79. *Cook*, 733 F.3d at 8 (emphasis added).
80. *Id.*
81. *Id.*
82. *See supra* note 59 and accompanying text.
83. *See supra* notes 74–75 and accompanying text.
84. *Id.* at 4.

pentobarbital. Part III.C then considers several states' return to past methods of execution as backups. Finally, Part III.D evaluates some states' decisions to ignore the FDA's regulations.

A. EXPERIMENTING WITH ALTERNATIVE DRUGS

One way in which states have responded to the *Cook* decision is to simply continue past practices and replace sodium thiopental with other sedatives. Most recently, states have experimented with midazolam, which "is sometimes used before medical procedures, or before anesthesia is given, to cause drowsiness, relieve anxiety and prevent a person from remembering a procedure."[85] Unlike sodium thiopental and pentobarbital, however, midazolam is a benzodiazepine, not a barbiturate.[86] Barbiturates have a far more potent, and potentially destructive, effect on the central nervous system than benzodiazepines, which is why sodium thiopental and pentobarbital were previously the drugs of choice for states carrying out lethal injections.[87] Comparatively, "[a]s the dose of benzodiazepine increases, the benzodiazepine curve plateaus, reaching a 'ceiling' before general anesthesia can be reached."[88] This ceiling effect has led many experts to conclude "that [midazolam] might not produce a deep enough level of unconsciousness to prevent an inmate from feeling the pain that comes from the injections that follow."[89]

The concerns of experts regarding the efficacy of midazolam are warranted. Four states—Oklahoma, Florida, Arizona, and Ohio—have used midazolam in place of sodium thiopental in their lethal injection protocols, and all have experienced troubling results. In October 2013, Florida became the first state to use midazolam in the execution of William Happ.[90] Witnesses of the execution noted that "Happ remained conscious longer and made more body movements after losing consciousness than other people

85. Rachael Rettner, *How Does Execution Drug Midazolam Work?*, LIVE SCI. (June 29, 2015, 5:17 PM), http://www.livescience.com/51384-execution-drug-midazolam-effect.html.

86. Ed Cara, *What Is Midazolam: Why Are Doctors Worried the Lethal Injection Drug Won't Sedate Death Row Inmates?*, MED. DAILY (June 29, 2015, 7:35 PM), http://www.medicaldaily.com/what-midazolam-why-are-doctors-worried-lethal-injection-drug-wont-sedate-death-row-340468.

87. *Id.*

88. *Id.* (quoting Brief of Sixteen Professors of Pharmacology as Amici Curiae in Support of Neither Party, Glossip v. Gross, 135 S. Ct. 2726 (2015) (No. 14-7955)).

89. Brady Dennis & Lena H. Sun, *For More States, Execution Means Improvisation as Drug Supplies Dwindle*, WASH. POST (Apr. 30, 2014), https://www.washingtonpost.com/national/health-science/for-more-states-execution-means-improvisation-as-drug-supplies-dwindle/2014/04/30/53167218-do88-11e3-937f-d3026234b51c_story.html.

90. Lauren Barbato, *Which States Use Midazolam for Executions? The Supreme Court Is Examining Whether It's Humane Enough*, BUSTLE (Apr. 29, 2015), http://www.bustle.com/articles/79729-which-states-use-midazolam-for-executions-the-supreme-court-is-examining-whether-its-humane-enough; Morgan Watkins, *Happ Executed Using New Drug*, GAINESVILLE SUN (Oct. 15, 2013, 10:18 PM), http://www.gainesville.com/news/20131015/happ-executed-using-new-drug/1.

executed . . . by lethal injection under the old formula."[91] In January 2014, Ohio used midazolam to execute Dennis McGuire.[92] For the first ten minutes, "McGuire . . . gasped, choked, clenched his fists and appeared to struggle against his restraints."[93] Three months later, Oklahoma executed Clayton Lockett using midazolam.[94] Lockett woke up midway through the execution and attempted to get off the table before he succumbed to the drugs.[95] In July 2014, Arizona used midazolam to execute Joseph Wood.[96] The execution, which lasted nearly two hours due to the impotency of the midazolam, "was the longest execution in modern U.S. history."[97]

These botched executions prompted inmates awaiting lethal injection in Oklahoma to challenge the state's use of midazolam in its three-drug lethal injection protocol in federal court.[98] The case eventually made its way to the Supreme Court, and, in *Glossip v. Gross*, the Court considered whether "the method of execution now used . . . violates the Eighth Amendment because it creates an unacceptable risk of severe pain."[99] At the outset, the Court noted that "because some risk of pain is inherent in any method of execution, we have held that the Constitution does not require the avoidance of all risk of pain."[100] Thus, the Court required, consistent with its holding in *Baze*,[101] that the inmates identify: (1) a "substantial risk of serious harm"; and (2) a "feasible, readily implemented" alternative that "in fact significantly reduce[s]" the risk of harm.[102] The Court ultimately found the inmates failed

91. *Florida Executes Woman's Killer*, HERALD-TRIB. (Oct. 16, 2013, 12:01 AM), http://www.heraldtribune.com/news/20131016/florida-executes-womans-killer.

92. Alan Johnson, *Dennis McGuire's Execution Was Not 'Humane,' Doctor Says*, COLUMBUS DISPATCH (Aug. 13, 2014, 7:19 AM), http://www.dispatch.com/content/stories/local/2014/08/12/inmate-suffered-pain-during-execution-doctor-says.html.

93. *Id.* After McGuire's botched execution, Ohio announced it would no longer use midazolam in its lethal injection protocol. Josh Sanburn, *Ohio Abandons Controversial Execution Drug Cocktail*, TIME (Jan. 8, 2015, 5:14 PM), http://time.com/3660290/ohio-lethal-injection-sodium-thiopental/.

94. Jeffrey E. Stern, *The Cruel and Unusual Execution of Clayton Lockett*, ATLANTIC (June 2015), http://www.theatlantic.com/magazine/archive/2015/06/execution-clayton-lockett/392069.

95. *Id.*

96. *Id.*

97. Ben Crair, *Lethal Entanglements*, NEW REPUBLIC (May 19, 2015), http://www.newrepublic.com/article/121845. After Wood's botched execution, Arizona announced that it would no longer use midazolam in its lethal injection protocol. Michael Kiefer, *Arizona: Wood Execution Not Botched, but Drug Cocktail to Change*, ARIZ. REPUBLIC (Dec. 23, 2014, 8:42 AM), http://www.azcentral.com/story/news/local/arizona/2014/12/22/arizona-execution-drug-change/20774877.

98. Ziva Branstetter & Cary Aspinwall, *With Glossip Stay, Lethal Injection Faces New Challenge in Oklahoma*, FRONTIER (Sept. 16, 2015), https://www.readfrontier.com/investigation/with-glossip-stay-lethal-injection-faces-new-challenge-in-oklahoma.

99. Glossip v. Gross, 135 S. Ct. 2726, 2731 (2015).

100. *Id.* at 2733.

101. *See supra* notes 23–24 and accompanying text.

102. *Glossip*, 135 S. Ct at 2737 (alteration in original) (quoting Baze v. Rees, 553 U.S. 35, 52 (2008)).

to identify either and held that states' use of midazolam did not violate the Eighth Amendment.[103]

While the Court's decision in *Glossip* constitutes a significant victory for proponents of the death penalty, that victory may be fleeting. Even before the *Glossip* decision was announced, anti-death penalty activists had begun campaigning against manufacturers of midazolam. Shortly after his execution, the family of Dennis McGuire sued Hospira, the manufacturer of the midazolam used in McGuire's execution, for allowing its products to be used in executions.[104] Hospira, a veteran of such campaigns,[105] issued a statement on its website stating it had "ceased the direct sale to U.S. prison hospitals of products . . . that have been part of, or are being considered by, some states for their lethal injection protocols."[106] A little more than a month later, another manufacturer of midazolam, Akorn Pharmaceuticals ("Akorn"), announced that it too would no longer "sell any product directly to any prison"[107] after court documents revealed it had sold midazolam to Alabama.[108] Akorn also asked states to "return any remaining supply of drugs procured through Akorn."[109]

Though the argument that midazolam should not be used in lethal injection protocols may soon be moot due to the dwindling number of suppliers, the overarching problem remains. Just as anti-death penalty advocates succeed in taking one lethal injection drug off the market, states will inevitably find a new, less reliable drug to replace it with. Already, "[t]here have been more changes in lethal injection protocols during the past five years than there have been in the last three decades."[110] While presumably,

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103. *Id.* at 2731.

