

Lethal Attack on Lethal Injection: A Proposal to End the Final Loophole in the Death Penalty Debate

Jasmine Sharma*

INTRODUCTION

This Note addresses a very controversial topic in our criminal justice system: capital punishment by lethal injection. Since 2017 state corrections have become desperate to get their hands on lethal injection drugs to continue with execution timelines.¹ As European and other developed nations have come out against capital punishment in their own systems and admonished the United States for continuing to execute death row inmates,² large drug manufacturers have followed suit for strategic business reasons, as well as moral and ethical considerations.³ As large drug manufacturers, which are subject to the FDA regulations standards, refused to sell lethal injection drugs to state corrections that were executing inmates, state corrections reacted in a myriad of ways. First, state corrections attempted to get compounding pharmacies, which are pharmacies that are only subject to state licensing boards that mix and compound generic drugs, to make lethal injection drugs to execute inmates.⁴ Unsurprisingly, since compounding pharmacies are not subject to FDA regulations, the drugs that these compounding pharmacies release into the public are less safe as a result of fewer regulations and more unsafe practices.⁵ These unsafe practices have led to many botched and highly controversial executions.⁶ Second, state legislatures and other state leaders attempted to shield their lethal injection protocols, including the

*. J.D. 2019, Washington University School of Law.

1. Garrett Epps, *Arkansas Wants to Execute Seven Inmates Before Their Drugs Expire*, ATLANTIC (April 13, 2017), <https://www.theatlantic.com/politics/archive/2017/04/arkansas-wants-to-execute-seven-inmates-before-their-drugs-expire/522861/>. See *infra* note 33.

2. Editorial, *Europe's View of the Death Penalty*, N.Y. TIMES (May 13, 2001), <http://www.nytimes.com/2001/05/13/opinion/europe-s-view-of-the-death-penalty.html>.

3. Adam Gabbatt & David Batty, *Danish Firm Lundbeck to Stop US Jails Using Drug for Lethal Injections*, GUARDIAN (July 1, 2011), <https://www.theguardian.com/world/2011/jul/01/lundbeck-us-pentobarbital-death-row>.

4. *Compounding Pharmacies and Lethal Injection*, DEATH PENALTY INFO. CTR., <https://deathpenaltyinfo.org/compounding-pharmacies> (last visited Oct. 19, 2017).

5. Kevin Outterson, *Regulating Compounding Pharmacies after NECC*, 367 NEW ENG. J. MED. 1969 (2012), <http://www.nejm.org/doi/full/10.1056/NEJMp1212667#t=article>.

6. See *infra* notes 77–81, 193.

types of drugs they use, how they were made, and where they come from under broad secrecy laws within each jurisdiction.⁷ This meant that inmates who sued under the First Amendment for the right to know what substance was used to execute them were unsuccessful.⁸

This Note discusses how state corrections have tried to obtain drugs from precarious sources. This Note also proposes to close loopholes that have allowed executions to continue and to eventually eliminate the supply of lethal injection drugs. These loopholes refer to the fact corrections are able to bypass federally regulated lethal injection drugs of major drug manufacturers and gain access through compounding pharmacies. This Note recommends that just as Congress passed an act to increase federal regulation of compounding pharmacies after controversial outbreaks, Congress should also increase federal regulation of compounding pharmacies that sell lethal injection drugs to state manufacturers. This provision would have to overcome state secrecy laws and require compounding pharmacies to register with the FDA. This would subject the drugs to oversight and safer testing mechanisms.

The first part of this Note delves into the history of the death penalty by lethal injection, the most preferred and popular form of execution in the United States by state corrections and state legislatures alike. It will delve into the roles of drug manufacturers, state corrections, compounding pharmacies, as well as the Federal Drug Administration in ending the death by lethal injection. The second part of this Note proposes that Congress should pass legislation in order to make compounding pharmacies that sell to state corrections subject to federal regulations. This proposal would protect inmates' First Amendment rights, make safer drugs, and protect the legitimacy of interstate commerce that should be subject to FDA regulation. The third part of the Note concludes by analyzing other loopholes that may exist and where the death penalty is likely to exist in the foreseeable future. Thus, lifting the veil of secrecy, forcing compounding drugs to be subject to federal regulation, as well as monitoring the use of these drugs would obviate a practical end to death

7. Josh Sanburn, *States Try Secrecy to Protect Lethal Injection Drugmakers*, TIME (Oct. 1, 2014), <http://time.com/3450777/ohio-lethal-injection-secrecy-law-drugs/>.

8. *Id.*

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by lethal injection. The Note then concludes with areas of necessary further research.

I. GENESIS OF LETHAL INJECTION AS A METHOD OF PUNISHMENT

Death by lethal injection is supposedly the most sterile method of execution, which may explain its place as a standard method of execution in the United States.⁹ While execution by lethal injection had been popularized in the late 19th century¹⁰ and World War II, it was not until the late 20th century that lethal injection became a viable method of execution in the United States.¹¹ Lethal injection as a method of execution was first used by Texas in 1982¹² after Oklahoma became the first state to enact legislation adopting such a method to execute prisoners.¹³ Other states quickly followed and adopted lethal injection proposals, which included three drugs in a specific sequence: a barbiturate¹⁴ to anesthetize the prisoner, pancuronium bromide to paralyze the prisoner, and potassium

9. Kate Pickert, *A Brief History of Lethal Injection*, TIME (Nov. 10, 2009), <http://content.time.com/time/nation/article/0,8599,1815535,00.html>. Other methods of execution have included electrocution, gas inhalation, hanging, and firing squad. *Id.* Since 1977, 936 out of 1,107 U.S. prisoners have been executed by lethal injection. *Id.* Since 2000 only 5 inmates have died by the electric chair. *Id.* There are a few states that still have the option of other methods of execution. *Id.* For example, Utah allows for execution by firing squad, Washington allows for execution by hanging, and Arizona allows for execution by gas. *Id.*

