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EXPERIMENTAL EXECUTION

Seema K. Shah^{*}

Abstract: On July 23, 2014, an execution in Arizona lasted nearly two hours, with the inmate struggling to breathe and gasping over 600 times, according to a local reporter witnessing the execution. This was the third example of a botched execution in seven months. The Supreme Court last evaluated the constitutionality of execution by lethal injection in 2008, but did not provide a clear standard for evaluating risks. Since that time, the lethal injection landscape has transformed. States are using entirely new drugs and drug combinations, and sometimes obtain these drugs from questionable sources, making it hard to predict what will happen in any given execution. The Court has now granted certiorari to examine the constitutionality of Oklahoma's lethal injection protocol in the case of *Glossip v. Gross*.

Although it is increasingly common to refer to lethal injection executions as experimental, this Article is the first to conduct a rigorous analysis of whether and to what extent executions by lethal injection involve the conduct of research and therefore should be analyzed under the ethical and regulatory framework that governs biomedical research. I argue that an important factor driving this high error rate is that the use of novel drugs, drug combinations, and dosages in lethal injection executions is a type of research. More specifically, it is poorly designed experimentation that is not based on evidence. If the death penalty is justified, individual inmates are being exposed to uncertain (and sometimes unnecessary) risks in order to obtain benefits for others by furthering the underlying aims of capital punishment.

This insight suggests three important conclusions. First, states should draw from existing scholarship on ethics and regulations that apply to biomedical research with captive and vulnerable populations. Prisoners are considered a vulnerable population, and experimental executions involving prisoners should abide by the general principles that are applicable to research: respect for autonomy, non-maleficence, and justice. Second, legal safeguards that follow from these principles should be applied to executions—in particular, states should ask for informed consent from prisoners to modifications of lethal injection protocols, obtain independent review by a regulatory body like the Food and Drug Administration, and apply a

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standard requiring risk minimization in the choice of drugs and procedures. Finally, states should systematically gather data as they engage in experimental execution.

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INTRODUCTION

An execution in Oklahoma went terribly awry on April 28, 2014.¹ Oklahoma was administering a new execution protocol that used the drug midazolam, a sedative that is often used in combination with other anesthetic agents.² Oklahoma had never used this drug in executions before; in fact, only a few states had any experience with using the drug in lethal injections.³ Florida had previously used this drug in lethal injections, but with a dose five times higher than what was indicated in Oklahoma's protocol.⁴ If the execution had gone as planned, Clayton Lockett would have first received midazolam; been declared

1. Helen Pow, *Execution Horribly Botched in Oklahoma*, DAILY MAIL (Apr. 29, 2014), <http://www.dailymail.co.uk/news/article-2615631/Oklahoma-prepares-execute-2-inmates.html>.

2. *Manufacturer's Drug Catalog for Midazolam*, SAGENT PHARMACEUTICALS (2014), http://www.sagentpharma.com/Products/Midazolam/Catalog/Midazolam_Catalog.pdf.

3. Pow, *supra* note 1.

4. *Id.*

unconscious; then received vecuronium bromide (a paralytic/neuromuscular blocking agent that would restrict his movements); and finally received potassium chloride (the drug likely to end his life).⁵ A few minutes after a prison official declared him unconscious, Lockett mumbled statements including the word, “man.”⁶ He “began breathing heavily, writhing, clenching his teeth and straining to lift his head off the pillow.”⁷ Prison officials then blocked the witnesses from observing the rest of the proceedings.⁸ The Department of Corrections then called off the execution and unsuccessfully tried to resuscitate Lockett, and Lockett eventually died of a heart attack approximately forty-five minutes after the execution began.⁹ Although a Department of Corrections official stated that Lockett’s veins “exploded,”¹⁰ an autopsy examination performed by a forensic pathologist hired by death row inmates appears to contradict official reports.¹¹ Prison officials claimed that they had to inject the drugs into Lockett’s femoral vein, located in his groin, which is riskier and more difficult than using more common injection sites.¹² However, the autopsy report contradicts this claim, finding that Lockett’s surface and deep veins had “excellent” integrity.¹³ Another execution scheduled to occur that same night was stayed for several months, pending an investigation into Mr. Lockett’s execution, but took place on January 15, 2015.¹⁴ Clayton Lockett’s estate has brought suit against the State of

5. OKLA. STATE PENITENTIARY, OSP 040301-01, PROCEDURES FOR THE EXECUTION OF OFFENDERS SENTENCED TO DEATH (2014), available at <http://bloximages.newyork1.vip.townnews.com/tulsaworld.com/content/tncms/assets/v3/editorial/e/37/e3763982-d19c-11e3-addc-0017a43b2370/5362fb4c11d06.pdf>; see also *State-by-State Lethal Injection Information, Oklahoma*, DEATH PENALTY INFO. CTR., <http://www.deathpenaltyinfo.org/state-lethal-injection> (last visited Jan. 5, 2015).

6. Greg Botelho & Dana Ford, *Oklahoma Stops Execution After Botching Drug Delivery; Inmate Dies*, CNN (Oct. 9, 2014, 2:55 PM), <http://www.cnn.com/2014/04/29/us/oklahoma-botched-execution/index.html>.

7. Pow, *supra* note 1.

8. *Id.*

9. Michael Muskal, *Private Autopsy Blames Oklahoma for Botched Execution*, L.A. TIMES (June 13, 2014), <http://www.latimes.com/nation/nationnow/la-na-nn-autopsy-botched-oklahoma-execution-20140613-story.html>; Michele Richinick, *White House Weighs in on Botched Oklahoma Execution*, MSNBC (Apr. 30, 2014, 8:23 AM), <http://www.msnbc.com/morning-joe/oklahoma-governor-lockett-botched-execution>.

10. Botelho & Ford, *supra* note 6

11. Muskal, *supra* note 9.

12. *Id.*

13. *Id.*

14. Josh Sanburn, *Oklahoma Executes First Inmate Since Botched Lethal Injection in April*, TIME (Jan. 15, 2015), <http://time.com/3669126/oklahoma-lethal-injection-execution-charles-warner->

Oklahoma and a physician alleged to have been involved in the execution, claiming violations of the Eighth Amendment to the U.S. Constitution, international law, and human decency.¹⁵ Meanwhile, Oklahoma has already modified the state's protocol by increasing the dose of midazolam that will be administered to inmates in future executions.¹⁶

More recently, on July 23, 2014, the execution of Joseph Wood in Arizona lasted for nearly two hours, with the inmate struggling to breathe and gasping over 600 times, according to a local reporter witnessing the execution.¹⁷ As the reporter described it: "The movement was like a piston: The mouth opened, the chest rose, the stomach convulsed . . ." ¹⁸ Arizona used two drugs, hydromorphone and midazolam,¹⁹ which had previously been used in a botched execution in Ohio in January 2014.²⁰ The execution log reveals that Wood was injected with the drugs fifteen times in 114 minutes.²¹ In the middle of

clayton-lockett/; see also Katie Zezima, *Okl. Attorney General Seeks Execution Delay Following Botched Lethal Injection*, WASH. POST (May 8, 2014), <http://www.washingtonpost.com/blogs/post-politics/wp/2014/05/08/okla-attorney-general-seeks-execution-delay-following-botched-lethal-injection>.

15. Complaint at 1–2, *Lockett v. Fallin*, No. 5:2014-cv-01119-HE (W.D. Okla. Oct. 13, 2014) (arguing that "[d]espite innumerable treaties, protocols and accepted norms of human decency prohibiting human experimentation on unwilling subjects, while cast in the unwitting role of human lab rat for the Defendants, Clayton Lockett was administered an untested mixture of drugs that had not previously been used for executions in the United States"). The ACLU and news organizations have also filed suit since reporters were not allowed to observe the entire Lockett execution. See *Lawsuit Seeks Uncensored Access to Executions, Citing First Amendment Press Freedom*, ACLU (Aug. 25, 2014), <https://www.aclu.org/free-speech/aclu-and-news-organizations-sue-over-closed-blinds-during-botched-lockett-execution>.

16. Erik Eckholm, *Oklahoma Executes First Inmate Since Slipshod Injection in April*, N.Y. TIMES (Jan. 15, 2015), http://www.nytimes.com/2015/01/16/us/oklahoma-execution-charles-warner-lethal-injection.html?_r=2; see also Josh Sanburn, *Ohio Ups Lethal-Injection Dosages After Controversial Execution*, TIME (Apr. 28, 2014), <http://time.com/80092/ohio-lethal-injection-dosages-execution>.

17. Fernanda Santos & John Schwartz, *A Prolonged Execution in Arizona Leads to a Temporary Halt*, N.Y. TIMES (July 24, 2014), http://www.nytimes.com/2014/07/25/us/a-prolonged-execution-in-arizona-leads-to-a-temporary-halt.html?_r=0.

18. Mark Kiefer, *Reporter Describes Arizona Execution*, ARIZ. REPUBLIC (July 26, 2014), <http://www.azcentral.com/story/news/arizona/politics/2014/07/24/arizona-execution-joseph-wood-eyewitness/13083637/>.

19. Santos & Schwartz, *supra* note 17.

20. *Ohio to Increase Lethal Injection Drug Dosages After Execution Leads to Lawsuit*, THE GUARDIAN (Apr. 28, 2014, 5:45 PM), <http://www.theguardian.com/world/2014/apr/28/ohio-increase-lethal-drug-dosages>.