104. *Family Sues in Protracted Ohio Execution*, N.Y. TIMES (Jan. 25, 2014), http://www.nytimes.com/2014/01/26/us/family-sues-in-protracted-ohio-execution.html.

105. *See supra* notes 26–28 and accompanying text.

106. *Hospira Position on Use of Our Products in Lethal Injections in the U.S.*, HOSPIRA, https://www.hospira.de/en/about_hospira/government_affairs/hospira_position_on_use_of_our_products (last visited Nov. 11, 2016). Hospira also noted, however, that "due to the complex supply chain and the gray market in the United States . . . Hospira cannot guarantee that a U.S. prison could not secure restricted products through other channels not under Hospira's control." *Id.*

107. Press Release, Akorn, Akorn Adopts Comprehensive Policy to Support the Use of Its Products to Promote Human Health (Mar. 4, 2015), http://investors.akorn.com/phoenix.zhtml?c=78132&p=irol-newsArticle&ID=2022522.

108. Tracy Connor, *Drug-Maker Akorn Bans Sedative Midazolam for Executions*, NBC NEWS (Feb. 20, 2015, 8:34 AM), http://www.nbcnews.com/storyline/lethal-injection/drug-maker-akorn-bans-sedative-midazolam-executions-n309191.

109. Kim Bellware, *Manufacturer Asks Prisons to Return Supply of Controversial Lethal Injection Drug*, HUFFINGTON POST (Apr. 22, 2015, 4:15 PM), http://www.huffingtonpost.com/2015/04/22/arizona-lethal-injection-drug-return_n_7118486.html.

110. Denno, *supra* note 12, at 1335; *see also* Lincoln Caplan, *The End of the Open Market for Lethal-Injection Drugs*, NEW YORKER (May 21, 2016), http://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs ("In 2012, Missouri replaced its three-drug protocol for lethal injections with a one-drug protocol, using propofol. Within a year,

this dangerous cycle will eventually end with states running out of new lethal injection drugs to try, the consequences of allowing that process to play out would be even more undesirable. As Justice Sotomayor argued in her dissenting opinion in *Glossip*, "[t]he execution protocols [s]tates hurriedly devise as they scramble to locate new and untested drugs are all the more likely to be cruel and unusual—presumably, these drugs would have been the [s]tates' first choice were they in fact more effective."[111] Thus, the use of alternative lethal injections drugs is not a viable solution to the *Cook* decision.

B. ENGAGING WITH COMPOUNDING PHARMACIES

Another way in which the states have responded to the *Cook* decision is by finding new ways to procure old drugs. One popular new method is pharmacy compounding. According to the FDA, "[p]harmacy compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient."[112] Pharmacies engaged in compounding "typically mix small batches of drugs to order"[113] and account for only one to three percent of all pharmaceuticals manufactured in the United States.[114] It is important to note that compounding pharmacies "serve an important public health need if a patient cannot be treated with an FDA-approved medication."[115] However, states seeking lethal injection drugs have asked compounding pharmacies to produce drugs that are "technologically too difficult to [create] outside of FDA-regulated facilities."[116] This is problematic because, unlike drugs manufactured by pharmaceutical companies, drugs crafted by compounding pharmacies are subject to state, rather than federal, regulations, which are often less rigorous.[117]

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the drug-makers Fresenius Kabi, Teva, and Hospira had put distribution controls on propofol and other drugs that were part of state protocols for lethal injections. In 2013, Arkansas replaced its three-drug protocol with a one-drug protocol, using phenobarbital; the next month, the British company Hikma put controls on phenobarbital. In the past five years, about two dozen companies, making thirteen different drugs, have blocked their use in lethal injections . . . .").

111. Glossip v. Gross, 135 S. Ct. 2726, 2796 (2015) (Sotomayor, J., dissenting) (citation omitted).

112. *The Special Risks of Pharmacy Compounding*, U.S. FOOD & DRUG ADMIN. (Dec. 3, 2012), http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm.

113. Eric Berger, *Lethal Injection Secrecy and Eighth Amendment Due Process*, 55 B.C. L. REV. 1367, 1382 (2014).

114. T.R. GOLDMAN, HEALTH AFF., REGULATING COMPOUNDING PHARMACIES 1 (2014), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_114.pdf.

115. *The Special Risks of Pharmacy Compounding*, *supra* note 112.

116. Berger, *supra* note 113, at 1383.

117. *Id.* at 1382. To qualify for exemption compounding pharmacies must meet certain conditions such as having an "individual physician's prescription and a requirement that the compounds are not copies of commercially available drugs." Ellen Killoran, *Arizona Botched Lethal Injection: Secrecy, Compounding Pharmacies and the Eighth Amendment*, INT'L BUS. TIMES (July 26, 2014, 2:13 PM), http://www.ibtimes.com/arizona-botched-lethal-injection-secrecy-compounding-pharmacies-

The lack of oversight and regulation of compounding pharmacies has, in the past, had deadly consequences. In 2012, New England Compounding Center of Framingham ("NECC"), illegally manufactured a large batch of injectable steroids.[118] The steroids were prepared in a room with a "leaky boiler [that] stood in a pool of stagnant water; powder hoods [that] were covered with dirt and fuzz; and [an] air intake [that] came from vents that were about 30 yards from a dust-spewing recycling plant."[119] Due to the unsterile conditions, many of the steroids were contaminated during the manufacturing process with lethal fungal spores.[120] NECC ultimately manufactured over 17,000 vials of the steroids and distributed them to more than 20 states.[121] What followed was "the country's worst compounded drug crisis,"[122] as the steroids "infected more than 800 people with fungal meningitis in 2012, 64 of whom died."[123] The incident prompted a massive FDA investigation of dozens of compounding pharmacies all over the country, which revealed "objectionable conditions at more than sixty facilities."[124]

The NECC incident is a good example of what can happen when compounding pharmacies engage in activities beyond their expertise and should serve to caution states that are now considering purchasing lethal injection drugs from such pharmacies. Indeed, the use of compounded drugs by states carrying out lethal injections has already led to several botched executions. For instance, in October 2012, South Dakota executed Eric Robert using compounded pentobarbital.[125] During the execution witnesses reported that he "appeared to be clearing his throat and then began gasping

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eighth-amendment-1639770.

118. Kurt Eichenwald, *Killer Pharmacy: Inside a Medical Mass Murder Case*, NEWSWEEK (Apr. 16, 2015, 7:07 AM), http://www.newsweek.com/2015/04/24/inside-one-most-murderous-corporate-crimes-us-history-322665.html.

119. *Id.* For a more thorough description of what the FDA found at NECC, see Ryan Jaslow, *FDA Finds Contaminated Vials, Bacteria and Mold at New England Compounding Center*, CBS NEWS (July 29, 2013, 4:52 PM), http://www.cbsnews.com/news/fda-finds-contaminated-vials-bacteria-and-mold-at-new-england-compounding-center.

120. Jaslow, *supra* note 119.

121. David Brown & Lena H. Sun, *Medicine Implicated in Rare Meningitis Cases Went to 23 States*, WASH. POST (Oct. 4, 2012), https://www.washingtonpost.com/national/health-science/medicine-implicated-in-rare-meningitis-cases-went-to-23-states/2012/10/04/725c1b42-0e64-11e2-bd1a-b868e65d57eb_story.html.