10. *Id.* A New York commission on capital punishment suggested injecting drugs as a more humane alternative to executing prisoners but it was later rejected over public concerns it would cause a public scare over associating drug injections with the hypothermic needle. *Id.*

11. *Id.* The Nazis during World War II used lethal injection as a way of getting rid of sick and disabled prisoners in concentration camps during World War II. *Id.* After World War II the United Kingdom proposed and rejected death by lethal injection because of concerns from the medical community. *Id.*

12. *Id.* Texas executed Charles Brooks for murdering a mechanic named David Gregory. *Id.*

13. *Id.* A medical examiner named Jay Chapman proposed the three-drug protocol. *Id.* His proposal was popular because it avoided concerns of the inmates catching on fire from the execution chair and made it easier on witnesses who would execute. *Id.*

14. *Id.* The most popular barbiturate, type of sedative or sleep inducing drug, that state corrections like to use is sodium thiopental. Matt Ford, *Can Europe End the Death Penalty in America?*, ATLANTIC (Feb 18, 2014), <https://www.theatlantic.com/international/archive/2014/02/can-europe-end-the-death-penalty-in-america/283790/>. Sodium thiopental has a shelf life of about four years, which makes stockpiling the drug extremely difficult. *Id.*

chloride to stop the heart of the prisoner.¹⁵ Since then, lethal injection has become the standard method of execution for prisoners who receive the death penalty.¹⁶

Today, capital punishment has become an impediment in diplomatic circles for the United States.¹⁷ World leaders have criticized the United States for its continued use of the death penalty.¹⁸ Meanwhile, the European Union has enshrined its disapproval of capital punishment by refusing extradition of individuals that could be sentenced to death.¹⁹ It was abolished in Germany, Austria, and Italy immediately following World War II.²⁰ The United States is one of the few countries that continue to use the death penalty.²¹

II. CHALLENGES TO LETHAL INJECTION

Death row inmates in *Baze v. Rees*²² brought one of the first challenges to lethal injection. In *Baze*, the Supreme Court agreed to review Kentucky's lethal injection protocol. The Supreme Court held the protocol was consistent with the Eighth Amendment²³ because the petitioners failed

15. Ford, *supra* note 14. A simpler, one-drug protocol was also proposed but was rejected because it too-closely modeled the method of killing animals. *Id.*

16. Pickert, *supra* note 9. The basic method for executing prisoners via lethal injection has remained relatively consistent. *Id.* The prisoner is strapped to a gurney with intravenous lines through their arms. *Id.* An employee or medical professional administers the drug in another room as witnesses are allowed to watch the execution. *Id.* After given the last rites and an opportunity for final words a cardiac monitor indicates when the inmate's heart has stopped and the prisoner is declared dead. *Id.*

17. Editorial, *supra* note 2. Some European countries will refuse to extradite suspected murders, will allow other kinds of suspects to stay in their countries, and allow some allies to vote against American membership in the United States Human Rights Commission. *Id.*

18. *Id.* Felix Rohatyn, an ambassador to France during Clinton's presidency, said French audiences would constantly ask him about America's continued use of the death penalty. *Id.* Frequent use of the death penalty hurts United States legitimacy as a global moral leader. *Id.*

19. *Id.* The European Union will not admit any new country that executes criminals and adheres strongly to promoting anti-death penalty protocols in its foreign relations. *Id.*

20. *Id.* Slowly, European Nations abolished use of the death penalty and signed treaties to enshrine their moral displeasure of the death penalty. *Id.*

21. *Death Penalty 2015: Facts and Figures*, AMNESTY INT'L (April 16, 2016, 6:05 PM), <https://www.amnesty.org/en/latest/news/2016/04/death-penalty-2015-facts-and-figures/>. Currently 22 other countries still use the death penalty as a method of punishment, as of 2014. *Id.* Some include Iran, Pakistan and Saudi Arabia. *Id.*

22. 553 U.S. 35 (2008).

23. *Id.* Justice Stevens' concurrence is often cited in modern anti-death penalty litigation. He

to show that the implementation created a “demonstrated risk of severe pain.”²⁴ After the Supreme Court ruled Kentucky’s protocol constitutional in *Baze*, states attempted to quell litigation even though their inconsistent modifications to their own protocols did not resemble that of the Kentucky protocol.²⁵ States’ protocols that attempted to match Kentucky’s protocol, which included sodium thiopental, was upheld.²⁶

While the Supreme Court has yet to reject death as a form of punishment in the United States, much of society and drug manufacturers have refused to contribute to lethal injection promulgation.²⁷ Many European countries have also been strong opponents of the death penalty.²⁸ As European countries opposed the death penalty, attitudes in the United States started to change as well.²⁹ Drug companies that originally supplied the lethal injection drugs to state corrections started to heed to public pressure, and refused to supply these drugs to execute prisoners.³⁰ In 2011, Lundbeck, a Copenhagen pharmaceutical company, stopped the sale of pentobarbital.³¹ Vince Cable, the Secretary of State for Business, Innovation and Skills in the UK from 2010 to 2015, further banned the exportation of the sodium thiopental.³² In 2009, Hospira, an Illinois based

argued that imposing the death penalty would constitute “pointless and needless extinction of life with only negligible social or public returns.” *Id.* at 87 (Stevens, J., concurring).

24. *Id.* at 61.

25. Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEO. L.J. 1331, 1358 (2014). Here, Denno studied 300 cases citing *Baze*, revealing that states have tried modifying their protocols to quell litigation. *Id.* They did so haphazardly and inconsistently. *Id.* at 1331.

26. *Baze*, 553 U.S. at 53.