21. Mark Berman, *The Prolonged Arizona Execution Used 15 Doses of Lethal Injection Drugs*, WASH. POST (Aug. 4, 2014), <http://www.washingtonpost.com/news/post-nation/wp/2014/08/04/the-prolonged-arizona-execution-used-15-doses-of-lethal-injection-drugs/>. The execution log has been made available here: <http://www.scribd.com/doc/235854026/Joseph-Wood-execution-log>.

the execution, attorneys for Mr. Wood filed an emergency appeal to a federal district court to stop it.²² The transcript of this appeal reveals a great deal of confusion, with the state attorney general initially stating that Wood was brain dead, even though he was still breathing independently—a medical impossibility.²³ The court was not convinced that stopping the execution would eliminate pain or suffering given that the inmate’s heart rate was slowing, and was also concerned that stopping the execution might do more harm than good.²⁴ Mr. Wood was declared dead before the hearing concluded.²⁵ The governor of Arizona, Jan Brewer, has announced that an investigation will be conducted into Wood’s execution, while expressing that eyewitness and media reports indicated that he did not suffer.²⁶

These examples are illustrative of a larger problem facing executions by lethal injection—the predominant method of execution used in the United States.²⁷ A recent study has estimated that seven percent of all lethal injection executions have involved serious errors, which is a higher rate of failure than any other method of execution.²⁸ Commentators have begun to argue that when executions by lethal injection try out unproven drugs and novel procedures for use on non-consenting inmates, lethal injection resembles “a nationwide, government-sponsored clinical trial”²⁹ that raises ethical and regulatory concerns and violates international legal norms.³⁰ Following the Lockett execution, a group of inmates in Oklahoma filed a lawsuit arguing that

22. Kiefer, *supra* note 18.

23. Transcript of Telephonic Motion for Emergency Stay of Execution at 7–8, *Wood v. Ryan*, No. CV 14-1447-PHX-NVW (D. Ariz. July 23, 2014), available at <http://www.scribd.com/doc/234993495/Transcript-related-to-Joseph-Wood-execution>.

24. *Id.* at 15–18.

25. *Id.* at 16.

26. Jacob Gershman, *Arizona Inmate Dies 2 Hours After Start of Execution*, WALL ST. J. (July 24, 2014, 7:11 AM), <http://www.wsj.com/articles/arizona-inmate-joseph-rudolph-wood-dies-2-hours-after-start-of-execution-1406159321>.

27. Deborah W. Denno, *Lethal Injection Chaos Post-Baze*, 102 GEO. L.J. 1331, 1342–43 (2014).

28. AUSTIN SARAT ET AL., GRUESOME SPECTACLES: BOTCHED EXECUTIONS AND AMERICA’S DEATH PENALTY 120, app. A at 177 (2014).

29. Jeff Stryker, *Lethal Injections: Medicine and Research*, HASTINGS CTR. REP., Jan.–Feb. 2008, at 53.

30. Johnny Holschuh, *Experimenting with Death: Baze v. Rees, the Execution of Dennis McGuire, and the Constitutionality of Experimenting with Lethal Injection Drugs*, U. CIN. L. REV. BLOG (May 13, 2014), <http://uclawreview.org/2014/05/13/experimenting-with-death-baze-v-rees-the-execution-of-dennis-mcguire-and-the-constitutionality-of-experimenting-with-lethal-injection-drugs/>.

lethal injection involves unconstitutional experimentation on prisoners.³¹ Although it is increasingly common to refer to lethal injection executions as experimental,³² this Article is the first to conduct a rigorous analysis of whether and to what extent executions by lethal injection involve the conduct of research and therefore should be analyzed under the ethical and regulatory framework that governs biomedical research.

In this Article, I argue that it is theoretically helpful to understand recent changes to execution protocols as a kind of biomedical research. By trying novel drugs, drug combinations, and dosages to see if they will work, states are conducting a type of biomedical research—namely, research that is poorly designed and not based in evidence. Although each execution involves changes that affect only one inmate, states make changes after botched executions and try to improve their protocols to use on other inmates on death row. There are several different regulations governing research, some promulgated by federal agencies (like the Department of Health and Human Services (DHHS), the Bureau of Prisons, and the Food and Drug Administration (FDA)), and also state statutes on research on prisoners. These regulations define research very differently. Not all regulations will cover this type of research, but state statutes and FDA regulations have broad enough

31. Katie Fretl, *Oklahoma Inmates File Lawsuit over “Unconstitutional” Executions*, THE GUARDIAN (June 25, 2014, 3:39 PM), <http://www.theguardian.com/world/2014/jun/25/oklahoma-death-row-inmates-file-lawsuit-unconstitutional-executions> (“The plaintiffs are not challenging their convictions or sentences of death in this action, They are challenging only the way in which their sentences of death will be carried out by the defendants.” (internal quotations omitted)).

32. See, e.g., *In re Ohio Execution Protocol Litig.*, 994 F. Supp. 2d 906, 913 (S.D. Ohio 2014) (“There is absolutely no question that Ohio’s current protocol presents an experiment in lethal injection processes. The science involved, the new mix of drugs employed at doses based on theory but understandably lacking actual application in studies, and the unpredictable nature of human response make today’s inquiry at best a contest of probabilities.”); JOHNS HOPKINS CLINIC FOR PUB. HEALTH LAW & POLICY, STATE DEPARTMENTS OF CORRECTIONS ARE VIOLATING FDA’S INVESTIGATIONAL NEW DRUG REGULATIONS BY EXPERIMENTING WITH LETHAL INJECTION DRUGS (2014), available at <http://www.jhsph.edu/research/centers-and-institutes/center-for-law-and-the-publics-health/Lethal%20Injection%20Policy%20Paper%20Final.pdf>; Leonard G. Koniaris et al., *Ethical Implications of Modifying Lethal Injection Protocols*, 5 PLOS MED. 845 (2008); Seema K. Shah, *How Lethal Injection Reform Constitutes Impermissible Research on Prisoners*, 45 AM. CRIM. L. REV. 1101 (2008); Della Hasselle, *Lawyers Argue that Next Week’s Execution Could Amount to “Human Experimentation,”* THE LENS (Jan. 28, 2014), <http://thelensnola.org/2014/01/28/lawyers-argue-that-next-weeks-execution-could-amount-to-human-experimentation/>; Sarah Lazare, *“Experimenting” on a Death Row Inmate: Florida to Execute Man by Untested Drug*, COMMON DREAMS (Oct. 15, 2014), <http://www.commondreams.org/news/2013/10/15/experimenting-death-row-inmate-florida-execute-man-untested-drug>; Ruth Macklin, *Is Execution by Lethal Injection Medical Research?*, DOCTOR’S TABLET BLOG (May 6, 2014), <http://blogs.einstein.yu.edu/is-execution-by-lethal-injection-medical-research/>.

definitions to apply to experimental executions. However, states are conducting experimental executions without considering the ethical and regulatory framework that has been developed for biomedical research and the resulting legal safeguards. In particular, research with captive and vulnerable populations requires adherence to the ethical principles of respect for autonomy, non-maleficence, and justice. Viewing lethal injection executions through this lens can help ensure that states have a solid scientific basis and are neither excessively risky nor disrespectful of inmates on death row.

Additionally, the ethical and regulatory framework governing biomedical research can complement an Eighth Amendment analysis. A research ethics framework offers a way to adjudicate amongst competing risk standards for determining how to apply the prohibition on cruel and unusual punishment to risks posed by executions by lethal injection. The most recent lethal injection case to be heard by the Supreme Court, *Baze v. Rees*,³³ did not provide clear guidance on the appropriate standard for weighing risks.³⁴ The Supreme Court has now granted certiorari to review Oklahoma's execution protocol in the case of *Glossip v. Gross*,³⁵ and is likely to address the changes in execution drugs being used since its ruling in *Baze*.³⁶ Importantly, the plurality opinion in *Baze* indicated that a lethal injection protocol would violate the Eighth Amendment if it involves a "substantial risk of serious harm" or an "objectively intolerable risk of harm," and there are alternative execution methods that effectively address this risk.³⁷ When faced with examples of problematic executions, the Court opined that "an isolated mishap," or an "accident, with no suggestion of malevolence" would not be enough to sustain a challenge based on the Eighth Amendment.³⁸ Yet, states are increasingly engaged in experimentation that disregards many potential risks and the considerable uncertainty as to whether procedures will work as planned. Given the growing number of examples of executions gone wrong, it is difficult to believe that these failures are merely a series of accidents. Rather, the problem is systemic and foreseeable. Poorly regulated and haphazard experimentation on inmates predictably leads to bad outcomes.

33. 553 U.S. 35 (2008).

34. *Id.* at 52.

35. *Warner v. Gross*, No. CIV-14-0665-F, 2014 WL 7671680 (W.D. Okla. Dec. 22, 2014), *aff'd*, 776 F.3d 721 (10th Cir. 2015), *cert. granted*, No. 14-7955, 2015 WL 302647 (U.S. Jan. 23, 2015).

36. *Id.*

37. *Baze*, 553 U.S. at 50, 52.

38. *Id.* at 50.

To put this argument in context, it is important to understand that the examples of botched executions described above and in the media are attributable to the recent, rapid pace of change in executions by lethal injection across the country. These developments give new reason to be concerned about the uncertain and troubling risks of excruciating pain and suffering prior to death. The lethal injection approach traditionally used by states was a three-drug protocol, which led to a risk that any pain and suffering experienced by the inmate would be masked by the use of a paralytic agent.³⁹ Now, states are using new drugs, in new combinations and doses, and making such quick changes to their protocols that it is increasingly difficult to predict what the outcome of a given execution might be.⁴⁰ Moreover, many inmates were or could be subjects of this experimentation: thirty-nine inmates were executed in 2013, thirty-five were executed in 2014, and over 3,000 inmates remain on death row.⁴¹

For the sake of clarity, a caveat may be in order. This Article is not advocating for or against the death penalty or executions by lethal injection. Rather, the goal of this Article is to ensure that—given that execution by lethal injection persists in many states—it is properly regulated and borrows from well-thought-out standards developed in bio-medical research that address the concerns that arise when the interests of experimenters, their subjects, and the rest of society diverge, and the subjects of these experiments face uncertain risks of bodily harm.