122. Goldman, *supra* note 114, at 2. For a more detailed account of the turmoil surrounding compounding pharmacies, see Nathaniel A.W. Crider, Note, *What You Don't Know Will Kill You: A First Amendment Challenge to Lethal Injection Secrecy*, 48 COLUM. J.L. & SOC. PROBS. 1, 14–19 (2014).

123. Eichenwald, *supra* note 118. The victims of the outbreak later settled with the NECC for $200 million dollars. *Judge Approves $200 Million Settlement over Meningitis Outbreak*, CBS NEWS (May 20, 2015, 11:58 AM), http://www.cbsnews.com/news/judge-approves-200-million-settlement-over-meningitis-outbreak.

124. Goldman, *supra* note 114, at 3.

125. Megan McCracken & Jennifer Moreno, Opinion, *Secret Drugs, Agonizing Deaths*, N.Y. TIMES (Apr. 13, 2014), http://www.nytimes.com/2014/04/14/opinion/secret-drugs-agonizing-deaths.html.

heavily" and that "[h]is eyes remained opened throughout."[126] It was later discovered that the pentobarbital used to execute Robert "was contaminated with fungus."[127] In January 2014, Oklahoma also experienced problems with compounded pentobarbital when it executed Michael Lee Wilson.[128] Shortly after being injected Wilson declared, "I feel my whole body burning."[129] While it was never discovered whether the compounded pentobarbital used in Wilson's execution was contaminated, his "reaction [was] consistent with contaminated pentobarbital, which experts explain creates the excruciating sensation of sandpaper scraping the insides of a person's veins."[130]

In light of the turmoil surrounding compounding pharmacies, Congress passed the Drug Quality and Security Act ("DQSA") to expand FDA regulation of the drugs these pharmacies produce. The DQSA is designed "to give the FDA more . . . unambiguous authority over the compounding drug industry."[131] However, it remains unclear "what effect the DQSA will have on improving the safety of compounded drugs," specifically those produced for lethal injections.[132] The DQSA only increases FDA regulation of drugs produced by compounding pharmacies engaged in large-scale manufacturing, leaving regulation of drugs produced by traditional compounding pharmacies "for an identified individual patient based on the receipt of a valid prescription order," to the states.[133] Given this distinction, the DQSA's increased regulations are unlikely to reach the drugs compounded by pharmacies for lethal injection because the states ordering the drugs usually do so with prescriptions.[134]

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126. Dave Kolpack & Kristi Eaton, *S. Dakota Executes Inmate Who Killed Prison Guard*, ASSOCIATED PRESS: BIG STORY (Oct. 16, 2012, 4:42 AM), http://bigstory.ap.org/article/sd-death-row-inmate-be-executed-monday-0.

127. *South Dakota Carries Out Execution Using Contaminated Compounded Drugs*, REPRIEVE (Oct. 17, 2012), http://www.reprieve.org.uk/press/2012_10_17_compound_pharmacy_death_penalty.

128. Charlotte Alter, *Oklahoma Convict Who Felt "Body Burning" Executed with Controversial Drug*, TIME (Jan. 10, 2014), http://nation.time.com/2014/01/10/oklahoma-convict-who-felt-body-burning-executed-with-controversial-drug.

129. *Id.*

130. Berger, *supra* note 113, at 1385 (citing Molly Redden, *New Lethal Injections Could Cause Extreme Pain, Make Deaths "Drag On" for Hours*, MOTHER JONES (Nov. 7, 2013, 7:00 AM), http://www.motherjones.com/politics/2013/11/ohio-lethal-injection-cocktail-execution-drugs).

131. Goldman, *supra* note 114, at 3.

132. Crider, *supra* note 122, at 18.

133. *See* 21 U.S.C. § 353a (2012).

134. *See* Killoran, *supra* note 117 (noting that "[a]s long as these pharmacies are getting prescriptions, even though it's not pursuant to the medical needs of the patient, they are still sort of working within the framework that was set up by Congress"); Ross Levitt & Deborah Feyerick, *Death Penalty States Scramble for Lethal Injection Drugs*, CNN (Nov. 16, 2013, 1:44 PM), http://www.cnn.com/2013/11/15/justice/states-lethal-injection-drugs (discussing a federal civil complaint filed in Texas that alleged officials from the Texas Department of Criminal Justice falsified prescriptions to obtain pentobarbital).

Due to their limitations and lack of oversight, traditional compounding pharmacies cannot be relied upon to produce safe lethal injection drugs. Once again, however, the issue may soon be moot due to significant external pressures. In February 2014, attorneys for Michael Taylor, an inmate on death row in Missouri, filed a lawsuit against The Apothecary Shoppe, an Oklahoma compounding pharmacy, for supplying drugs across state lines to Missouri's Department of Corrections.[135] As one commentator noted, such litigation "is a shot across the bow of compounding pharmacies[.] . . . [If] they're doing things across state lines that they don't have full permission for, if they're not fully licensed, [or] if they have had some sanctions in the past[,] . . . those things are going to come out."[136] Then, in March 2015, both the International Academy of Compounding Pharmacists and the American Pharmacist Association publicly discouraged their members from compounding drugs for executions.[137] Thus, in light of these problems and external pressures, the use of lethal injection drugs manufactured by compounding pharmacies is not a viable solution to the *Cook* decision.

C. RETURNING TO PAST METHODS OF EXECUTION

Perhaps the most extreme way in which states have responded to the *Cook* decision is to pass legislation mandating a return to past methods of execution in the event that correctional facilities are unable to procure the necessary drugs. For example, in May 2014, legislators in Tennessee passed a law requiring death row inmates to be executed by electric chair if "[one] or more of the ingredients essential to carrying out a sentence of death by lethal injection is unavailable."[138] The law was the first of its kind.[139] While several states have laws on their books allowing "[p]risoners [to] choose between injection or sanctioned alternatives,"[140] no state had ever gone so far as to

135. Laura Sullivan, *Missouri Execution Stalled Over Lethal Drugs in Short Supply*, NPR (Feb. 18, 2014, 6:39 PM), http://www.npr.org/2014/02/18/279216377/missouri-execution-stalled-over-lethal-drugs-in-short-supply. In 2015, the FDA investigated The Apothecary Shoppe and discovered "more than a thousand pharmaceutical violations," forcing the compounding pharmacy to auction off its assets. Chris McDaniel, *Pharmacy That Mixed Executions Drugs Is Being Sold After Admitting Numerous Violations*, BUZZFEED NEWS (Apr. 21, 2016, 9:45 PM), https://www.buzzfeed.com/chrismcdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc.

136. Sullivan, *supra* note 135.

137. Press Release, Int'l Acad. of Compounding Pharmacists, IACP Seeks to Ensure Patient Access to Vital Compounded Medications in Comments to FDA (July 21, 2015), http://c.ymcdn.com/sites/www.iacprx.org/resource/resmgr/Media/072115_IACP_MOU_comment_rele.pdf; Tracy Connor, *Pharmacy Groups Balk at Supplying Lethal Injection Drugs*, NBC NEWS (Mar. 31, 2015, 9:56 AM), http://www.nbcnews.com/news/us-news/pharmacy-groups-balk-supplying-lethal-injection-drugs-n332656.

138. TENN. CODE ANN. § 40-23-114(e)(2) (2015); *see also* Lindsey Bever, *Tennessee's New Law Brings Back Electric Chair*, WASH. POST (May 23, 2014), https://www.washingtonpost.com/news/morning-mix/wp/2014/05/23/tennessees-new-law-brings-back-electric-chair.