27. See *infra* text accompanying note 31.

28. Ford, *supra* note 14. The European Union guidelines called for the complete abolition of the death penalty to contribute to “the enhancement of human dignity and the progressive development of human rights.” *Id.* European Union agencies contribute millions of dollars in donations to anti-death penalty organizations and frequently petition state governors and state parole boards to halt executions. *Id.*

29. *Id.*

30. *Id.*

31. Gabbatt & Batty, *supra* note 3. Lundbeck, Danish drug manufacturer, required U.S. distributors to sign an agreement that they will not sell their drugs, namely pentobarbital (a drug used to treat epileptic seizures), to state corrections. *Id.*

32. Peter Walker, *Vince Cable Restricts Export of Drug Used in US Executions*, GUARDIAN (Nov. 29, 2010), <https://www.theguardian.com/science/2010/nov/29/sodium-thiopental-export-restrictions>. While the drug has legitimate pain medical uses, a “licence will have to be obtained every time the drug is exported and will be refused if the business department has any suspicions it is destined...for the execution chamber.” *Id.*

pharmaceutical company, refused to continue producing sodium thiopental.³³ While initially citing problems with raw-material suppliers, the company eventually cited concerns with continuing to supply lethal injection drugs for moral reasons.³⁴ Since sodium thiopental became more difficult for state corrections to acquire as a result of restricted access, states started changing the original three-drug protocol by using pentobarbital instead of sodium barbital.³⁵ After Lundbeck imposed further controls on pentobarbital as an anesthetic in drug protocols, states started using a one-drug protocol of propofol, another anesthetic.³⁶ However, shortly thereafter, many drug makers like Fresenius Kabi, Teva, and Hospira started restricting their distribution of propofol in their use in executions.³⁷ Arkansas changed their drug protocols to another one-drug protocol using phenobarbital.³⁸ About a month later, the drug company Hikma placed heavy controls on the sale of phenobarbital after learning state corrections were using their drug in their one-drug protocol.³⁹ As a

33. Nathan Koppel, *Drug Halt Hinders Executions in the U.S.*, WALL ST. J (Jan. 22, 2011), <https://www.wsj.com/articles/SB10001424052748704754304576095980790129692>. Hospira was receiving extreme pressure from activist groups who were protesting their production of lethal injection drugs. *Id.* Their final decision to halt lethal injection production came in the face of opposition by the Italian government, where Hospira was planning on putting the new pharmaceutical plant. *Id.*

34. 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&ID=1518610>.

35. *Id.* In 2010, Oklahoma became the first state to execute an inmate using pentobarbital. Lincoln Caplan, *The End of the Open Market for Lethal-Injection Drugs*, NEW YORKER (May 21, 2016), <https://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs>.

36. Caplan, *supra* note 35. Missouri was the first state to replace their three-drug protocol with the one-drug propofol protocol. (I don't see Missouri listed) *Id.* Eight states have used a single-drug method for executions and six other have announced they plan to use the one-drug protocol. *State by State Lethal Injection*, DEATH PENALTY INFORMATION CENTER, <https://deathpenaltyinfo.org/state-lethal-injection> (last visited Oct. 19, 2017).

37. Caplan, *supra* note 35.

38. Caplan, *supra* note 35.

39. *Use of Products in Capital Punishment*, HIKMA, <https://www.hikma.com/about/our-policies/use-of-products-in-capital-punishment/> (last visited Oct. 21, 2018). Hikma, a British pharmaceutical company, sent out an official press release in order to appease their investors and customers. *Id.* “[W]e will not accept orders for these products directly from any Departments of Correction or correctional facilities in the United States, unless accompanied by an original, raised seal copy of an affidavit signed by the state attorney general (or governor).” *Id.* See also Ed Pilkington, British drug company acts to stop its products being used in US executions, THE GUARDIAN, (May 15, 2013), <https://www.theguardian.com/world/2013/may/15/death-penalty-drugs-us-uk>.

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result of this limited supply, state corrections have become desperate⁴⁰ to find lethal injection drugs, drug manufacturers willing to supply these drugs, and new creative protocols.⁴¹

III. DESPERATE TIMES: USING COMPOUNDING PHARMACIES AND FDA OVERSIGHT

As drug manufacturers began to refuse to sell drugs to state corrections, states became desperate to get their hands on the drugs. States have increasingly used compounding pharmacies in order to stay on schedule with executions.⁴² Compounding pharmacies are traditionally pharmacies that mix or alter drugs for individual patients.⁴³ Compounding pharmacies must be licensed within their state's pharmacy board but are not subject to FDA regulations.⁴⁴ While Congress could regulate these compounding pharmacies, it is likely compounding pharmacies will continue to operate without federal oversight.⁴⁵ Since compounding pharmacies that provide drugs within the same state work intra-state and do not deal with issues of interstate commerce, which would subject them to FDA regulation,⁴⁶ the state corrections have been free to utilize these compounding pharmacies

40. Epps, *supra* note 1. "Increasingly, states committed to lethal injection behave like addicts desperate for another fix. They have resorted to such expedients as interfering with contracts, purchasing drugs from sketchy foreign suppliers, and...sending state employees out with bags of cash to buy lethal drugs." *Id.*

41. *Id.* Substitutions for protocols from a lack of supply of lethal injection drugs "meant that inmates were guinea pigs for new forms of lethal injections." Caplan, *supra* note 35. In the past few years, more than twenty-four drug manufacturing companies have blocked, restricted, or halted the sale of lethal injection drugs to state corrections. *Id.*

42. *Compounding Pharmacies and Lethal Injection*, *supra* note 4.