This argument is developed in four parts. In Part I of the Article, I describe the history of research ethics and regulation, with extra attention to research conducted on prisoners. Understanding the troubled history of research on prisoners helps make sense of the existing ethical and regulatory protections governing research on prisoners. In Part II, I explain how current lethal injection protocols came into being. I then argue in Part III that the best way to understand lethal injection experimentation is through the lens of evidence-based medicine. I contend that executions by lethal injection involve biomedical research

39. Denno, *supra* note 27, at 1333–34.

40. *Id.* at 1358 chart 3.

41. *Death Row Inmates by State as of October 1, 2014*, DEATH PENALTY INFO. CTR., <http://www.deathpenaltyinfo.org/death-row-inmates-state-and-size-death-row-year> (last visited Jan. 23, 2014); *Execution List 2013*, DEATH PENALTY INFO. CTR., <http://www.deathpenaltyinfo.org/execution-list-2013> (last visited Feb. 9, 2015). Thirty-five people were executed in 2014. *Execution List 2014*, DEATH PENALTY INFO. CTR., <http://www.deathpenaltyinfo.org/execution-list-2014> (last visited Feb. 9, 2015).

that is poorly designed and not based in evidence. Part IV argues that states should therefore either rely on existing evidence or conduct more systematic research, and identifies the regulations that should be applied to lethal injection. In this section, I also take note of the gaps in the regulation of poorly conducted research, and determine which regulations are drafted broadly enough to apply to experimental executions. I conclude by briefly addressing alternative approaches to executions and the challenges they involve, and considering the implications of this analysis for future scholarly work on both execution by lethal injection and biomedical research regulation and ethics.

I. A BRIEF HISTORY OF RESEARCH ON PRISONERS

This section first provides historical background for the development of principles and regulations that govern the conduct of biomedical research in the United States, with a particular focus on research on prisoners. Next, I address a potential objection to the line of argument contained in this Article: Why is it appropriate to apply the principles and protections governing biomedical research with human subjects to the context of capital punishment? I argue that the contexts of research and capital punishment are not as different as they might initially seem to be, and that there are important lessons learned from the history of research on prisoners that should not be forgotten. The mere fact that an inmate is sentenced to death should not suspend the standard protections to which all of us are entitled.

A. *History of Research Ethics and Regulation*

The ethics and regulation of clinical research have famously been described as “born in scandal and reared in protectionism.”⁴² This quote is a particularly apt characterization of the history of research on prisoners. In his book, *Acres of Skin*, Allen Hornblum chronicles several studies in which prisoners were used as research subjects without concern for their welfare.⁴³ Many of these early experiments demonstrated a willingness to expose inmates to very high risks of injury or death, and also had an insufficient scientific basis for pursuing such an investigation in the first place.⁴⁴ In fact, in the Nuremberg trials, Nazi

42. Carol Levine, *Has AIDS Changed the Ethics of Human Subjects Research?*, 16 L. MED. & HEALTH CARE 167, 167 (1988).

43. See generally ALLEN M. HORNBLUM, *ACRES OF SKIN: HUMAN EXPERIMENTS AT HOLMESBURG PRISON* (1998).

44. *Id.* at xviii–xx.

physicians who had conducted unconscionable experimentation on victims of the Holocaust tried to defend their actions by arguing that U.S. physicians had long conducted similarly disturbing experiments on prisoners.⁴⁵ In describing what motivated these uses of prisoners in research, some scholars argue that “a social consensus that certain subgroups are unequal can seem to justify experimentation that otherwise might not occur.”⁴⁶

One example cited at Nuremberg was a poorly run cholera trial conducted by an American physician in the Philippines in 1906.⁴⁷ At the time, the Philippines was an American territory, and Dr. Richard Strong was a laboratory director at the Philippine Bureau of Science. Dr. Strong conducted potentially fatal experiments on death row inmates in Manila without their consent.⁴⁸ Although a U.S. government report concluded that the deaths occurred because these inmates were mistakenly injected with plague serum instead of cholera serum, others believed that the inmates were deliberately injected with plague to try to induce an immune response.⁴⁹ Dr. Strong subsequently conducted experiments on prisoners by withholding adequate nutrition and thereby causing them to develop beriberi, a serious disease that could cause paralysis and heart failure.⁵⁰ These experiments also resulted in several deaths.⁵¹ Similar research on nutrition occurred within the United States. Around this same time, the Louisiana Board of Health put black prisoners on a strict diet of molasses for five weeks to learn whether sulfuric acid (used in making molasses) was harmful.⁵²

Experimentation on prisoners became much more prevalent during World War II, when physicians struggled to find treatments for the diseases that were afflicting American soldiers.⁵³ The Terre Haute Experiments, which were conducted between 1943 and 1944,⁵⁴ were designed to develop a technique that would consistently infect prisoners

45. *Id.* at xvi.

46. Valerie H. Bonham & Jonathan D. Moreno, *Research with Captive Populations: Prisoners, Students, and Soldiers*, in THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 461, 463 (Ezekiel J. Emanuel et al. eds., 2008).

47. HORNBLUM, *supra* note 43, at 76.

48. *Id.*

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.* at 76–77.

53. *Id.* at 80–83.

54. PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, “ETHICALLY IMPOSSIBLE” STD RESEARCH IN GUATEMALA FROM 1946 TO 1948, at 13 (2013).

with gonorrhea by applying bacteria to the prisoners' genitals.⁵⁵ These experiments were the precursor to even more egregious experiments later conducted in Guatemala, for which the U.S. government has formally apologized.⁵⁶

Some experiments even involved prisoners on death row. The *New York Times* wrote about a case where a prisoner was pardoned from a death sentence as a result of participation in a risky medical experiment.⁵⁷ One physician wrote a letter to the *New York Times* criticizing the lack of a scientific basis for the study and the risks involved.⁵⁸ Human experimentation with prisoners was commonplace by the 1950s and 60s.⁵⁹ By the 1970s, approximately eighty-five percent of all phase I trials (or studies conducted with the primary objective of learning about the safety of the experimental intervention, and not to benefit the subjects of the research) were conducted on prisoners.⁶⁰

In 1962, one of the first efforts to examine the ethics of research on prisoners took place at a conference held at Boston University.⁶¹ The conference attendees, among whom were both researchers and prison officials, felt that research on prisoners was not likely to be of concern for the general public, stating: "When the public hears that inmates are [participating in a seemingly very hazardous study], they rationalize 'Well, I wouldn't do it, but it's all right with prisoners.'"⁶² Many also thought that the public would be more willing than researchers to have prisoners be exposed to high risks.⁶³

Given this history, it is surprising to learn that the principles governing ethically responsible research were established prior to these scandals, in the early twentieth century.⁶⁴ The physician William Osler

55. *Id.* at 21 (the presumption was that prisoners would volunteer in order to help the war effort).

56. Donald G. McNeil, Jr., *Syphilis Experiment Is Revealed, Prompting U.S. Apology to Guatemala*, N.Y. TIMES, Oct. 1, 2010, at A1.

57. *Id.* at 87–88.

58. *Id.* at 89.

59. HORNBLUM, *supra* note 43, at xviii.

60. Proposed Rules, 42 Fed. Reg. 3085 (proposed Jan. 14, 1977) (to be codified at 45 C.F.R. pt. 46); NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, REPORTS & RECOMMENDATIONS: RESEARCH INVOLVING PRISONERS 47 (1976) [hereinafter RESEARCH INVOLVING PRISONERS].

61. Bonham & Moreno, *supra* note 46, at 463.

62. *Id.* at 463.

63. *See id.*

64. *See, e.g.*, SUSAN E. LEDERER, SUBJECTED TO SCIENCE: HUMAN EXPERIMENTATION IN AMERICA BEFORE THE SECOND WORLD WAR 22 (1995) (citing prominent physician William Osler for his criticism of a study that failed to obtain informed consent in 1898); Paul J. Weindling, *The Nazi Medical Experiments*, in THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 18, 19

argued in 1907 that interventions could be tested in humans only after animal testing had occurred, consent was obtained from the research subjects, and direct benefit to the individual subjects was likely.⁶⁵ Eventually, research on prisoners that violated these and other ethical principles led to controversy. Newspaper editorials questioned whether prisoners were coerced into research participation.⁶⁶ Congressional hearings were held in 1973, in which concerns about “exploitation, secrecy, danger, and the impossibility of obtaining informed consent” were cited as reasons to prohibit research on prisoners.⁶⁷ As a result of these hearings, a bill was introduced to establish the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.⁶⁸

In the late 1970s, Congress gave the Commission the task to “identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines to assure that such research is conducted in accordance with those principles.”⁶⁹ The Commission authored the Belmont Report, one of the most influential documents in research ethics to date. In this report, the Commission addressed “the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine.”⁷⁰ The resulting discussion is particularly instructive here.

The Commission recognized that it is important to distinguish between biomedical research and clinical practice, but that it can be challenging to draw this distinction given that “notable departures from standard practice are often called ‘experimental’ when the terms

(Ezekiel J. Emanuel et al. eds., 2008) (citing the German Reich Circular on Human Experimentation from 1931, which required advance consent to research and limits on research with children).

65. Arthur O. Anderson & James R. Swearingen, *Scientific and Ethical Importance of Animal Models in Biodefense Research*, in *BIODEFENSE: RESEARCH METHODOLOGY AND ANIMAL MODELS* 25, 27 (James R. Swearingen ed., 2012) (citing William Osler, *The Historical Development and Relative Value of Laboratory and Clinical Methods in Diagnosis. The Evolution of the Idea of Experiment in Medicine*, in *TRANSACTIONS OF THE CONGRESS OF AMERICAN PHYSICIANS AND SURGEONS* 1–8 (1907)), available at <http://artandersonmd.com/2006.animal.models.biodefense.research.pdf>.

66. *Id.* at 3.

67. RESEARCH INVOLVING PRISONERS, *supra* note 60, at 3.

68. *Id.* at 3–4.

69. NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH* 1 (1979) [hereinafter *THE BELMONT REPORT*].

70. *Id.*

‘experimental’ and ‘research’ are not carefully defined.”⁷¹ The Commission argued that the distinction is largely based on the intent behind the activity. Essentially, medical practice is about helping individual patients, whereas research is about learning from individuals to develop knowledge that can be applied to other, future patients.⁷² Any departure from standard practice does not necessarily constitute research, however; nor does “the fact that a procedure is ‘experimental,’ in the sense of new, untested or different” turn it into research.⁷³ Yet, the Commission cautioned, experimental procedures should “be made the object of formal research at an early stage in order to determine whether they are safe and effective.”⁷⁴

After discussing the boundary between research and practice, the Commission turned its attention to the general principles that should govern the conduct of research. It determined that three core ethical principles should apply to research: respect for persons, beneficence, and justice.⁷⁵ Respect for persons requires recognizing that individuals should be treated as autonomous agents, and individuals who are not able to make their own decisions should be protected from risk. Respecting autonomous individuals serves at least two functions. The value of treating individuals as autonomous agents is not just to show them respect by letting them do as they choose (within certain constraints, of course), but also because individuals are often best-positioned to make decisions that protect their own interests. The Commission specifically applied this principle to the conduct of research involving prisoners as follows:

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of

71. *Id.* at 3.

72. *Id.* More specifically, the National Commission contended that medical practice refers to “interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose . . . is to provide diagnosis, preventative treatment, or therapy to particular individuals.” *Id.* at 3–4. By contrast, research is an “activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.” *Id.* at 4.

73. *Id.* at 4.

74. *Id.*

75. *Id.*

respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to “volunteer” or to “protect” them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.⁷⁶

The Commission determined that, in research, the principle of respect for persons requires asking potential research subjects for their informed and voluntary consent to participate in the research, provided that they are capable of making their own decisions. They also specified that this requires informing potential research subjects about “the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.”⁷⁷

The second principle the Commission thought should be applied to research with human subjects is the principle of beneficence. Although it described this principle as requiring that researchers do no harm, maximize possible benefits, and minimize potential harms,⁷⁸ it is not straightforward to apply the principle of beneficence to research. Because research involves testing interventions with uncertain risks and benefits, and research procedures are sometimes needed to understand how these interventions are working in the body, it is difficult to conceive of research that would not do any harm. Moreover, the requirement to maximize benefits could be overly demanding and come into conflict with the primary duty that researchers have to develop generalizable knowledge. Therefore, scholars now understand the obligation of beneficence to require that harms are minimized in research, and that unnecessary harms are not imposed on research subjects.⁷⁹ This is also consistent with the way the Commission applied the principle of beneficence in the Belmont Report—it notes that beneficence requires the systematic assessment of risks and benefits, and ensuring that “risks should be reduced to those necessary to attain the

76. *Id.* at 5.

77. *Id.* at 7.

78. *Id.* at 5.

79. Steven Joffe & Franklin G. Miller, *Bench to Bedside: Mapping the Moral Terrain of Clinical Research*, HASTINGS CTR. REP., Mar.–Apr. 2008, at 30, 36.

research objective.”⁸⁰

The final principle the Commission argued should apply to research is justice. In research, justice requires the fair and equal distribution of the burdens and benefits of research. In particular, it explained that “the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.”⁸¹ It was particularly concerned that only “undesirable” persons might be selected for risky research.⁸²

In a subsequent report, the Commission was also charged with specifically addressing the participation of prisoners in biomedical and behavioral research.⁸³ The Commission noted that, in general, prisoners did not participate in biomedical research outside the United States, and attributed this to international concern about experiments conducted by the Nazis on holocaust victims.⁸⁴ The Commission raised two important ethical concerns about prisoner participation in research: exploitation and autonomy. The Commission specifically was concerned that (1) prisoners were being exploited by being exposed to risky research, and (2) prisoners may not be able to give voluntary informed consent to research participation because they live in a coercive environment.⁸⁵ The Commission made a strong statement about the importance of protecting prisoners from exploitation:

It has become evident to the Commission that, although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deprivation in which they live compromise their freedom. The Commission believes, therefore, that the appropriate expression of respect consists in protection from exploitation. Hence it calls for certain safeguards intended to reduce the elements of constraint under which prisoners give consent and suggests that certain kinds of research would not be permitted where such safeguards cannot be assured.⁸⁶

The Commission’s report led to strict regulations governing research on prisoners. Various federal agencies have promulgated regulations greatly influenced by the Commission’s report. For example,

80. THE BELMONT REPORT, *supra* note 69, at 10.

81. *Id.* at 11.

82. *Id.*

83. See RESEARCH INVOLVING PRISONERS, *supra* note 60, at vii–ix.

84. *Id.* at 2–3.

85. *Id.* at 5.

86. *Id.* at 6–7.

Department of Health and Human Services (DHHS) regulations provide that research on prisoners should not take place unless the research is likely to have some benefit for prisoners as a group or for individual prisoners enrolled in the research.⁸⁷ There are also regulations promulgated by the Federal Bureau of Prisons that stem from the Commission's work; these regulations govern research involving prisoners that is conducted within the Federal Bureau of Prisons. These regulations are slightly different from the DHHS regulations.⁸⁸ Finally, the Food and Drug Administration (FDA) attempted to enact a set of prisoner regulations similar to those adopted by the DHHS in 1978.⁸⁹ However, presumably out of concern that they would not have access to potentially beneficial research, prisoners in the Michigan State Penitentiary alleged that these proposed regulations violated the Equal Protection and Due Process Clauses of the Fifth Amendment.⁹⁰ The existing FDA regulations that cover human subjects research in general do, however, have at least one protection that would apply to research with prisoners. Current FDA regulations require that Institutional Review Boards (IRBs), which regularly review research involving a particular vulnerable group (such as prisoners), consider including someone on the board who has knowledge and expertise in working with members of the group.⁹¹

Many states have also passed laws of varying degrees of restrictiveness that limit or even prohibit the conduct of research on prisoners within state departments of corrections.⁹² This protectionist response was viewed by many as an overcorrection, which led to prisoners being denied the benefits associated with some types of research and insufficient investigation of the kinds of illnesses that

87. See 45 C.F.R. § 46 subpart C (2014). The exceptions provided in this subpart are discussed at greater length in Part III.C, *infra*.

88. See 28 C.F.R. § 512 (2014). Note that unlike the DHHS regulations, which only apply to federally funded research, the Bureau of Prisons regulations appear to apply to any research conducted within the Bureau. *Id.* § 512.10. Furthermore, although some research conducted by employees of the Bureau is exempt from some regulations, no research is exempt from part 512, which is the relevant part for my analysis. *Id.*

89. 45 Fed. Reg. 19,417, 19,418 (May 5, 1978) (to be codified at 21 C.F.R. pt. 50 Subpart C) (referring to subpart C of the DHHS regulations, but going beyond these regulations by including statements such as: "no prisoner may serve as a placebo control").

90. See Sharon Hoffman, *Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials*, 33 IND. L. REV. 475, 491–92 (2000).

91. 21 C.F.R. § 56.107(a) (2014); *id.* § 56.111. Note, however, that the FDA revoked these regulations in 1997 for being "obsolete or no longer relevant to public health goals." 62 Fed. Reg. 39,439 (July 23, 1997).

92. Shah, *supra* note 32, at 1146 app. 1.

disproportionately affect prisoners. In fact, an Institute of Medicine committee issued a report in 2006, in which it acknowledged “that access to research may be critical to improve the health of prisoners and the conditions in which they live.”⁹³ The report argued that more research calculated to benefit individual inmates and prisoners as a group should be permitted.⁹⁴ Despite this regulatory response to abuses and scandals of the past, public distrust of biomedical research persists,⁹⁵ particularly among African-Americans.⁹⁶ This distrust may stem from historical scandals in research involving African-Americans, and may also incorporate a more general lack of trust based on the legacy of discrimination against African-Americans in the U.S.⁹⁷

In sum, the history of research involving prisoners in the United States led to the recognition that the principles of respecting autonomy, beneficence, justice, and avoiding exploitation should guide the conduct of research with human subjects. This history also led to the development of strict research regulations that, as I will argue below, apply to some of the current experimentation on lethal injection. First, I will head off an important potential objection to this line of inquiry—should ethical principles and legal protections developed for research subjects be applied to the domain of capital punishment?

B. *Should Research Protections Apply to Capital Punishment?*

Biomedical research involves risks of bodily harm and a divergence

93. COMM’N ON ETHICAL CONSIDERATION FOR REVISIONS TO DHHS REGULATIONS FOR PROT. OF PRISONERS INVOLVED IN RESEARCH, ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS 4 (Lawrence O. Gostin et al. eds., 2007) [hereinafter ETHICAL CONSIDERATIONS]. The Institute of Medicine is an arm of the National Academy of Sciences that regularly convenes committees to issue influential reports, often at the behest of Congress or federal agencies. See *About the IOM*, INST. OF MED., <http://iom.edu/About-IOM.aspx> (last visited Nov. 4, 2013).

94. ETHICAL CONSIDERATIONS, *supra* note 93, at 4.

95. Raegan W. Durant et al., *Different Types of Distrust in Clinical Research Among Whites and African Americans*, 103 J. NAT’L MED. ASS’N. 123, 123 (2011).

96. See, e.g., Joel B. Braunstein et al., *Race, Medical Research Distrust, Perceived Harm, and Willingness to Participate in Cardiovascular Prevention Trials*, 87 MED. 1, 5 (2008); Giselle Corbie-Smith et al., *Distrust, Race, and Research*, 162 ARCHIVES OF INTERNAL MED. 2458, 2459 (2002); Vickie L. Shavers, Charles F. Lynch, & Leon F. Burmeister, *Knowledge of the Tuskegee Study and its Impact on the Willingness to Participate in Medical Research Studies*, 92 J. NAT’L MED. ASS’N. 563, 567 (2000). I have noted elsewhere that lethal injection research has the potential to harm biomedical research, given that distrust of research is particularly high among African-Americans, and that African-Americans are overrepresented on death row. Shah, *supra* note 32, at 1146 n.232.