139. Bever, *supra* note 138.

140. Niraj Chokshi, *Map: How Each State Chooses to Execute Its Death Row Inmates*, WASH. POST

mandate the use of a sanctioned alternative if lethal injection became impossible.[141] The main sponsor of the law, state Senator Ken Yager, said it was necessary due to "a real concern that we could find ourselves in a position that if the chemicals were unavailable to us that we would not be able to carry out the sentence."[142] Alabama and Virginia considered a similar mandate, though neither state ultimately passed it into law.[143]

Since Tennessee's electric chair mandate, several states have considered statutes requiring execution by firing squad if lethal injection drugs become unavailable. In September 2014, legislators in Wyoming debated passing a firing squad mandate, with one of the leading proponents arguing that, "[i]f we are going to continue to have the death penalty, then we are going to have to have an available secondary form of execution."[144] The legislative session ended, however, before any action could be taken.[145] Arkansas, South Carolina, and Missouri also briefly considered such a mandate.[146] In March 2015, Utah became the first state to pass a firing squad mandate.[147] Utah's

(Apr. 30, 2014), https://www.washingtonpost.com/blogs/govbeat/wp/2014/04/30/map-how-each-state-chooses-to-execute-its-death-row-inmates ("Prisoners can choose between injection or sanctioned alternatives in six states—Alabama, California, Florida, South Carolina, Virginia and Washington. In California, the alternative is lethal gas and in Washington it's hanging. In the rest, it's electrocution.").

141. Mark Berman, *Tennessee Has Long Had the Electric Chair, but Now It's Going to Be Available for More Executions*, WASH. POST (May 23, 2014), https://www.washingtonpost.com/news/post-nation/wp/2014/05/23/tennessee-has-long-had-the-electric-chair-but-now-its-going-to-be-available-for-more-executions.

142. Ed Pilkington, *Tennessee Brings Back Electric Chair While Wyoming Considers Firing Squad*, GUARDIAN (May 22, 2014), http://www.theguardian.com/world/2014/may/22/wyoming-drafts-bill-reintroduce-firing-squads-execution.

143. Kim Bellware & Willa Frej, *Virginia Governor Scraps Electric Chair Law*, HUFFINGTON POST (Apr. 10 2016, 8:18 PM), http://www.huffingtonpost.com/entry/virginia-electric-chair-law-decision_us_570ab2eae4b0885fb50d5db2; Brian Lyman, *Electric Chair Won't Come Back to Alabama*, MONTGOMERY ADVERTISER (June 4, 2015, 12:28 AM), http://www.montgomeryadvertiser.com/story/news/politics/southunionstreet/2015/06/03/electric-chair-come-back-alabama/28442249.

144. Dan Frosch, *Wyoming Considers Firing Squad as Death-Row Backup*, WALL STREET J. (Jan. 25, 2015, 8:00 PM), http://www.wsj.com/articles/wyoming-considers-firing-squad-as-death-row-backup-1422230396.

145. Dan Frosch, *Utah Passes Bill Allowing Execution by Firing Squad*, WALL STREET J. (Mar. 11, 2015, 12:04 PM), http://www.wsj.com/articles/utah-lawmakers-pass-bill-allowing-firing-squads-for-executions-1426035376.

146. Kim Bellware, *As Arkansas Moves to Abolish Death Penalty, Lawmaker Shoots Back with Firing Squad Proposal*, HUFFINGTON POST (Mar. 2, 2015), http://www.huffingtonpost.com/2015/02/27/arkansas-firing-squad_n_6764518.html; Tony Burbeck, *SC Lawmaker Proposes 'Death by Firing Squad' for Death Row Inmates*, WCNC (Apr. 23, 2015, 8:11 PM), http://www.wcnc.com/news/politics/sc-lawmaker-proposes-death-by-firing-squad-for-death-row-inmates/21322880 8; Alex Stuckey, *Missouri Bill Would Allow Execution Using Firing Squad*, ST. LOUIS POST-DISPATCH (Jan. 17, 2014), http://www.stltoday.com/news/local/govt-and-politics/missouri-bill-would-allow-execution-using-firing-squad/article_2a60d84c-f66b-5262-9da9-bb2a59264c81.html.

147. Terrence McCoy, *Why Utah's 'Gruesome' Firing Squads Might Not Be Such a Bad Alternative*, WASH. POST (March 24, 2015), https://www.washingtonpost.com/news/morningmix/wp/2015/03/24/why-utahs-gruesome-firing-squads-might-not-be-such-a-bad-alternative.

mandate requires death row inmates to be executed by firing squad if "the state is unable to lawfully obtain the substance or substances necessary to conduct an execution by lethal intravenous injection" within 30 days of the execution date.[148] Utah Governor Gary Hubert remarked that, while execution by firing squad is "a little bit gruesome,"[149] the state "need[ed] to have a fallback" due to the lethal injection drug shortage.[150]

Only one state has mandated the use of gas chambers in the event that it is unable to procure lethal injection drugs. In April 2015, Oklahoma Governor Mary Fallin signed into law a bill requiring "the sentence of death [to] be carried out by nitrogen hypoxia" if execution by lethal injection is "otherwise unavailable."[151] While Oklahoma's mandate, like those passed by Tennessee and Utah, continues the trend of returning to a past method of execution, it also includes a significant twist: nitrogen gas has never before been used to execute humans.[152] Oklahoma's decision to use a new type of gas[153] mirrored its decision to use lethal injection in 1977.[154] Oklahoma state legislator Mike Christian asked Michael Copeland, a professor of criminal justice at East Central University in Oklahoma, to conduct a study regarding the efficacy of using nitrogen gas for executions.[155] The report concluded nitrogen hypoxia was "a humane and dignified process to achieve death"[156] and the Oklahoma legislature almost unanimously voted to adopt it as a backup to lethal injection.[157] Upon its passage, Christian declared nitrogen hypoxia to be "foolproof."[158]

The appeal of returning to older methods of execution is clear. Unlike with lethal injection, anti-death penalty advocates would have trouble restricting the supply of the means needed to carry out executions by electric

148. UTAH CODE ANN. § 77-18-5.5(4) (Supp. 2015).

149. Lauren Gambino, *Utah Governor Signs Law Bringing Back Firing Squad for Executions*, GUARDIAN (Mar. 23, 2015, 7:08 PM), http://www.theguardian.com/us-news/2015/mar/23/utah-governor-firing-squad-executions.

150. Tracy Connor, *Utah Governor Gary Herbert 'Leaning Toward' Firing Squad*, NBC NEWS (Mar. 19, 2015, 9:41 PM), http://www.nbcnews.com/news/us-news/utah-governor-gary-herbert-leaning-toward-firing-squad-n326711.

151. H.B. 1879, 55th Leg., 1st Reg. Sess. (Okla. 2015); *see also Oklahoma Governor Signs 'Foolproof' Nitrogen Gas Execution Method*, GUARDIAN (Apr. 17, 2015, 7:06 PM), http://www.theguardian.com/us-news/2015/apr/17/oklahoma-nitrogen-execution-method-death-penalty.

152. *Oklahoma Governor Signs 'Foolproof' Nitrogen Gas Execution Method*, *supra* note 151.

153. Maurice Chammah et al., *After Lethal Injection*, MARSHALL PROJECT (June 1, 2015, 7:15 AM), https://www.themarshallproject.org/2015/06/01/after-lethal-injection.

154. *See supra* notes 10–13 and accompanying text.

155. Chammah et al., *supra* note 153; Jack Shuler, *Can Executions Be More Humane?*, ATLANTIC (Mar. 20, 2015), http://www.theatlantic.com/politics/archive/2015/03/can-executions-be-more-humane/388249.

156. MICHAEL COPELAND ET AL., NITROGEN INDUCED HYPOXIA AS A FORM OF CAPITAL PUNISHMENT 10 (2015), https://localtvkfor.files.wordpress.com/2015/03/nitrogen-hypoxia.pdf.