43. *Id.*

44. *Id.* Further, compounding pharmacies do not even have to inform the FDA of what drugs they are making because of the deference to state oversight over federal oversight when dealing with compounding pharmacies. *Id.*

45. *Id.* Congress passed the Drug Quality and Security Act, which President Obama signed into law in late 2013. *Id.* It allows large-scale compounding pharmacies to be subject to FDA regulations. *Id.* Since compounding pharmacies do not produce lethal injection drugs in large-scale quantities, this statute is unlikely to affect the lax state regulation of compounding pharmacies. *Id.* Further, this law was promulgated in an effort to protect health and safety, which illustrates legislative understanding of the health risks of compounding pharmacies. (not supported) *Id.*

46. See Anna B. Laakman, *Customized Medicine and the Limits of Federal Regulatory Power*, 19 VAND. J. ENT. & TECH. L. 285, 288 (2016) (noting that "[the FDA's authority] falls short of the outer limits of the federal commerce power").

for lethal injections, under the protection of secrecy laws.⁴⁷ While compounding pharmacies are usually accredited, it is not required that a compounding pharmacy be accredited to compound drugs, including those used in lethal injection.⁴⁸ Even when accredited, the attendant procedures are significantly less cumbersome than FDA regulations, which raise serious concerns about the safety of compounding pharmacies and its subsequent use in executions.⁴⁹

Specifically, federal authority to regulate compounding pharmacies stems from the Food, Drug, and Cosmetic Act (FDCA).⁵⁰ In 1997, Congress amended the statute to address concerns that compounding pharmacies were acting under the guise of manufacturers and were attempting to thwart federal regulation.⁵¹ The new amendments allow compounding pharmacies to avoid FDA regulation if they meet three of the FDCA provisions.⁵² The FDCA is inapplicable to drug compounding pharmacies that comply with provisions on (1) the sale of a “new drug,” (2) adulteration and the need to adhere to “good manufacturing practices,” and (3) misbranding and the need to provide “adequate directions for use.”⁵³ There are many requirements that FDA applies to compounding pharmacies once under federal regulation.⁵⁴ Specifically, the FDA requires the compounded drugs to be made of FDA approved ingredients, it

47. *Id.*

48. *Id.*

49. *Id.* A compounding pharmacy in 2012, called The New England Compounding Center, was the center of a scandal where it was the site of a fungal meningitis outbreak, which infected over 700 people in 20 states. *Id.* 63 people died from that outbreak. *Id.* The pharmacy was unaccredited and was only subject to state regulation. *Id.*

50. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.*); ANDREW NOLAN, CONG. RESEARCH SERV., R43038, FEDERAL AUTHORITY TO REGULATE THE COMPOUNDING OF HUMAN DRUGS 2 (2013).

51. *Id.* at 5. Congress amended the FDCA through the Food and Drug Administration Modernization Act (FDAMA). *Id.* Specifically, the FDA was concerned “some pharmacists were manufacturing and selling drugs under the guise of compounding,” as a way of avoiding the FDCA’s “new drug,” “adulteration,” and “misbranding” provisions.” *Id.*

52. *Id.*

53. *Id.* at 5–6. Meeting these provisions would not(?) make a compounding pharmacy subject to the FDCA. *Id.*

54. *See id.* at 6. A licensed physician must compound the drugs in response to a valid prescription for an individual patient. *Id.* If the drug is not compounded in response to a prescription, it must be made in “limited quantities” and in response to a “history of the licensed pharmacist’s or physician’s receipt of valid prescription orders for that drug product within an established relationship between the pharmacist, the patient, and the prescriber.” *Id.*

prohibits drugs that appear on the list of withdrawn or removed products, prohibits drugs compounded in “inordinate amounts,”⁵⁵ and allows the FDA to identify and prohibit unsafe and ineffective products.⁵⁶

While Congress has attempted to remedy the safety concerns that emanate from compounding pharmacies that manufacture drugs in bulk, it does not adequately address the lack of safety when compounding pharmacies make individualized drugs for state corrections.⁵⁷ Further, there are other loopholes within the FDCA that allow compounding pharmacies that make lethal injection drugs to sell to state corrections.⁵⁸ Other than safety, there are many other policy levers that weigh in favor of enhancing state regulation.⁵⁹ While states have raised many First Amendment concerns over the promulgation of 503A of the FDCA, the provision of the FDCA that “describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility”,⁶⁰ there are many reasons to extend

55. *Id.* The FDAMA aims to prohibit compounding in “inordinate amounts” in order to make the drugs “essentially copies of a commercially available drug product.” *Id.*

56. *Id.*

57. Sabrina Tavernise, *Bill on Drug Compounding Clears Congress a Year After a Meningitis Outbreak*, N.Y. TIMES (Nov. 18, 2013), http://www.nytimes.com/2013/11/19/us/bill-on-regulating-drug-compounding-clears-senate.html?_r=1&. A year after the meningitis outbreak in the New England compounding pharmacy, Congress passed a bill to increase federal oversight of compounding pharmacies. *Id.* The bill does not force companies to register with the FDA. *Id.* The bill called the “Drug Quality and Security Act” allows compounders that mass-produce compounded drugs to register with the FDA as “outsourcing facilities.” *Id.* Under this law they would be subject to some federal regulation. *Id.* However, those companies that continue to produce under a narrower definition of compounding, i.e. “mixing medicines for individual patients, or limited quantities” would not be subject to the federal oversight and are not required to register with the FDA. *Id.*

58. See Outterson, *supra* note 5. “Section 503A provided a test for distinguishing between the two: it limited interstate shipments to no more than 5% of the compounder’s business, unless the home state had entered into a ‘memorandum of understanding’ with the FDA, bolstering state and federal cooperation.” *Id.* at 1971.

59. *Id.* at 1971–72.

Other policy levers that may be needed include enhanced transparency for state-level regulation, mandatory disclosures to physicians and patients, mandatory reporting of adverse events, user fees to support oversight, clear FDA authority to register and inspect nontraditional compounding pharmacies, enhanced incentives for internal whistleblowers, and modification of reimbursement rules to blunt the economic incentives driving industrial-scale compounding.

Id.

60. *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*:

federal regulation over compounding.⁶¹ Such reasons include enhanced safety and monitoring of these powerful barbiturates.