97. Jill A. Fisher & Corey A. Kalbaugh, *Challenging Assumptions About U.S. Minority Participation in U.S. Clinical Research*, 101 AM. J. PUB. HEALTH 2217, 2218–19 (2011).

of interests between those conducting research and those subjected to it. It is particularly vulnerable to exploitation and abuse. Research is an activity that involves trying interventions that may or may not work to produce scientific knowledge that can benefit others in society, and may pose risks of bodily harm for the individual subjects of the research. The interests of the researcher and the sponsors of the research are to find out something that was not previously known, and to receive benefits from the production of that knowledge. These benefits may include prestige, status, career advancement, satisfaction of curiosity, and money. By contrast, research subjects may benefit from the research intervention, but may also face significant risk. They are also unlikely to benefit from the production of the knowledge in a significant way. Safeguards for research have therefore been developed that help protect research subjects and ensure that valuable research can proceed and new knowledge can be generated.

The current approaches to lethal injection executions involve exposing inmates to new and uncertain risks of bodily harm from untested drugs and drug combinations. The interests of prison officials are to find methods of lethal injection that are effective, appear to have a low risk of causing significant pain and suffering, and are based on using drugs they can access and procedures they can implement. There is great potential for abuse and exploitation of prisoners because prison officials' interests differ so dramatically from those of inmates. There is considerable uncertainty about whether some of these drugs will cause death without also causing excessive and torturous pain. Additionally, executions are justified on the basis that they further societal goals of deterrence and retribution. The potential for abuse suggests that the principles and protections developed for biomedical research could be very helpful in regulating executions by lethal injection.

Some might still question whether a research ethics framework is the right approach to address worries about execution methods for several reasons. First, perhaps executions should not be thought of as "medical" in any respect. Second, the historical examples of research on prisoners may differ in important respects from modern day executions by lethal injection. Third, one might argue that capital punishment should be judged on the basis of considerations specific to the criminal justice system (such as whether the approach to executions furthers its goals of deterrence and retribution), rather than the "subject protection" framework that applies to research. Perhaps the research ethics framework assumes a more robust conception of the interests and rights of subjects than should be applied to capital punishment. Finally, maybe death is different, and people who are already sentenced to death should

not receive the same protections that others would.⁹⁸

Some have argued that lethal injections should be considered outside of the practice of medicine altogether, and some states indicate in their statutory codes that lethal injection does not constitute the practice of medicine.⁹⁹ However, for the purposes of this analysis, lethal injections do not have to be considered part of the practice of medicine. My argument is that lethal injection executions involve a type of biomedical research—something that is also outside the practice of medicine.¹⁰⁰ Additionally, Mark Heath argues that some components of lethal injection clearly use medical procedures for medical purposes. The administration of drugs that paralyze the inmate or that have the sole effect of causing death do not have clear medical purposes. But Heath argues that “[a]dministration of general anesthesia, including the induction, maintenance, and continued assessment of anesthetic depth, is done to prevent severe pain; it is a therapeutic procedure and a medical procedure.”¹⁰¹ The use of anesthesia is necessary for all current lethal injection protocols to avoid an unconstitutionally high risk of pain. This suggests that lethal injections in the United States have a medical component to them that cannot be removed.

It is true that there are some important differences between the history of research on prisoners and current experimentation in lethal injection executions that may support differential treatment. First, execution research on inmates, unlike most research and most of the historical research on prisoners, enrolls individuals who are going to die shortly. This can be compared, however, to some examples of research on individuals who suffer from terminal illnesses¹⁰² or who will likely die

98. Note that the Supreme Court has explained that the fact that “the penalty of death is different in kind from any other punishment imposed under our system of criminal justice” is a justification for heightened protections, and not a justification for less scrutiny. *Gregg v. Georgia*, 428 U.S. 153, 188 (1976).

99. See, e.g., Amended Order Granting Plaintiff’s Request for Declaratory Relief and Denying Defendant’s Motion to Dismiss, N.C. Dep’t of Corr. v. N.C. Med. Bd., No. 07-CV-003574 (N.C. Oct. 1, 2007); Complaint, N.C. Dep’t of Corr. v. N.C. Med. Bd., No. 07-CV-003574 (N.C. March 6, 2007); Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 *FORDHAM L. REV.* 49, 89 (2007) (explaining that eight states have statutes expressly indicating that lethal injection executions do not constitute the practice of medicine); William L. Lanier & Keith H. Burge, *Physician Involvement in Capital Punishment: Simplifying a Complex Calculus*, 82 *MAYO CLINIC PROC.* 1043, 1046 (2007).

100. Paul Litton & Franklin G. Miller, *What Physician-Investigators Owe Patients Who Participate in Research*, 304 *J. AM. MED. ASS’N* 1491, 1491 (2010).

101. Mark J. Heath, *Revisiting Physician Involvement in Capital Punishment: Medical and Nonmedical Aspects of Lethal Injection*, 83 *MAYO CLINIC PROC.* 115, 116 (2008).

102. Erika Kleiderman et al., *Recruiting Terminally Ill Patients into Non-Therapeutic Oncology Studies: Views of Health Professionals*, 13 *BMC MED. ETHICS* 33, 34 (2012).

imminently.¹⁰³ In these categories of research, although long-term risks may be discounted because subjects may not live long enough to experience these consequences, the ethical issues regarding the treatment of research subjects are still taken seriously.¹⁰⁴ Similarly, there is no reason to disregard the risk of significant pain and suffering that an inmate will experience before being executed, simply because he will most likely be dead soon after experiencing them. Depending on why we think pain is a negative experience, however, there may be some reason to discount the pain experienced at the very end of life. There are at least two aspects of pain that make it bad—the actual experience of pain and the memory of it. Because inmates being executed will not live to remember their experience of pain, how bad it is for them to suffer at the end of life may need to be discounted from how we might ordinarily evaluate pain. On the other hand, studies conducted by psychologists asking subjects to evaluate the quality of different individuals' lives suggest that negative experiences at the end of life color the evaluation of the life as a whole significantly.¹⁰⁵ Somewhat counterintuitively, this research implies that there may be *extra* reason to think that severe pain at the end of life is bad. Thus, it is hard to establish conclusively whether the negative aspects of pain are diminished or increased if pain is experienced at the end of life. Perhaps the safest conclusion is that the fact that an inmate who is executed will not live to remember the pain may give some reason to discount the level of pain an inmate experiences, but does not eliminate other reasons to care about the experience of pain in an execution.

Second, lethal injection experimentation may also differ from most of human subjects experimentation because it may be less motivated by scientific curiosity and the desire to improve human health. Such experimentation is presently motivated at least in part by political considerations and drug embargos that stem from ethical concerns about the death penalty.¹⁰⁶ For example, a Danish drug maker and some American pharmaceutical companies have taken steps to prevent their drugs from being supplied to states for use in executions.¹⁰⁷ Yet, at least

103. Kate Murphy, *Killing a Patient to Save His Life*, N. Y. TIMES (June 9, 2014), <http://www.nytimes.com/2014/06/10/health/a-chilling-medical-trial.html>.

104. Kleiderman et al., *supra* note 102, at 36–38.

105. See DANIEL KAHNEMAN, THINKING FAST AND SLOW 387–88 (2011).

106. Josh Sanburn, *The Hidden Hand Squeezing Texas' Supply of Execution Drugs*, TIME (Aug. 7, 2013), <http://nation.time.com/2013/08/07/the-hidden-hand-squeezing-texas-supply-of-execution-drugs/>.

107. *Id.*; see also *Par Pharmaceutical Statement on Brevital® Sodium*, PAR PHARMACEUTICALS (May 27, 2014), <http://pr.parpharm.com/phoenix.zhtml?c=81806&p=irol-newsArticle&ID=>

some biomedical research is conducted because of political considerations or moral concerns. Consider, for example, the increased research by the states and private companies spurred by President George W. Bush's decision to severely restrict federal funding for research on the use of embryonic stem cell lines.¹⁰⁸

A third objection to considering certain aspects of lethal injection executions medical research is that execution and research serve different goals. In the history of research on prisoners and other vulnerable subjects, the aim was to test products that could benefit others. By contrast, some might argue that the goal of lethal injection experimentation is to successfully execute the particular inmate, or perhaps to make future executions of inmates more effective and less objectionable. If the goals of the two types of research are different, the history of research on prisoners may not help us to understand current experimentation on death row inmates.

This objection, however, does not rely on an accurate view of the motivations of both stakeholders in research and those involved in conducting executions. Researchers and sponsors of research can have many different motivations. They may want to test a treatment on particular patients hoping to help those patients, and still have interests in whether the treatment is likely to be safe and effective for use in future patients.¹⁰⁹ Researchers may also conduct research in order to satisfy their curiosity, build their reputation, or make money.¹¹⁰ Similarly, although prison officials may want to ensure that a particular inmate is executed without incident, they may also be very interested in finding a method of execution that they can use without raising concern from activists, judges, and the general public. And those who support executions do so for at least one of a few different reasons. They may believe that executions have a deterrent effect and prevent future crime; they may think that punishment and retribution are morally appropriate for those who have committed crimes of a certain degree; or they may think that an execution gives comfort or justice to the victims of a crime and their families.¹¹¹ This suggests that the purposes behind capital

1935104 ("As a pharmaceutical company, Par's mission is to help improve the quality of life. The state of Indiana's proposed use is contrary to our mission.").