157. *Oklahoma Governor Signs 'Foolproof' Nitrogen Gas Execution Method*, *supra* note 151.

158. *Id.*

chair, firing squad, or gas chamber.[159] In addition, many experts argue that, in light of the recent botched executions, these alternate methods may actually be more humane than lethal injection.[160] Indeed, when Oklahoma adopted nitrogen hypoxia as its primary backup to lethal injection, Christian cited these two benefits, availability and humaneness, as the primary justifications for the switch.[161] While no one has seriously argued that the electric chair is a more humane method of execution than lethal injection,[162] many commentators contend that death by firing squad is perhaps the most humane form of execution.[163] As Fordham Law School professor and death penalty expert Deborah Denno writes, "there is only one method of execution

159. As Ohio state Senator Bill Seitz remarked, "[w]e've got plenty of electric and plenty of rope." Andrew Welsh-Huggins, *Lethal Drug Shortage Has Some U.S. Death Penalty Supporters Thinking Electrocution, Firing Squad*, STAR (Oct. 20, 2015), https://www.thestar.com/news/world/2015/10/20/lethal-drug-shortage-has-some-us-death-penalty-supporters-thinking-electrocution-firing-squad.html.

160. *See, e.g.*, Tracy Connor, *Firing Squad to Gas Chamber: How Long Do Executions Take?*, NBC NEWS (Mar. 25, 2015, 6:05 PM), http://www.nbcnews.com/news/us-news/firing-squad-gas-chamber-how-long-executions-take-n329371 (noting that "some proponents [of the firing squad] say[] it's the fastest and most humane way of killing"); Austin Sarat, *The Trouble with Oklahoma's New Execution Technique*, POLITICO MAG. (Apr. 20, 2015), http://www.politico.com/magazine/story/2015/04/oklahoma-death-penalty-gas-chamber-117156 (calling the use of nitrogen hypoxia for execution "painless and humane" and noting that, although lethal injection was initially intended to be "more humane relative to other methods," failure rates demonstrate that it is not).

161. Mark Berman, *Oklahoma Says It Will Now Use Nitrogen Gas as Its Backup Method of Execution*, WASH. POST (Apr. 17, 2015), https://www.washingtonpost.com/news/post-nation/wp/2015/04/17/oklahoma-says-it-will-now-use-nitrogen-gas-as-its-backup-method-of-execution. In a statement, "Christian called nitrogen hypoxia 'practical, efficient and humane'" and stated that "[t]here is no way for death penalty opponents to restrict its supply." *Id.*

162. *See* Denno, *supra* note 13, at 62–63. As one commenter noted:

> [E]lectric-chair deaths are some sort of combination of asphyxiation and cardiac arrest, and the nervous system is usually paralyzed. The body tenses up—sometimes violently—and inmates often defecate. Smoke and steam rise out of the body probably because the inmate's blood is boiling. The inmate's temperature become so hot, flesh falls off if someone touches the body, and the inmate usually receives third and fourth-degree burns under the electrode cap. . . . "Sometimes the eyeballs can pop out.". . . The body can also bleed because of the pressure of the expanding tissue. . . . "It's horrible, but it's really like the body is cooking."

Grace Wyler, *This Is How You Die in an Electric Chair*, VICE (May 25, 2014), http://www.vice.com/read/how-you-die-in-an-electric-chair.

163. *See, e.g.*, P. Thomas DiStanislao, III, Comment, *A Shot in the Dark: Why Virginia Should Adopt the Firing Squad as its Primary Method of Execution*, 49 U. RICH. L. REV. 779, 797, 801 (2015) (suggesting that "the most favorable [method of execution is] firing squads" because "execution by firing squad is both more reliable and more 'humane'"); Patrik Jonsson, *Utah Firing Squad Decision: Could It Actually Make Death Penalty More Humane?*, CHRISTIAN SCI. MONITOR (Mar. 11, 2015), http://www.csmonitor.com/USA/Justice/2015/0311/Utah-firing-squad-decision-Could-it-actually-make-death-penalty-more-humane-video ("People say firing squad is so brutal, but . . . it's probably the most humane, it kills people the quickest, and it's one we have expertise for."); Erin McCann, *Why Did Utah Bring Back the Firing Squad? How the U.S. Kills People in 2015*, GUARDIAN (Mar. 24, 2015, 5:46 PM), http://www.theguardian.com/world/2015/mar/24/utah-execution-firing-squad-death-penalty ("[Death by firing squad] sounds like the wild west, but it's probably the most humane way to kill somebody."); McCoy, *supra* note 147 ("[T]he firing squad . . . may even be the most humane of all methods.").

that merits a positive rating: the firing squad. This method stands alone because it is the only one that involves experts specifically trained to kill human beings as well as a record of relative speed and certainty."[164]

While turning back the clock and "reviving older methods of execution"[165] may be appealing to states facing the lethal injection drug shortage, the harm caused by such a decision outweighs the benefits. Lethal injection is the primary method of execution in all states[166] for a reason: the public perceives execution by electric chair, gas chamber, and even firing squad to be far more barbaric and inhumane.[167] For instance, after witnessing his brother, Ronnie Lee Gardner, become the latest person to be executed by firing squad in 2010, Randy Gardner described the process and having to "see[] his brother's bullet-riddled body" as "pretty barbaric."[168] Similarly, watching the "reactions and resistance for the first time" to death by nitrogen hypoxia would likely lead to the same conclusion.[169] Inmates facing execution clearly share the public's perception as they "have overwhelmingly chosen lethal injection over alternative methods such as hangings, firing squads, or electrocution when given a choice."[170] Ultimately, as Jay Chapman, the creator of the original lethal injection protocol, has said, if lethal injection is "administered correctly" there is "[nothing] that is more humane."[171] Thus, a return to past methods of execution is not a viable solution to the *Cook* decision.

D. IGNORING THE FDA'S RESTRICTIONS

The most recent way in which states have responded to the *Cook* decision is by ignoring the FDA's restrictions. Though the *Cook* decision effectively prohibited the importation of sodium thiopental, states like Nebraska and Ohio have continued to seek out foreign producers.[172] On May 14, 2015,

164. Deborah W. Denno, *Kill Lethal Injection and Bring Back the Firing Squad*, TIME (Apr. 28, 2015), http://time.com/3831515/execution-lethal-injection-supreme-court.

165. Fan, *supra* note 32, at 457.

166. *See supra* note 20 and accompanying text.

167. *See* Frank Romanelli et al., *Issues Surrounding Lethal Injection as a Means of Capital Punishment*, 28 PHARMACOTHERAPY 1429, 1430 (2008) ("The popularity of lethal injection as a means of execution is supported by a belief that it is a more humane method compared with other options.").

168. Brady McCombs & Lindsay Whitehurst, *Brother of Man Executed by Utah Firing Squad Calls It Brutal*, YAHOO! NEWS (Mar. 12, 2015), http://news.yahoo.com/frustration-pushes-utah-toward-renewed-firing-squads-090004298.html.

169. Josh Sanburn, *The Dawn of a New Form of Capital Punishment*, TIME (Apr. 17, 2015, 4:51 PM), http://time.com/3749879; *see also* Chammah et al., *supra* note 153 ("There is a huge difference between someone accidentally (or intentionally) breathing pure nitrogen, versus forcing them to breathe it. We have absolutely no evidence about what will happen if a human being is thrashing and breaking the seal of his mask, or refusing to breathe, which might delay the whole thing and lead to carbon dioxide painfully accumulating in his lungs.").