IV. CHALLENGES TO FDA REGULATION OF COMPOUNDING PHARMACIES

Courts have also examined the extent of the FDA to regulate compounding pharmacies. Very few courts, however, have discussed the extent of FDA regulation of compounding.⁶² According to the plain meaning of the statute, “new drug” and “introduce or deliver for introduction into interstate commerce any new drug” has broad meaning within the FDCA.⁶³ In all three provisions mentioned above, the FDCA gives the FDA broad power to regulate compounding pharmacies.⁶⁴ Currently, the FDA has a variety of factors to provide guidance for when to subject a compounding pharmacy to FDA regulations.⁶⁵

Guidance for Industry, (December 2016), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf>. See also Outterson, *supra* note 5, at 1971.

61. Nolan, *supra* note 47, at 2. States filed suit for a First Amendment violation over 503A advertising provisions that the Supreme Court struck down, see *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002), which created a split among federal circuit courts regarding severability and thus the continued validity of the federal regulation over compounding pharmacies. Compare *Western States Medical Center v. Shalala*, 238 F.3d 1090, 1097 (9th Cir. 2001), *aff'd on other grounds*, 535 U.S. 357 (2002) (finding the provision unseverable) with *Medical Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 401 (5th Cir. 2008) (finding the provision severable).

62. *Id.* at 12. So far, FDA has generally declined to test the current limits of federal authority over the traditional compounding pharmacies. *Id.*

63. *Id.*

64. *Id.* at 9–10. This argument is buttressed by the fact “that because exemptions exist under the FDCA’s provisions for other types of drugs, such “investigational drugs,” one can presume from Congress’s refusal to create a general exemption for traditional compounding an implicit extension of federal authority over all forms of compounding.” *Id.* at 11.

65. *Id.* at 8. Some factors include:

“done in anticipation of receiving prescriptions?

... involving a drug that was withdrawn or removed from the market for safety reasons?

... based from bulk active ingredients?

... done without obtaining written assurance from the supplier that the drug substances were made in an FDA-registered facility?

... not in compliance with official compendia requirements?

... using commercial scale manufacturing or testing equipment? ... done for third parties who will resell the drugs?

... of drug products that are commercially available in the marketplace or essentially copies of commercially available drugs?

The FDA is an important actor within the lethal injection debate. The power of the FDA's discretion came about after a highly controversial incident after the supply of lethal injection drugs in Arizona and Georgia ran dry.⁶⁶ This controversy was litigated in *Cook v. FDA*.⁶⁷ Between 2010-2011, the FDA had seized multiple shipments of the lethal injection drug sodium thiopental but soon released them to the states to be used in executions.⁶⁸ These drugs were taken from a non-FDA approved foreign supplier, Dream.⁶⁹ Plaintiffs in the suit were death row inmates in Arizona, California, and Tennessee who argued the FDA failed its duties under the Federal Food, Drug and Cosmetic Act, which makes it unlawful to introduce into interstate commerce a misbranded drug⁷⁰ or unapproved drug.⁷¹ More specifically, plaintiffs alleged a violation of § 381(a) of the FDCA.⁷² Plaintiffs argue that FDA seized the drugs as per their duties

... failing to comply with applicable state law?"

Id.

These factors are guiding factors for whether the FDA will take action against a compounder of human drugs. *Id.* If answered in the affirmative, the FDA is more likely to assert its regulatory authority against the compounding pharmacy." *Id.*

66. Denno, *supra* note 25. See *supra* notes 13–23 for a discussion on reduced supply of lethal injection drugs.

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

68. *Id.* at 4. The court cites the FDA statement, where

[t]he FDA further released a statement 'that it neither approves nor reviews [thiopental] for use in lethal injections.' Rather, in 'defer[ence] to law enforcement' agencies, henceforth it would exercise its 'enforcement discretion not to review these shipments and allow processing through [Customs'] automated system for importation.

Id.

69. *Id.* In fact, Dream Pharma in Britain was a British distributor, which operated out of the back of a driving school in the city of London. Ford, *supra* note 14.

70. 21 U.S.C. § 331(a) (2018).

71. 21 U.S.C. § 355(a) (2018).

72. *Cook*, 733 F.3d at 4. The statute provides:

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services [HHS], upon his request, samples of . . . drugs . . . being imported or offered for import into the United States. . . . The Secretary of [HHS] shall furnish to the Secretary of the Treasury a list of establishments registered [with the FDA] . . . and shall request that if any drugs . . . manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs . . . be delivered to the Secretary of [HHS]. . . . If it appears from the examination of such samples or otherwise that . . . such article is adulterated, misbranded, or [an unapproved new drug] . . . , then such article shall be refused admission.

under §381(a) but violated their duties when they released the shipments and allowed states to thereafter import thiopental without interference.⁷³ The court held that the FDA violated the FDCA and violated its duties such that:

[T]he FDA acted in derogation of those 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.⁷⁴

The decision in *Cook* is significant for a variety of reasons. First, it further limited the supply of sodium thiopental.⁷⁵ As a result, states continued to experiment with different drugs and different protocols in order to continue with their execution schedules, with troubling results.⁷⁶ One of the most popular drug that states began to use is midazolam,⁷⁷ which is not a barbiturate like sodium thiopental but instead is used to relieve anxiety.⁷⁸ While midazolam became a part of the protocol as early as 2009 for some states,⁷⁹ the drug became a crucial drug in at least six states.⁸⁰

Recently, the promulgation of lethal injections has become more and more concerning.⁸¹ As a result of the decision in *Cook*, the lack of supply

21 U.S.C. § 381(a) (2018).

73. *Cook*, 733 F.3d at 5.

74. *Id.* at 11.

75. *Id.* See *supra* note 41.

76. Caplan *supra* note 35.

77. See *supra* note 73. A recent controversy surrounding midazolam is in Arkansas. See *infra* note 78. The purpose of midazolam is to render a prisoner unconscious to keep him from experiencing pain later on when the other drugs that are meant to stop the heart and breathing. See *infra* note 78.