108. Eileen Burgin, *Human Embryonic Stem Cell Research and Proposition 71: Reflections on California's Response to Federal Policy*, 29 POL. & LIFE SCI. 73 (2010); Constance Holden, *States, Foundations Lead the Way After Bush Vetoes Stem Cell Bill*, 313 SCI. 420 (2006).

109. Joffe & Miller, *supra* note 79, at 33.

110. David Korn, *Conflicts of Interest in Biomedical Research*, 284 J. AM. MED. ASS'N 2234, 2234 (2000).

111. Cass R. Sunstein & Adrian Vermeule, *Is Capital Punishment Morally Required?: Acts,*

punishment, like the purposes behind research, may include a desire to benefit society in some way. Thus, inmates on death row are not immune from the possibility of exploitation for the benefit of society.

Some might object that there is no reason to apply extra protections for research on lethal injection because these prisoners are already sentenced to death. A more extreme view might be that any additional suffering is what death row inmates deserve, based on the crimes that led to a death sentence.¹¹² Although the Constitution has been interpreted to permit the imposition of death sentences, it expressly forbids cruel and unusual punishment. Thus, unless the Constitution is amended to eliminate the cruel and unusual punishment clause of the Eighth Amendment or the death penalty is determined to be unconstitutional under evolving standards of decency,¹¹³ we must evaluate methods of execution to ensure that they are not cruel and unusual. As the U.S. Supreme Court explained in *In re Kemmler*,¹¹⁴ “[p]unishments are cruel when they involve torture or a lingering death; but the punishment of death is not cruel within the meaning of that word as used in the constitution. It implies there is something inhuman and barbarous—something more than the mere extinguishment of life.”¹¹⁵ Austin Sarat further argues that an important purpose is served by ensuring that the death penalty is administered humanely:

Even as capital punishment seeks to do justice and/or satisfy the public desire for vengeance, the state has countervailing concerns. It must distinguish execution from the acts to which it is a supposedly just response. The state must also find ways of killing in a manner that does not allow the condemned to become an object of pity, or to appropriate the status of the victim.¹¹⁶

Sarat goes on to note that, “[l]aw imposes on sovereignty the requirement that no matter how heinous the crime or how reprehensible the criminal, we not do death as death has been done by those we

Omissions, and Life-Life Tradeoffs, 58 STAN. L. REV. 703, 704–05 (2006).

112. See Matt McCarthy, *What's the Best Way to Execute Someone?*, SLATE (Mar. 27, 2014, 11:44 PM), http://www.slate.com/articles/health_and_science/medical_examiner/2014/03/death_penalty_drugs_lethal_injection_executions_are_so_bad_that_it_s_time.html.

113. *Trop v. Dulles*, 356 U.S. 86, 100–01 (1958).

114. 136 U.S. 436 (1890).

115. *Id.* at 447. Although *Kemmler* has been cited in subsequent Supreme Court cases as confined to outlawing “barbarous” forms of punishment, the standards used by the Supreme Court today are meant to be broader than this and to reflect “evolving standards of decency.” See *Gregg v. Georgia*, 428 U.S. 153, 173 (1976).

116. SARAT ET AL., *supra* note 28, at 5.

punish We kill humanely, not out of concern for the condemned but rather to vividly establish a hierarchy between the law-abiding and the lawless.”¹¹⁷ This suggests that there is reason to ensure the death penalty is administered humanely whether or not one has any concern for the welfare of the inmates being executed.

The research enterprise also depends on trust in the system, and to the extent that the public is beginning to view executions as poorly conducted research, public trust in research may be affected by lethal injection executions.¹¹⁸ Allowing death penalty research to proceed unchecked and immune from regulatory scrutiny sets a precedent that could erode confidence in research more generally, particularly as questions about the experimental nature of executions are asked more frequently.¹¹⁹ It is also true that many historical scandals arose out of research conducted on people who were considered disposable, or unworthy of moral consideration, by mainstream society.¹²⁰

Finally, and perhaps most importantly, it is not clear why the imposition of the death penalty should suspend all other legal protections. As the Supreme Court explained in a case about FDA review of lethal injection drugs, “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 to the United States Constitution into the domain of administrative law.”¹²¹ The same logic applies to the domain of research regulation.

In sum, there are enough similarities and common principles shared between new death penalty protocols and more traditional biomedical research that it is appropriate to evaluate them in similar ways. As I will demonstrate below, insights from the domain of research ethics and regulation can help to ensure that executions by lethal injection are not excessively risky or disrespectful of inmates.

II. HISTORICAL AND CURRENT DEVELOPMENTS IN EXECUTION BY LETHAL INJECTION

Many articles have described the history of how the first lethal

117. *Id.* at 28.

118. See Alex J. London, *A Non-Paternalistic Model of Research Ethics and Oversight: Assessing the Benefits of Prospective Review*, 40 J.L. MED. & ETHICS 930, 930 (2012).

119. See Kiefer, *supra* note 18.

120. See Bonham & Moreno, *supra* note 46, at 461–63.

121. Heckler v. Chaney, 470 U.S. 821, 838 (1985).

injection protocol was developed,¹²² so I will discuss the history only briefly and then turn to more recent changes to and problems with executions by lethal injection.

A. *Brief History of Execution by Lethal Injection*

The first time lethal injection was considered as a possible method of execution was in the late nineteenth century, when a New York state commission rejected it as an option based on the concern that the public would associate the practice of medicine with causing death.¹²³ The U.K.'s Royal Commission on Capital Punishment conducted a study in the 1950s to evaluate the relative merits of execution by lethal injection versus execution by hanging, and identified several problems that led the members of the commission not to recommend lethal injection as a possible execution method.¹²⁴ The Royal Commission was particularly concerned about problems associated with individuals with veins that were difficult to access and the need for someone on the execution team to have complex medical skills.¹²⁵ The British Association of Anaesthetists explained to the Royal Commission that lethal injection was impractical because of concerns that: (1) it would be impossible to administer intravenous injections to people with "certain physical abnormalities," (2) it is difficult to inject people against their will, and (3) medical skills and training would be needed, but members of the medical profession would not be willing to provide their assistance.¹²⁶ The Commission did believe, however, that lethal injection might be a more humane and painless method than other methods, and suggested that gradual adoption of lethal injection in a systematic manner, coupled with the state taking "all possible means to ensure that the act is

122. Denno, *supra* note 99, at 64–65; *see generally* Shah, *supra* note 32.

123. Denno, *supra* note 99, at 64.

124. ROYAL COMM'N ON CAPITAL PUNISHMENT, 1949–1953, REPORT 261 (1953) (U.K.) ("Our own collective verdict must be a negative one: we cannot agree to recommend that in the present circumstances lethal injection should be substituted for hanging as the method of judicial execution in this country. If we could have been satisfied that executions could be carried out in this way quickly, painlessly and decently in all cases, we should have recommended its adoption unanimously. But we are bound to conclude from our expert evidence that there is not at present a reasonable certainty of this. We do, however, recommend, unanimously and emphatically, that the question should be periodically examined, especially in the light of progress made in the science of anaesthetics, with a view to a change of system being proposed to Parliament as soon as it can be shown that there are no longer any grounds for the doubts that now deter us from recommending it.").

125. *Id.* at 257–59.

126. *See id.* at 258–59.

performed with dignity, solemnity, speed, and certainty,” might make sense in the future.¹²⁷

Notwithstanding these earlier qualms about execution with lethal injection, along with the views of its own state senators that there was a need for more research before lethal injection should be adopted,¹²⁸ the State of Oklahoma adopted a lethal injection protocol in 1977.¹²⁹ Jay Chapman, the state’s medical examiner, was asked by a state legislator to develop a lethal injection protocol. Dr. Chapman initially replied that he “was an expert in dead bodies but not an expert in getting them that way.”¹³⁰ Yet, Dr. Chapman first proposed that lethal injection could involve an “ultra-short-acting barbiturate in combination with a chemical paralytic.”¹³¹ In 1981, Chapman modified his initial proposal protocol to add a third drug, potassium chloride, thereby developing the three-drug protocol that became the standard for execution in the United States until recently.¹³²

B. *More Recent Developments in Executions*

By 2008, all of the thirty-eight jurisdictions¹³³ that permitted execution by lethal injection used the protocol Chapman developed and administered a sequence of three drugs intravenously.¹³⁴ The first drug was a dose of sodium thiopental that was given in a lethal dose. But this dose takes a relatively long time to result in death, and the drug was not expected to cause death before the rest of the drugs take effect. Rather, it was administered for its anesthetic effects. The second chemical was pancuronium bromide, a neuromuscular blocking agent that paralyzes the inmate. This chemical was used to further the state’s interest in dignity by making the dying process appear serene.¹³⁵ However,

127. *Id.* at 259.

128. John Greiner, *Drug Execution Plan Suffers Senate Setback*, DAILY OKLAHOMAN, Feb. 16, 1977, at 16.

129. OKLA. DEP’T OF CORR., NO. P-090901, OKLAHOMA POLICY STATEMENT, PROCEDURES FOR CARRYING OUT THE DEATH SENTENCE (1978) (citing OKLA. DEP’T OF CORR., NO. P-090900, OKLAHOMA POLICY STATEMENT, PROCEDURES FOR CARRYING OUT THE DEATH SENTENCE (1977)).

130. Denno, *supra* note 99, at 65–66.

131. *Id.* at 66–67.

132. *Id.* at 74.

133. TRACY L. SNELL, U.S. DEP’T OF JUSTICE, BUREAU OF JUSTICE STATISTICS, CAPITAL PUNISHMENT, 2008—STATISTICAL TABLES, at 5 tbl.2 (2009), available at <http://www.bjs.gov/content/pub/pdf/cp08st.pdf>.