170. Fan, *supra* note 32, at 458.

171. Sanburn, *supra* note 10.

172. Andrew Welsh-Huggins, *Ohio Looks Overseas in Search for Lethal Drugs*, MSN (July 3,

Nebraska Governor Pete Ricketts announced that the state had purchased 1,000 vials of sodium thiopental from Harris Pharma ("Harris"), a pharmaceutical company based out of Kolkata, India.[173] Email communications from Harris to the Nebraska Department of Correctional Services ("NDCS"), obtained by the American Civil Liberties Union of Nebraska via a Freedom of Information Act ("FOIA") request, revealed that Harris was selling the drug to "a few other states" in addition to Nebraska.[174] Then, in June a report surfaced that the Ohio Department of Rehabilitation and Correction ("ODRC") planned to import sodium thiopental from an unidentified foreign source.[175]

The FDA responded by sending letters to the respective heads of the NDCS and ODRC and Harris. The letters reminded all parties involved that, in *Beaty*, the district court had "permanently enjoined FDA from permitting the entry of, or releasing any future shipments of, foreign manufactured sodium thiopental that appears to be misbranded or an unapproved new drug" and "that there is no FDA approved application for sodium thiopental" in the United States.[176] The DEA issued a separate statement explaining that "[t]he DEA is in sync with the FDA on the importation of barbiturate anesthetics such as sodium thiopental from foreign companies. We allow their importation if they come from an FDA-approved source."[177] Nebraska never

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2015), http://www.msn.com/en-us/news/crime/ohio-looks-overseas-in-search-for-lethal-drugs/ar-AAcwdKh.

173. Shubhankar Chhokra, *Nebraska's Death Penalty Fight Isn't Over*, NAT'L REV. (June 11, 2015, 11:01 AM), http://www.nationalreview.com/article/419625/nebraskas-death-penalty-fight-isnt-over-shubhankar-chhokra; Paul Hammel & Martha Stoddard, *Nebraska Has Purchased Drugs Necessary for Lethal Injections, Gov. Ricketts Says*, OMAHA WORLD-HERALD (May 14, 2015), http://www.omaha.com/news/crime/nebraska-has-purchased-drugs-necessary-for-lethal-injections-gov-ricketts/article_3423d60a-fa8c-11e4-a761-1f25f74fc5ba.html.

174. Chris McDaniel, *Federal Official: More than One State Has Bought Illegal Execution Drugs from a Foreign Supplier*, BUZZFEED NEWS (June 26, 2015, 6:18 PM), http://www.buzzfeed.com/chrismcdaniel/federal-official-more-than-one-state-has-bought-illegal-exec.

175. Chris McDaniel, *Ohio Intended to Illegally Import Execution Drugs, FDA Letter Says*, BUZZFEED NEWS (Aug. 18, 2015, 6:19 PM), http://www.buzzfeed.com/chrismcdaniel/ohio-intended-to-illegally-import-execution-drugs-fda-letter. An ODRC spokesperson would neither confirm nor deny whether the state had purchased the drugs from Harris. *Id.*; *see also* Chris McDaniel & Tasneem Nashrulla, *This Is the Man in India Who Is Selling States Illegally Imported Execution Drugs*, BUZZFEED NEWS (Oct. 20, 2015, 1:54 PM), http://www.buzzfeed.com/chrismcdaniel/this-is-the-man-in-india-who-is-selling-states-illegally-imp.

176. Letter from Domenic J. Veneziano, Dir., Div. of Imp. Operation, U.S. Pub. Health Serv., to Gary C. Mohr, Dir., Ohio Dep't of Rehab. & Corr. (June 26, 2015), http://www.dispatch.com/content/downloads/2015/08/FDA_letter_to_Ohio_on_execution_drugs.pdf; Letter from Thaddeus Poplawski on behalf of Domenic J. Veneziano, Dir., Div. of Imp. Operation, U.S. Pub. Health Serv., to Scott R. Frankes, Dir., Neb. Dep't of Corr. Servs. (May 28, 2015) (on file with author); Letter from Domenic J. Veneziano, Dir., Div. of Imp. Operation, U.S. Pub. Health Serv., to Chris Harris, CEO, Harris Pharma LLP (May 28, 2015) (on file with author).

177. *#NEWS: DEA "in Lockstep" with FDA, Will Not Allow Nebraska to Import Execution Drug*, NAT'L COALITION TO ABOLISH DEATH PENALTY (June 16, 2015), http://www.ncadp.org/blog/entry/news-dea-in-lockstep-with-fda-will-not-allow-nebraska-to-import-lethal-inje.

received the sodium thiopental it purchased from Harris[178] and passed a law abolishing the death penalty, though voters opted to repeal that law in November 2016.[179] Ohio did not follow through on its plan to import sodium thiopental and announced in October 2016 that it had revised its execution protocol, switching from sodium thiopental back to midazolam.[180]

In July 2015, two more states, Texas and Arizona, attempted to import sodium thiopental from Harris.[181] While details of the Texas Department of Criminal Justice's ("TDJC") transaction with Harris are confidential under state law, the details of the Arizona Department of Corrections ("ADOC") contract, obtained by the *Arizona Republic* via a FOIA request, reveal that the terms were very similar to the terms Harris agreed to with Nebraska.[182] However, when the shipments arrived in Houston and Phoenix, respectively, they were flagged by the FDA and detained by Customs and Border Protection ("CBP").[183] Both Texas and Arizona demanded that the FDA immediately release the shipments, but the FDA refused.[184] An FDA statement reiterated that the "FDA has determined that this shipment should not be allowed to move to [its] destination at this time and thus will not be requesting that CBP lift its detention."[185] As of July 2015, the TDJC was "going through internal proceedings set up for addressing the lawful status of imports with the FDA and is awaiting their decision."[186] The ADOC also appealed the FDA's

178. Chris McDaniel & Tasneem Nashrulla, *$25,000 Shipment of Illegal Execution Drugs to Nebraska Gets Held Back in India*, BUZZFEED NEWS (Sept. 17, 2015, 11:15 AM), https://www.buzzfeed.com/chrismcdaniel/illegal-execution-drugs-held-in-india. Harris attempted to ship the drugs in August but FedEx returned them before they left the country due to "improper or missing paperwork." *Id.*

179. Julie Bosman, *Nebraska to Vote on Abolishing Death Penalty After Petition Drive Succeeds*, N.Y. TIMES (Oct. 16, 2015), http://www.nytimes.com/2015/10/17/us/politics/nebraska-to-vote-on-abolishing-death-penalty-after-petition-drive-succeeds.html; Josh Sanburn, *Nebraska Restores the Death Penalty One Year After Eliminated It*, TIME (Nov. 9, 2016), http://time.com/4563703/nebraska-restores-death-penalty-election.

180. Chris McDaniel, *Ohio Plans to Return to Its Controversial Execution Sedative*, BUZZFEED NEWS (Oct. 2, 2016, 12:19 PM), https://www.buzzfeed.com/chrismcdaniel/ohio-to-return-to-its-controversial-execution-sedative.

181. Chris McDaniel & Chris Geidner, *Arizona, Texas Purchased Execution Drugs Illegally Overseas, but FDA Halts the Import*, BUZZFEED NEWS (Oct. 22, 2015, 6:24 PM), http://www.buzzfeed.com/chrismcdaniel/arizona-texas-purchased-execution-drugs-illegally. Health Biotech Limited, a pharmaceutical company in India, manufactured the sodium thiopental sold by Harris to Texas and Arizona. Tasneem Nashrulla et al., *Three States Bought Illegal Execution Drugs from Supplier in India*, BUZZFEED NEWS (Oct. 23, 2015, 4:23 PM), http://www.buzzfeed.com/tasneemnashrulla/three-states-bought-illegal-execution-drugs-from-supplier-in.

182. Michael Kiefer, *Arizona Again Tries to Illegally Import Execution Drug*, ARIZ. REPUBLIC (Oct. 23, 2015, 9:27 AM), http://www.azcentral.com/story/news/arizona/investigations/2015/10/22/arizona-corrections-import-thiopental-illegal-execution-drug/74406580.