78. Alan Blinder, *When a Common Sedative Becomes an Execution Drug*, N.Y. TIMES (March 13, 2017), <https://www.nytimes.com/2017/03/13/us/midazolam-death-penalty-arkansas.html>. Midazolam works similarly to valium and is meant to decrease painful side effects. *Id.*

79. *Id.* Ohio was the first state to include midazolam in its the drug protocol but simply used it as an alternative. *Id.*

80. *Id.* Florida became the first state to use midazolam in its official execution protocol. *Id.* It also became the first state to use midazolam in an actual execution. *Id.*

81. Caplan *supra* note 35. Currently, at least ten states have used or intent to use compounding pharmacies to obtain their drugs for lethal injection death penalty. *State by State Lethal Injection*,

from the embargo by drug manufacturers, and the rise in compounding pharmacies not subject to FDA regulations because of dealings of purely state matters of execution, there has been an advent of botched executions.⁸² As mentioned above, compounding pharmacies are usually less safe because the state licensing regulations are not as stringent as the FDA regulations.⁸³ Some examples include the execution of Clayton Lockett,⁸⁴ Ronald Smith,⁸⁵ Kenneth Williams,⁸⁶ Dennis McGuire,⁸⁷ and Joseph Wood.⁸⁸ These are some of the most recent documented examples of botched executions, however death row inmates have been executed for many years with lethal injections that have been subject to state secrecy laws so there could be many more.

supra note 36.

82. *See infra* note 87.

83. Nolan, *supra* note 47, at 1. One example of the unsafe nature of compounding pharmacies that occur as a result of lax regulations occurred in 2012. *Id.* A fungal meningitis outbreak, which was believed to have been caused by contaminated compounded steroids from a New England compounding pharmacy, which was linked to a multistate fungal meningitis outbreak resulting in over 50 deaths. *Id.*

84. *State by State Lethal Injection*, *supra* note 34. Oklahoma used midazolam in the execution of Clayton Lockett in April 2014. *Oklahoma Botches Execution of Clayton Lockett*, DEATH PENALTY INFORMATION CENTER, <https://deathpenaltyinfo.org/node/5760> (last visited Oct. 21, 2018). The state administered the midazolam in the three-drug protocol. *Id.* After he was declared unconscious, witnesses claim that he began to seize on the gurney. *Id.* He died of a massive heart attack approximately forty minutes after the midazolam was administered. *Id.* Further, the midazolam was made from a compounding pharmacy. *State by State Lethal Injection*, *supra* note 34. *See also* Jeffrey E. Stern, *The Cruel and Unusual Execution of Clayton Lockett*, THE ATLANTIC, (June 2015), <https://www.theatlantic.com/magazine/archive/2015/06/execution-clayton-lockett/392069/>.

85. *State by State Lethal Injection*, *supra* note 34. After the state administered the midazolam, Ronald Smith spent fifteen minutes of coughing and convulsing on the gurney before he was declared dead. *Ronald Smith Heaves and Coughs During Alabama Execution After Tie Vote in Supreme Court Denies Him Stay*, DEATH PENALTY INFORMATION CENTER, <https://deathpenaltyinfo.org/node/6623> (last visited Oct. 22, 2018).

86. *State by State Lethal Injection*, *supra* note 34. Witnesses report jerking and convulsing at Kenneth Williams execution after the midazolam was administered. *Id.*

87. *Id.* After McGuire's botched execution, Ohio briefly abandoned its use of midazolam in its protocol but opted to bring it back shortly after. *Id.*

88. *Id.* Joseph Wood gasped after being injected with midazolam and hydromorphone. *Arizona Botches Execution of Joseph Wood*, DEATH PENALTY INFORMATION CENTER, <https://deathpenaltyinfo.org/node/5828> (last visited Oct. 21, 2018). During the ordeal Mr. Wood's attorneys placed a phone call to Justice Anthony Kennedy in order to halt the execution because he Wood was still alive one hour in. *Id.* A reporter who witnessed the execution said he counted 600 gasps before Wood was declared dead. *Id.*

V. HIDING DRUGS AND COMPOUNDING PHARMACIES BEHIND SECRET LAWS

As a result of the substantial litigation, drug manufacturers, state corrections and subsequent state legislatures have attempted to insulate their methods of procuring and compounding the drugs.⁸⁹ The most effective way that states have been able to insulate themselves from litigation and public pressure is through the enactment of secrecy laws.⁹⁰ These secrecy laws have been implemented to protect state corrections and the source of their lethal injection drugs.⁹¹ For example, the plaintiffs in *Cook* were able to successfully challenge the source of the drugs to be used in their execution – state secrecy laws would obfuscate the source and prevent a similar future challenge. Further, these secrecy laws also protect modifications of the protocol itself.⁹² Inmates, newspapers, and the ACLU have tried suing state corrections, arguing keeping identity of drugs and the compounding pharmacy is a violation of the First Amendment.⁹³

Further, the cases of *Lockett*⁹⁴ and *Wood*⁹⁵ resulted in an extremely

89. See *infra* note 90 for discussion on secrecy laws.

90. Sanburn, *supra* note 7. States fear backlash of large drug manufacturers as well as activist groups. *Id.*

91. Josh Sanburn, *Oklahoma Judge Says State Can't Keep Execution Drugs Secret*, TIME, (Mar. 26, 2014), <http://time.com/39232/oklahoma-lethal-injection-drugs-unconstitutional/>. Secrecy laws were originally implemented in order to protect the physicians in the execution chamber and a variety of other medical professionals from being threatened or harassed by the public. *Id.* States later put compounding pharmacies under the umbrella of protection of these secrecy laws. *Id.*