134. Shah, *supra* note 32, at 1105.

135. *Baze v. Rees*, 553 U.S. 35, 49 (2008).

pancuronium bromide also makes problems in the administration of the first drug difficult, if not impossible, for witnesses to detect.¹³⁶ Finally, potassium chloride was administered to cause death by cardiac arrest.¹³⁷ If everything went according to plan, the first drug anesthetized the inmate from pain, the second drug prevented the inmate's spasms or death throes from disturbing the audience, and the third drug caused death quickly. If the anesthetic was not administered correctly, however, all parties now agree that the inmate would experience excruciating suffering before death.¹³⁸

Some examples of executions that seemed to go poorly raised concern about the three-drug protocol. In Florida, Governor Jeb Bush temporarily halted executions in the state after Angel Diaz's botched execution in December of 2006.¹³⁹ An autopsy revealed that the lethal injection administered to Mr. Diaz was not inserted into his veins, but rather into the soft tissue of his arms.¹⁴⁰ He sustained chemical blisters of a foot in length on both of his arms, and because the effect of the anesthesia administered was likely diluted, he seemed to have experienced agonizing pain.¹⁴¹

In California, a court reviewing lethal injection evidence was troubled by the fact that "anomalies in six execution logs raise substantial questions as to whether certain inmates may have been conscious" during the procedure.¹⁴² These outcomes were concerning because when an inmate is not sufficiently anesthetized before lethal drugs are administered, "the inmate may suffer excruciating suffocation."¹⁴³ Based on this and other evidence, executions in California were stayed by a district court judge.¹⁴⁴ Similar problems arose all over the country.¹⁴⁵ In

136. Denno, *supra* note 99, at 55–56.

137. Ty Alper, *Lethal Incompetence: Lethal Injection Litigation Is Exposing More Than Torturous Executions*, THE CHAMPION, Sept.–Oct. 2006, at 41.

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

139. Ben Crair, *Photos from a Botched Lethal Injection*, NEW REPUBLIC (May 29, 2014), <http://www.newrepublic.com/article/117898/lethal-injection-photos-angel-diazs-botched-execution-florida>.

140. *Id.*

141. Chris Tisch, *Doctor: Killing Flawed at Start*, ST. PETERSBURG TIMES (Feb. 12, 2007), http://www.sptimes.com/2007/02/12/news_pf/State/Doctor_Killing_flawe.shtml; *see also* Crair, *supra* note 139.

142. *Morales v. Tilton*, 465 F. Supp. 2d. 972, 980 (N.D. Cal. 2006).

143. Ty Alper, *supra* note 137, at 41.

144. Order Following Remand at 2, *Morales v. Cate*, No. 5-6-cv-219-JF-HRL (N.D. Cal. 2010).

2007, the U.S. Supreme Court granted certiorari to *Baze v. Rees* and seemed poised to address this controversy.¹⁴⁶ However, the Court found that there was insufficient reason to conclude that Kentucky's lethal injection protocol was unconstitutional, though it could reach agreement on little else.¹⁴⁷

Since that time, much has changed. States are facing drug shortages, drug embargoes, and ethical restrictions that may prevent qualified experts from becoming involved in executions. The FDA recently began regulating the importation of drugs for use in executions.¹⁴⁸ Drug manufacturers, particularly those based in Europe, have raised concerns that exportation of their drugs may result in those drugs being used for executions. These manufacturers have either stopped selling their drugs in American markets or specifically prohibited the use of their drugs in executions.¹⁴⁹ Experiencing greater difficulties in obtaining drugs that are already on the market for lethal injection purposes, state departments of corrections are turning to compounding pharmacies to obtain the drugs needed.¹⁵⁰ Compounding pharmacies are pharmacies that make drugs to fill individual prescriptions, as opposed to the bulk manufacturing of drugs by pharmaceutical companies.¹⁵¹ The production of drugs by compounding pharmacies has traditionally been much more lightly regulated than the manufacturing of most prescription medications.¹⁵² The use of compounding pharmacies, however, has undergone increased scrutiny after sixty-four deaths were attributed to the use of contaminated drugs produced at the New England

145. See Denno, *supra* note 99, at 76–77.

146. *Baze v. Rees*, 551 U.S. 1192 (2007).

147. Linda Greenhouse, *Justices to Enter the Debate Over Lethal Injection*, N.Y. TIMES (Sept. 26, 2007), http://www.nytimes.com/2007/09/26/washington/26lethal.html?_r=0.

148. Kevin O'Hanlon, *Company Recalls Nebraska's Lethal Injection Drug*, LINCOLN J. STAR (May 9, 2012), http://journalstar.com/news/local/crime-and-courts/company-recalls-nebraska-s-lethal-injection-drug/article_3694f11a-a844-5955-ae7f-a5d9253ed10a.html.

149. See *Proposal for a Regulation of the European Parliament and of the Council*, COM (2014) 1 final (Jan. 1, 2014), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2014:0001:FIN:EN:PDF> (prohibiting the exportation of drugs for use in capital punishment). Additionally, manufacturers in the United States have made anti-capital punishment statements and indicated that they will not sell drugs for use in executions. See, e.g., *Anti-Capital Punishment Statement*, SAGENT PHARMACEUTICALS, <http://www.sagentpharma.com/contactmenu/anti-capital-punishment-statement.html> (last visited Jan. 5, 2015).

150. Denno, *supra* note 27, at 1366.

151. Matt McCarthy, *FDA Inspections Find Unsafe Practices in Compounding Pharmacies*, 346 BMJ 1 (2013).

152. See *id.*

Compounding Center.¹⁵³ Congress recently passed a law heightening regulatory requirements for compounding pharmacies and for the reporting of adverse events from their products.¹⁵⁴ This law also creates a new category of regulated entities (“outsourcing facilities”) that compounding pharmacies can fall under.¹⁵⁵ If a compounding pharmacy voluntarily registers with the FDA as an “outsourcing facility,” certain FDA requirements would be relaxed, but FDA inspections of their facilities would be permitted.¹⁵⁶ It is not clear at present whether this law will also apply to drugs obtained from compounding pharmacies that are used in executions.

While many states are actively engaged in modifying their lethal injection protocols, these protocols are not uniform across the country. Different states use different drugs. Some states use midazolam, which is used for treatment of seizures and as premedication for anesthesia, and pentobarbital, a barbiturate commonly used to euthanize animals and to treat seizures in humans.¹⁵⁷ Eleven states have modified their protocols to allow for the possibility of execution with a single drug.¹⁵⁸ Because of drug shortages, sixteen states substituted the drug pentobarbital for sodium thiopental, the anesthetic they previously used.¹⁵⁹ Missouri also switched to a one-drug protocol and initially selected the drug propofol, but then later revised its execution procedures to require pentobarbital as well.¹⁶⁰ Even after its protocol was determined to be constitutional in *Baze*, Kentucky switched to a one-drug protocol, with a back-up of a

153. Stephen Barlas, *New Congressional Bill Attempts to Aid Pharmacy Response to Drug Shortages*, 39 P&T 51, 51 (2014).

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

155. Erika Lietzan & Mingham Ji, *Pharmacy Compounding After the Drug Quality and Security Act*, 26 HEALTH LAWYER 4–5 (2014).

156. *Id.* However, there is some concern that by passing this law, Congress may have actually undermined the FDA’s regulatory authority because compounding pharmacies are not required to register with the FDA, and FDA already had regulatory tools that it could apply to compounding pharmacies that are taken away if compounding pharmacies register as outsourcing facilities. *Id.* at 5. Nonetheless, the new law does clarify that FDA has some authority over compounding pharmacies, and this authority was arguably less clear before the law was passed.

157. Paul W. Shaw, *Federal Legislative Response to the Controversy over Drug Compounding*, 7 J. HEALTH & LIFE SCI. L. 84, 84 (2014).

158. *See* Denno, *supra* note 27, at 1359 chart 4.

159. *See id.*

160. *See* MO. DEP’T OF CORR., PREPARATION AND ADMINISTRATION OF CHEMICALS FOR LETHAL INJECTION (2013) (on file with Washington Law Review) *State by State Lethal Injection*, DEATH PENALTY INFO. CTR., <http://www.deathpenaltyinfo.org/state-lethal-injection> (last visited June 2, 2014).

two-drug protocol if necessary.¹⁶¹

In at least some cases, these changes have seemed to contribute to botched executions. In October 2012, an execution in South Dakota used compounded pentobarbital that was later found to be contaminated with fungus. Eric Robert, the inmate executed with the adulterated drug, had his eyes open throughout the execution, raising concern that he may not have been adequately anesthetized.¹⁶²

The process of experimentation is well illustrated by what has happened in Ohio. Ohio first allowed lethal injection in 1993 as a possible alternative to electrocution, and retired its electric chair and made lethal injection its sole method of execution in 2002.¹⁶³ The protocol in Ohio has changed several times. One of the most significant changes occurred in 2009. Ohio switched to a one-drug protocol (with a back-up plan) after an Ohio state court judge determined that the three-drug protocol violated Ohio's statutory requirement for a "quick and painless death."¹⁶⁴ Although this change was a big departure from prior protocols, it also was likely to decrease the risks of execution, and it introduced an option that inmates had been requesting and may reasonably have chosen in an informed consent process.¹⁶⁵ The State then switched from one barbiturate to another after a drug shortage, and then moved to a two-drug protocol involving midazolam after the Danish manufacturer of the barbiturate refused to sell it for use in executions.¹⁶⁶ In 2013, Ohio introduced another new protocol that included many changes from the previous protocols, including: (1) the intravenous administration of two execution drugs—hydromorphone and midazolam; (2) the use of compounded drugs; and (3) the availability of multiple options if the preferred method of execution will not work for some reason, including the possibility of intramuscular injection, which no other state has used.¹⁶⁷ In this lethal injection protocol, the state also added a quality assurance review with a designated official empowered

161. 501 KY. ADMIN. REGS. 16:330 (2012).

162. *South Dakota Covers Up Source of 'DIY' Death Penalty Drugs Ahead of Execution*, REPRIEVE (Oct. 30, 2012), http://www.reprive.org.uk/press/2012_10_30_South_Dakota_execution_drugs.