183. Nashrulla et al., *supra* note 181.

184. *Id.*

185. *Id.*

186. *Id.* A FDA spokesperson described the internal appeals process in the following way:

> The FDA will follow standard importation procedures, which allow for the importer

decision[187] and threatened to "sue if the FDA [does] not release the drugs."[188] Thus, it is clear, based on this strict enforcement, that ignoring the FDA's regulations is not a viable solution to the *Cook* decision.

IV. POTENTIAL SOLUTIONS TO THE D.C. CIRCUIT'S DECISION IN *COOK V. FDA*

In light of states' collective failure to circumvent the *Cook* decision, this Part argues that these states should focus on regaining access to sodium thiopental. It offers two potential solutions to the FDA's ban on the importation of sodium thiopental: Part IV.A explores the possibility of simply adhering to the FDA's regulations, while Part IV.B details the possibility of litigating against the FDA. This Part ultimately recommends the latter as the best solution to the *Cook* decision.

A. ADHERE TO THE FDA'S REGULATIONS

The first potential solution is for states to simply adhere to the FDA's regulations and import sodium thiopental according to the requirements of section 381(a) of the FDCA. Arizona, Texas, Ohio, and Nebraska have aggressively pursued this solution, contracting with FDAImports.com—a firm that "assists with importation of drugs and other FDA-regulated items"[189]—to guide them through the process of legally importing sodium thiopental.[190] In a letter to the FDA, presumably drafted with the assistance of FDAImports.com, Ohio accurately summarized the importation requirements under section 381(a):

> [I]mportation of sodium thiopental is not prohibited provided that: (1) the source of the sodium thiopental is an FDA-registered source, subject to FDA regulation and inspection; (2) the FDA-registered source of the sodium thiopental must have submitted sodium thiopental on its list of drugs in commercial distribution to the United States with the FDA; (3) the sodium thiopental is not

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> of the detained products to offer testimony as to why the shipment is in compliance with the [FDCA] and should not be refused entry. FDA will evaluate the importer's response and will determine if the product should be refused entry. . . . FDA will notify the importer once the evaluation is complete.

Chris Geidner & Chris McDaniel, *States Lawyer Up, Looking to Find a Way to Buy Execution Drugs From Overseas*, BUZZFEED NEWS (Oct. 26, 2015, 12:24 PM), http://www.buzzfeed.com/chrisgeidner/states-lawyer-up-looking-to-find-a-way-to-buy-execution-drug.

187. *Arizona Appeals Against FDA Seizure of Execution Drug*, GUARDIAN (Oct. 28, 2015, 3:06 PM), http://www.theguardian.com/us-news/2015/oct/28/arizona-appeals-fda-seizure-execution-drug.

188. Chris McDaniel & Chris Geidner, *Arizona Enlists Major Law Firm to Import Execution Drugs from India*, BUZZFEED NEWS (Jan. 28, 2016, 4:03 PM), http://www.buzzfeed.com/chrismcdaniel/arizona-enlists-major-law-firm-to-import-execution-drugs-fro.

189. Geidner & McDaniel, *supra* note 186.

190. Chris McDaniel & Chris Geidner, *Former FDA Investigator Now Backing Four States' Execution Drug Import Efforts*, BUZZFEED NEWS (Dec. 9, 2015, 6:30 PM), http://www.buzzfeed.com/chrismcdaniel/former-fda-investigator-consulting-states.

misbranded; (4) the sodium thiopental is not adulterated; and (5) the FDA examines the shipment to determine if any of the conditions outlined in 21 U.S.C. 381(a) exist.[191]

In theory, Arizona, Texas, Ohio, and Nebraska must simply ensure that Harris meets these requirements in order to legally import sodium thiopental from the company. Operating under that assumption, Nebraska hired FDAImports.com in July 2015 to cure the apparent legal deficiencies in Harris's importation process by registering Harris as an overseas supplier of sodium thiopental.[192] FDAImports.com then confirmed in September that it had submitted the necessary registration and product listing forms.[193] The status of these forms is unclear, though Governor Ricketts announced in December 2015 that Nebraska "will wait to . . . make additional efforts to acquire drugs" until after the state's death penalty referendum in November 2016.[194]

While in theory this compliance-based solution is easily implemented, the reality is that it will be extremely difficult to legally import sodium thiopental under the FDA's regulations. The difficulties stem from the nature of Harris's business and the current status of sodium thiopental in the United States. The nature of Harris's business complicates registration because Harris does not actually manufacture the sodium thiopental that it is selling.[195] Rather it is effectively operating as a middleman, purchasing the drugs from another company in India, called Health Biotech Limited, and marketing them as its own.[196] As a result, Harris does not appear to have an established base of operations that the FDA can readily inspect, which is a requirement for registration.[197] More importantly, the status of sodium thiopental in the

191. Letter from Stephen C. Gray, Chief Counsel & Managing Dir. of Risk Mgmt., Ohio Dep't of Rehab. & Corr., to Domenic J. Veneziano, Dir., Div. of Imp. Operation, U.S. Pub. Health Serv. (Oct. 9, 2015), http://www.documentcloud.org/documents/2623216-drc-to-fda-9-oct-2015.html.

192. Chris McDaniel & Chris Geidner, *Nebraska Paid Outside Lawyer to Register Overseas Execution Drug Supplier with FDA*, BUZZFEED NEWS (Nov. 8, 2015, 10:04 PM), https://www.buzzfeed.com/chrismcdaniel/nebraska-paid-outside-lawyer-to-register-overseas-execution.

193. *Id.*

194. Joe Duggan, *Ricketts Stops Trying to Import Death Penalty Drugs for Now*, OMAHA WORLD-HERALD (Dec. 7, 2015), http://www.omaha.com/news/nebraska/ricketts-stops-trying-to-import-death-penalty-drugs-for-now/article_85e2a404-9ae5-11e5-8d92-777450 6a50cb.html. As noted above, voters decided to reinstate the death penalty, though it remains unclear whether Nebraska intends to renew its efforts to obtain sodium thiopental. Sanburn, *supra* note 179.

195. Nashrulla et al., *supra* note 181.

196. *Id.* A Health Biotech employee claimed that the company did not know what Harris did with the products after purchasing them. *Id.* This is a common refrain among pharmaceutical companies that Harris has bought sodium thiopental from and one of the main reasons why states cannot simply cut Harris out as the middleman: plausible deniability. *See* McDaniel & Nashrulla, *supra* note 175 (detailing Harris's transactions with various pharmaceutical companies).

197. Nashrulla et al., *supra* note 181 ("BuzzFeed News traveled to Harris's business locations in August and discovered the facility he registered with the FDA as a facility that manufactures or processes drugs is actually a small rented office, and that the business address he lists on Drug

United States complicates registration because the FDA has repeatedly stated "that there is no FDA approved application for sodium thiopental" in the United States.[198] Consequently, "even if you have every permit, import license, registration, [and] everything else," it is unlikely sodium thiopental could be legally imported because "the drug has to be approved in the U.S., and right now sodium thiopental isn't."[199] Thus, adhering to the FDA's regulations is unlikely to result in renewed access to sodium thiopental.

B. LITIGATE THE FDA'S REGULATIONS

The second solution is for states to challenge the constitutionality of the FDA's regulations as applied to the importation of sodium thiopental under the Tenth Amendment. The Tenth Amendment states that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the [s]tates, are reserved to the [s]tates respectively, or to the people."[200] Interpreting this language, the Supreme Court has held that the federal "government is . . . one of enumerated powers. The principle, that it can exercise only the powers granted to it . . . is now universally admitted."[201] In contrast, the Court has determined that under the Tenth Amendment, the states retain plenary police powers, which "have always included authority to define criminal law and to protect the health, safety, and welfare of their citizens."[202] Thus, the Tenth Amendment is fundamental to "our Government's federal structure," because it "secures to citizens the liberties that derive from the diffusion of sovereign power," and solidifies the "divi[sion of] authority between federal and state governments for the protection of individuals."[203]

The fact that states have plenary power over criminal law, secured by the Tenth Amendment, means that states have "primary authority for defining and enforcing the criminal law."[204] As the Supreme Court has stated, "[i]t goes without saying that preventing and dealing with crime is much more the business of the [s]tates than it is of the Federal Government . . . and that we should not lightly . . . intrude upon the administration of justice by the

Enforcement Administration forms is a residential apartment he no longer lives in.").