92. *Id.* For example, Oklahoma ruled in 2014 to lift secrecy laws in order to protect inmates access to information. *Id.* “In addition to protecting drug makers’ anonymity, Oklahoma changed its drug protocol this week to allow the department of corrections to choose from one of five drug combinations after running into difficulty obtaining the necessary chemicals.” *Id.* Secrecy laws were an explicit attempt by state lawmakers to continue with drug protocols deadlines and not receive the backlash that drug manufacturers were subject to. *Id.*

93. Sanburn, *supra* note 7. *The Guardian*, AP, and Missouri’s largest three newspapers sued Missouri Department of Corrections arguing that it was a violation of the First Amendment to keep the different drugs and where the state was obtaining the drugs a secret. *Id.*

94. *Lockett v. Evans*, 330 P.3d 488, 489 (2014). Lockett was in death row for rape and murder. Stern, *supra* note 84. He sought a stay of execution based on the fact the state corrections kept secret the identity of the drug, the drug protocol, and the pharmacy to be used in his execution. *Id.* During the subsequent litigation, the execution was delayed after the corrections lacked the lethal injection drugs to carry out the execution. *Id.* The stay proved extremely controversial by the state leaders. *Id.* The Oklahoma Governor indicated she would defy the legislatures and call for the impeaching of the justices if they do not lift the stay of execution for Lockett. *Id.* A few short days later the Oklahoma Supreme Court dissolved the stay. *Id.*

dramatic illustration of the secrecy laws. These cases highlight the two different kinds of secrecy laws that have been challenged in court – confidentiality laws over the source (compounding pharmacies) and confidentiality laws over the lethal injection protocol (how the state correction will execute the inmate).⁹⁶ Many litigants have argued that these secrecy laws are an attempt to conceal the poor quality of drugs from compounding pharmacies.⁹⁷

Further, in the past few years a new controversy has reenergized the lethal injection debate. After an investigation by the *St. Louis Public Radio* and *St. Louis Beacon* regarding a compounding pharmacy, the issue of whether compounding pharmacies should be subject to FDA regulation arose again.⁹⁸ The investigation revealed that the pharmacy that the Missouri state correction was using was not licensed in Missouri but instead licensed in Oklahoma.⁹⁹ This has opened up a new line of inquiry and controversy since Oklahoma and Missouri are now engaged in interstate commerce, which opens up the potential to subject to the FDA.¹⁰⁰

95. *Wood v. Ryan*, 759 F.3d 1076, 1088 (9th Cir. 2014), preliminary injunction of execution vacated *sub nom.*, *Ryan v. Wood*, 132 S. Ct. 21 (2014). Wood similarly sued the state regarding the drug supply confidentiality laws. *Id.* Less than a month from his execution Wood sued, arguing for a stay for the state's refusal to release the source of the drugs that were to be used in his execution. *Id.* He argued the same constitutional violations that Lockett argued. *Id.* After the district court denied his petition, the Ninth Circuit reversed. *Id.* Dramatically, the Supreme Court reversed the grant of the stay of execution of the Ninth Circuit just a day before the execution and allowed the execution to proceed. *Id.*

96. *See infra* notes 89–90.

97. *See infra* note 57.

98. Chris McDaniel & Vernique Lacapra, *Investigation: Missouri's Execution Drug Source Raises Legal, Ethical Questions*, ST. LOUIS PUBLIC RADIO (Dec. 31, 2013) <http://news.stpublicradio.org/post/investigation-missouris-execution-drug-source-raises-legal-ethical-questions#three>. After a shortage of willing drug suppliers had refused to provide the requisite drugs, Missouri Governor Jay Nixon directed the state to adopt a new protocol with the use of pentobarbital. Pentobarbital, as stated above, is commonly used by veterinarians to euthanize animals. *Id.*

99. *Id.* A federal judge speaking on the subject called the execution drug a “shadow pharmacy by the hangman’s hood.” *Id.*

100. *See supra* note 71 regarding FDCA “interstate commerce” definition.

VI. PROPOSING AN END TO LETHAL INJECTION THROUGH FEDERAL REGULATION

This Note proposes a method of ending the death penalty by lethal injection because of moral, ethical, and practical implications.¹⁰¹ Further, the courts have followed public sentiment towards slowly eradicating the death penalty.¹⁰² This Note proposes closing the compounding pharmacy loophole in a few different ways. This topic is of particular relevance given the controversy regarding lethal injection from European countries¹⁰³ and drug manufacturers.¹⁰⁴ This Note proposes a multi-pronged approach in order to eliminate the supply of the lethal injection drugs. As mentioned above, there are a multitude of layers that exist that make lethal injection drugs a problem. First, after drug manufacturers refused to sell lethal injection drugs to state corrections, state corrections resorted to compounding pharmacies.¹⁰⁵ Further, compounding pharmacies, not subject to federal regulation, have resulted in many unsafe and botched executions.¹⁰⁶ Even further, secrecy laws governed by each state jurisdiction protect these compounding pharmacies from judicial scrutiny.¹⁰⁷

First, this Note proposes that the compounding pharmacies that supply lethal injection drugs should be subject to federal regulation. As mentioned above, the FDCA has “new drug” “adulteration” and “misbranding” provisions of a drug transported in interstate commerce.¹⁰⁸ Meeting these provisions would make a compounding pharmacy subject to the FDA regulation.¹⁰⁹ The government can label compounding pharmacies that mix and compound lethal injection drugs to be administered to death row as “misbranded”¹¹⁰ or “new drug”¹¹¹ to make

101. See *supra* note 24. Retired Justice Stevens advocates for an eventual end to lethal injection. *Baze v. Rees*, 553 U.S. 35, 87 (2008) (Stevens, J., concurring).

102. See *Baze*, 553 U.S. at 87 (Stevens, J., concurring).

103. See *supra* notes 2–4, 19 and accompanying text.

104. See *supra* note 34.

105. See *supra* notes 36–40.

106. See *supra* notes 70–71.

107. See *supra* notes 72–73.

108. See *supra* note 51.

109. See *supra* note 53.

110. See *supra* note 51.

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them subject to federal regulation. Essentially, requiring compounding pharmacies to ensure the safety and efficacy testing of drugs would be economically unfeasible.¹¹² As such, FDA regulation requiring rigorous testing¹¹³ would effectively eliminate the compounding pharmacies' desire to sell and compound these drugs to state corrections. Moreover, violation of these provisions is extremely costly to compounding pharmacies.¹¹⁴ Further, lessons from the *Cook*¹¹⁵ case show the Court's willingness to penalize the FDA from refusing to act in accordance for the public benefit for compounding pharmacies.¹¹⁶ Specifically, the *Cook* case shows an increased willingness to federally regulate unsafe drugs. While the *Cook* case involved an importation of drugs from the back of the London driving school,¹¹⁷ compounding pharmacies show an extreme and real risk.¹¹⁸

VII. PROPOSING AN END TO LETHAL INJECTION THROUGH CLOSING THE COMPOUNDING PHARMACY GAP

There are a variety of factors¹¹⁹ that the federal government uses to determine whether to regulate a compounding pharmacy. One factor is if it “involve[s] a drug that was withdrawn or removed from the market for safety reasons.”¹²⁰ Since each lethal injection drug has been removed from the drug manufacturer market as a result of big pharmaceutical companies, this factor weighs in favor of regulation. Another factor in favor of regulation is whether the compounding is “done without obtaining written assurance from the supplier that the drug substances were made in an

111. See *supra* note 53–54.

112. *Exploring the Right Mix to Protect Patients: Hearing on Federal and State Role in Pharmacy Compounding and Reconstitution Before the S. Comm. on Health, Educ., Labor, and Pensions*, 108th Cong. 1 (2003) (statement of Steven Galson, Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration).

113. See *supra* note 53.

114. Nolan, *supra* note 47, at 2. Section 301 of the FDCA allows the government to impose both civil and criminal fines to compounding pharmacies. *Id.* These penalties can be up to \$10,000 and three years in prison for repeat or knowing violations. See 21 U.S.C. § 333 (2018).

115. See *supra* note 67.

116. See *supra* note 77–81.

117. Ford, *supra* note 14.

118. See discussion *supra* note 49.

119. See *supra* note 65.

120. See *supra* note 60.

FDA-registered facility?”¹²¹ Here, the compounding pharmacies that compound lethal injection drugs are usually made without written assurance. Further, they aren’t made in an FDA-regulated facility given the secrecy surrounding compounding pharmacy. The last few factors, namely whether they have been subject to large scale testing and whether done for third parties who will resell the drugs, weigh in favor of federal regulation.¹²²

Additionally, because requiring an inquiry into whether a drug has been introduced in interstate commerce¹²³ is a prerequisite into deciding whether a drug can be subject to federal regulation, the protection of compounding pharmacies behind secrecy laws should be lifted. This Note proposes that in order to allow for the public safety over compounding drugs, an inquiry into whether or not section 503 applies to extend federal regulation into compounding pharmacy.¹²⁴ However, there are many issues over federal regulation of traditional compounding,¹²⁵ which includes generic drugs, small amounts of mixing for prescriptions etc. However, an amendment or interpretation of 503A to allow federal regulation over nontraditional compounding to protect the safety and efficiency of compounded drugs would not interfere with the issues of federalism and would strike a balance towards public safety. Further, the language of the statute provides the federal government broad regulatory power.¹²⁶

VIII. A NARROW SOLUTION TO THE LETHAL INJECTION DEBATE

This Note proposes that increasing federal regulation over compounding pharmacies would effectively mean that, at the very least, the lethal injection drugs would have to be subject to more rigorous testing and other federal standards. This scrutiny would help to avoid botched executions

121. *See supra* note 60.

122. *See supra* note 60.

123. *See supra* note 58.

124. Outterson, *supra* note 5 (explaining that Section 503A has a few limitations for federal regulation of compounding drugs).

125. *See supra* note 59.

126. *See supra* note 65.

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such as those mentioned above.¹²⁷ Further, in order to regulate these compounding pharmacies, secrecy laws that prevent the government and the public from knowing the drug protocol¹²⁸ and which compounding pharmacy the drug came from must be lifted. This move would signal the legislature that the last loophole for state corrections to receive lethal injection drugs has been exhausted. History within the United States shows that change within death penalty litigation moves slowly, and this proposal of increasing federal regulation, lifting secrecy laws, and making it impracticable and relying on public pressure would be the most apt way to end capital punishment by lethal injection.

CONCLUSION

The diplomatic cost of the death penalty is high. This Note does not argue that compounding pharmacies are bad or should be eliminated given their other benefits, it simply proposes a narrow reading to increase the safety and hopefully eliminate the unsafe and inhumane lethal injection drugs. Further, this Note also does not argue that secrecy laws are inherently bad since they have been empirically used to protect confidential information and prevents harm of individuals that work within the criminal justice system. This Note takes a narrow reading of the secrecy laws and opposes those secrecy laws used to hinder the constitutional rights of death row inmates, who have been constantly at limbo throughout the uncertainty of supply of lethal injection drugs. A narrow reading of statutes and laws that are meant to protect the public at its face has increasingly been used to thwart safety concerns in order to continue with execution timelines.

The stories of botched executions as well as the death anxiety suffered by death row inmates, illuminate the necessity to reform the criminal justice system as a modern and humane system.

Current anti-death penalty efforts should focus on utilizing large actors to stress the morality issues as well as the diplomatic problems with the death penalty, as mentioned during the history section of this note. Such

127. See *supra* notes 84–88 for a discussion on these botched executions.

128. See *supra* note 13; see also *supra* note 36.

large actors with political capital include large drug manufacturers, the federal agencies, and pharmacies that have a stake in ending the death penalty. Further, another inquiry into other potential gaps by state legislatures would further allow an effective end to the lethal injection.