198. *See supra* note 176 and accompanying text.

199. JoAnne Young, *FDA Spells It Out—Death Drug Illegal*, LINCOLN J. STAR (Nov. 1, 2015), http://journalstar.com/news/local/fda-spells-it-out——death-drug-illegal/article_5b56ffa6-2885-5547-8b56-51aod3a8o89b.html.

200. U.S. CONST. amend. X.

201. United States v. Lopez, 514 U.S. 549, 566 (1995) (quoting McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 405 (1819)).

202. Gonzales v. Raich, 545 U.S. 1, 42 (2005) (O'Connor, J., dissenting); *see also* Eileen M. Connor, *The Undermining Influence of the Federal Death Penalty on Capital Policymaking and Criminal Justice Administration in the States*, 100 J. CRIM. L. & CRIMINOLOGY 149, 154 n.18 (2010) (collecting cases).

203. New York v. United States, 505 U.S. 144, 181 (1992).

204. Brecht v. Abrahamson, 507 U.S. 619, 635 (1993) (quoting Engle v. Isaac, 456 U.S. 107, 128 (1982)).

individual [s]tates."[205] This primary authority over criminal law extends to the administration of criminal sentencing, including the death penalty.[206] As a result, the states have historically been left to their own devices in formulating and implementing the death penalty, so long as they do not run afoul of the cruel and unusual punishment clause of the Eighth Amendment.[207] The Supreme Court recently reaffirmed this principle in *Baze v. Rees*, where it noted that "determining 'best practices' for executions . . . would substantially intrude on the role of state legislatures in implementing their execution procedures—a role that by all accounts the States have fulfilled with an earnest desire to provide for a progressively more humane manner of death."[208]

Under this framework, states could file an as-applied constitutional challenge, arguing that FDA enforcement of section 381(a) of the FDCA infringes on their sovereign prerogatives contrary to the Tenth Amendment. An as-applied constitutional challenge is one "under which the plaintiff argues that a statute, even though generally constitutional, operates unconstitutionally as to him or her because of the plaintiff's particular circumstances."[209] Thus, while section 381(a) is generally constitutional, states could argue that it violates the Tenth Amendment as applied to the importation of sodium thiopental because it requires the FDA to interfere with the states' sovereign power to implement the death penalty. More specifically, the states could argue FDA enforcement of section 381(a) unconstitutionally overrides the states' legislative processes by effectively nullifying the numerous statutes that designate sodium thiopental as the primary anesthetic in lethal-injection protocols. In raising a Tenth Amendment challenge, the states would essentially be raising the "thorny" jurisdiction issue that the Supreme Court declined to address in *Heckler*[210] and the D.C. Circuit ignored in *Cook*.[211]

To buttress their Tenth Amendment argument, the states can cite the consequences of the ban on sodium thiopental importation and argue that these consequences are inconsistent with the Supreme Court's "evolving standards of decency" doctrine. The "evolving standards of decency" doctrine

205. Patterson v. New York, 432 U.S. 197, 201 (1977) (citation omitted).

206. DAVID GARLAND, WHY DOES THE U.S. HAVE CAPITAL PUNISHMENT? 1 (2012), http://photos.state.gov/libraries/amgov/133183/english/P_You_Asked_WhyCapitalPunishment_English.pdf.

207. *See generally* Charles E. MacLean & M. Akram Fazier, *Death Penalty Jurisprudence by Tallying State Legislative Enactments: Harmonizing the Eighth and Tenth Amendments*, 51 CRIM L. BULL. 839 (Summer 2015) (discussing the interaction between the Supreme Court's Eighth Amendment jurisprudence and its Tenth Amendment jurisprudence).

208. Baze v. Rees, 553 U.S. 35, 51 (2008) (plurality opinion).

209. Alex Kreit, *Making Sense of Facial and As-Applied Challenges*, 18 WM. & MARY BILL OF RTS. J. 657, 657 (2010) (quoting Tex. Workers' Comp. Comm'n v. Garcia, 893 S.W.2d 504, 518 n.16 (Tex. 1995)).

210. *See supra* note 58 and accompanying text.

211. *See supra* note 76 and accompanying text.

requires that punishment be in accordance with "the evolving standards of decency that mark the progress of a maturing society."[212] While the Court itself has never invalidated a method of execution under this doctrine, "society has nonetheless steadily moved to more humane methods of carrying out capital punishment."[213] Indeed, as the Court noted in *Baze*, "[t]he firing squad, hanging, the electric chair, and the gas chamber have each in turn given way to more humane methods, culminating in today's consensus on lethal injection."[214] Thus, the Court has effectively delegated enforcement of the "evolving standards of decency" doctrine to the states, allowing "legislatures [to] tak[e] the steps they deem appropriate, in light of new developments, to ensure humane capital punishment."[215]

FDA enforcement of section 381(a) clearly conflicts with the "evolving standards of decency" doctrine and the Court's policy of allowing states to ensure humane capital punishment. First, the enforcement of section 381(a) inhibits the states' ability to ensure humane capital punishment by restricting access to a "mainstay" anesthetic.[216] Second, the consequences of that enforcement—specifically states' decisions to experiment alternative drugs, engage with compounding pharmacies, and return to past methods of execution—have reversed the progress states have made by increasing the risk that inmates will suffer during execution. Ultimately, if the goals for capital punishment in today's society include "ensuring humane executions and preventing suffering,"[217] section 381(a), as applied to the importation of sodium thiopental, should not be upheld. Thus, an as-applied constitutional challenge to section 381(a) is significantly more likely to result in renewed access to sodium thiopental than adherence to section 381(a).

V. CONCLUSION

As the situation currently stands it is clear that "we have a far riskier, more haphazard lethal injection procedure than we ever have had throughout the country."[218] This increased risk can be directly attributed to the D.C. Circuit's decision in *Cook v. FDA*. The FDA's ban on the importation of sodium thiopental under section 381(a) of the FDCA has forced states to turn to less reliable drugs and manufacturers, leading to an increase in botched executions. And, as states give new life to past methods of execution, society

212. Trop v. Dulles, 356 U.S. 86, 101 (1958) (plurality opinion).

213. *Baze*, 553 U.S. at 48, 62 (plurality opinion).

214. *Id.* at 62.

215. *Id.*

216. *See* Lowes, *supra* note 3.

217. Fan, *supra* note 32, at 456.

218. Mark Berman, *The Recent History of States Scrambling to Keep Using Lethal Injections*, WASH. POST (Feb. 19, 2014), https://www.washingtonpost.com/news/post-nation/wp/2014/02/19/the-recent-history-of-states-scrambling-to-keep-using-lethal-injections.

seems to be "moving backward on the evolutionary scale."[219] Thus, states must find a way to legally import sodium thiopental—the most reliable anesthetic available for lethal injection—from foreign suppliers in order to reverse the current trends and bring a measure of reliability back to their lethal injection protocols. The best option for accomplishing that goal is for states to file an as-applied constitutional challenge to section 381(a) of the FDCA and argue that it interferes with the states' sovereign power over criminal law in violation of the Tenth Amendment.

219. Andrew Cohen, *What Happens to the Death Penalty When Lethal Injection Isn't Quick and Painless?*, DAILY BEAST (Jan. 21, 2014, 4:45 AM), http://www.thedailybeast.com/articles/2014/01/21/what-happens-to-the-death-penalty-when-lethal-injection-isn-t-quick-and-painless.html (emphasis omitted).