163. *Capital Punishment in Ohio*, OHIO DEP'T OF REHABILITATION & CORRECTION, <http://www.drc.ohio.gov/public/capital.htm> (last visited Jan. 5, 2015).

164. *State v. Rivera*, Nos. 04CR065940, 05CR068067, at 5 (Ohio Cnty. Ct. C.P. June, 10, 2008).

165. *See infra* Part IV.

166. Ben Crair, *Exclusive Emails Show Ohio's Doubts About Lethal Injection*, NEW REPUBLIC (Aug. 17, 2014), <http://www.newrepublic.com/article/119068/exclusive-emails-reveal-states-worries-about-problematic-execution>.

167. Denno, *supra* note 27, at 1354–58.

to review the conduct of executions in consultation with others (including a “properly trained medical person”), but it is not clear whether or how this is being implemented.¹⁶⁸ In January 2014, an execution was conducted under Ohio’s modified protocol that did not go according to plan. Dennis McGuire’s execution lasted twenty-six minutes, during which time he gasped, snorted, and appeared to be struggling for breath.¹⁶⁹

Notably, the introduction of several untested components at once makes it more difficult to determine what is responsible for problematic executions.¹⁷⁰ As another example, Florida was the first state to use midazolam, and did so in an execution that lasted much longer than average. Although the warden checked to confirm that the inmate was unconscious prior to authorizing the administration of the next drug, the inmate made several movements after the warden made this determination. To witnesses it appeared that he was not fully anesthetized.¹⁷¹ The drugs used were not based on prior experience in animal euthanasia—indeed, there was very limited evidence for this dramatic change.¹⁷² Some lethal injection experimentation today demonstrates a willingness to expose inmates to drugs that have never been used in this way before, even though the risks are highly uncertain. Like the troubling historical experiments I described in Part I, lethal injection experimentation has not been based on the kind of careful preparation and evidence gathering that should be done before exposing humans to new and uncertain risks. As I will explain below, using new drugs in humans requires a rigorous evidentiary foundation—one that lethal injection lacks.

III. FEATURES OF LETHAL INJECTION INVOLVING RESEARCH

In this section, I argue that by testing novel drugs, drug combinations, and doses in executions to see what will work, states are conducting a type of biomedical research, albeit one that is poorly designed and lacks

168. STATE OF OHIO DEP’T OF REHAB. & CORR., ORC 2949.22, 2949.25 (Oct. 10, 2013) (on file with Washington Law Review).

169. Holschuh, *supra* note 30.

170. Lazare, *supra* note 32.

171. Daily Mail Reporter & Reuters, *William Happ Executed: Florida Executes Man Using Untried Lethal Injection Drug*, DAILY MAIL (Oct. 15, 2013, 6:20 PM), <http://www.dailymail.co.uk/news/article-2462115/William-Happ-executed-Florida-executes-murderer-using-untried-lethal-injection-drug.html>.

172. Alper, *supra* note 137, at 41–42.

a solid basis in the available evidence. The flimsy evidence base for the use of various drugs, drug combinations, and doses makes it very difficult to predict the outcome of most executions today. That executions by lethal injection involve poorly conceived research suggests that states should adopt the safeguards that have been developed for human subjects research for executions by lethal injection. Current approaches to execution by lethal injection have been conducted in a manner that allows for rigorous and independent oversight by experts on research, that permits subjects to provide informed consent to protect their own interests, and that minimizes risks where possible. Furthermore, states should either adopt approaches that do have a rigorous evidentiary basis, or, if that is not possible, conduct research that is scientifically rigorous.

As I will further explain below, executions by lethal injection have some features of different categories of medical practice and innovation. Nevertheless, the most concerning features of experimental executions are the untested uses of new drugs, drug combinations, and dosages that can be understood as risky, poorly conceived research.

It is useful to look at lethal injection executions in this way because scholars of research ethics and regulation have already thought through related issues in the context of medical research and have designed structures and safeguards to promote the autonomy, safety, and ethics of research subjects. Importing research protections to the lethal injection context may help reduce the number of error-prone and haphazard executions that are receiving considerable public scrutiny.

Table 1: Non-validated Practice, Quality Improvement/Control, & Research

Category	Definition	Relevant Features of Lethal Injection Protocols	Response
Non-validated Practice	Use of a new or untested medical intervention, without good reason to believe it will work	Using drugs and drug combinations that have never been used for causing death in a single execution	Conduct systematic research or use one-drug protocols, as in animal euthanasia
Quality Improvement/Control (QI/QC)	Applying existing knowledge or practices to bring about immediate improvement of care in local settings	Procedures to facilitate administration of injections and test of consciousness by non-medically trained personnel	If high risk: Informed consent, independent expert oversight of QI/QC activities, minimize risks
Research	Testing intervention(s) to develop generalizable knowledge for future use	Using drugs never used for euthanasia, to find method for use in other death row inmates	Informed consent, independent expert oversight of research, risk minimization

A. *Lethal Injection Executions as Involving Non-validated Practice*

Some aspects of lethal injection experimentation involve the use of drugs and interventions that do not have a rigorous evidence base that assures states they will safely and effectively cause death. These features of lethal injection can be thought of as non-validated medical practice.

Non-validated practice involves using an intervention that is new or untested, without good reason to believe it will work.¹⁷³ As was previously discussed, the Commission grappled with this distinction while writing *The Belmont Report* and recommended that non-validated approaches “should be . . . made the object of formal research at an early stage in order to determine whether they are safe and effective.”¹⁷⁴ Similarly, the World Medical Association’s Declaration of Helsinki, an influential international code of ethics, states: “Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation.”¹⁷⁵ The practice of medicine improves by first testing novel agents in animals and in vitro, and then slowly introducing them in humans.¹⁷⁶ To the extent that execution by lethal injection involves entirely novel uses of experimental medications, reform of lethal injection should involve conducting careful and systematic research.

The scientific paradigm governing the adoption of new interventions was not used for lethal injection,¹⁷⁷ even though the first three-drug protocol was invented by a physician who had doubts about whether it would actually work,¹⁷⁸ and the first state legislature to adopt a lethal injection protocol was concerned about the lack of sufficient research on lethal injection. Preliminary animal and laboratory research and extensive experience of euthanizing animals have not been appropriately translated into executions of lethal injection in humans.¹⁷⁹ For instance, paralytic agents like pancuronium bromide are not used and are actually condemned as inhumane by veterinary and animal welfare experts for fear they might mask an animal’s suffering.¹⁸⁰ Significantly, the state of Texas rejected advice from a veterinarian about the use of single-drug protocols, used to euthanize animals, for fear the public would object to

173. See THE BELMONT REPORT, *supra* note 69, at 3–4.

174. *Id.* at 4.

175. Declaration of Helsinki, para. 21, June 1964, available at <http://www.wma.net/en/30publications/10policies/b3/>.

176. Carl Cohen, *The Case for the Use of Animals in Biomedical Research*, 315 NEW ENG. J. MED. 865, 865–69 (1986).

177. John Greiner, *Drug Execution Plan Suffers Senate Setback*, DAILY OKLAHOMAN, Feb. 16, 1977, at 16.

178. Denno, *supra* note 99.

179. Ty Alper, *Anesthetizing the Public Conscience: Lethal Injection and Animal Euthanasia*, 35 FORDHAM URB. L.J. 817, 835–37 (2008).

180. *Id.* at 837.

treating people as we treat animals.¹⁸¹

One way to move to a more evidence-based approach is to draw on related evidence and experience to develop protocols that one can have a reasonable degree of confidence will work. In particular, states could more carefully extrapolate from animal euthanasia protocols or euthanasia protocols for humans developed in other jurisdictions. Drawing from existing evidence is especially important when there are ethical concerns about randomizing participants to different approaches to collect data about their relative merits, as may be true for research to develop safe and effective methods of execution. Gathering observational data and any available data from other, related fields to improve an approach over time may sometimes be the best that can be done. There is extensive experience with animal euthanasia that has not been translated to the lethal injection context.¹⁸² This experience would rule out the use of the three-drug cocktail, and may suggest adoption of one-drug protocols. For drugs that have sufficient animal and laboratory data already on relevant clinical experience, there are still questions about how to translate those data into the use of the drugs for lethal injection in humans. Nevertheless, the risks of the use of these drugs are much better characterized, and much less than the risks associated with drugs that are in widespread use in executions by lethal injection today.

There is also some clinical experience with drugs that could be used for lethal injection protocols in other jurisdictions. Oregon, the Netherlands, Belgium, and other jurisdictions have experience with physician-assisted suicide and euthanasia, and have developed protocols over time to ensure death can occur humanely. These may be the only other examples of medical practice that involve interventions used to cause death.¹⁸³ Justice Alito's opinion in *Baze* attempted to cast doubt on the use of one-drug protocols by citing a study that showed that a small percentage of patients receiving one-drug protocols do not die.¹⁸⁴ But one-drug protocols do eliminate the risk of excruciating pain, so more doses of the drug can be given as a back-up plan without raising concern about the risk that the protocol will not work.¹⁸⁵ Over time, the experiences of physicians in administering these protocols in physician-

181. *Id.* at 817.

182. *See id.* at 817–18.

183. *Overview of Euthanasia*, KNMP, <http://www.knmp.nl/medicijnen-zorgverlening/overig/euthanasia> (last visited Feb. 21, 2014) (Dutch Professional Trade Association of Pharmacists).

184. *See Baze v. Reese*, 553 U.S. 35, 68 (2008) (Alito, J., concurring).

185. Eric Burger, *Lethal Injection and the Problem of Constitutional Remedies*, 27 YALE L. & POL'Y REV. 259, 317–18 (2009).

assisted suicide in the Netherlands have been systematically collected and published to improve the process.¹⁸⁶ However, one key problem in translating from protocols used in the Netherlands is that these protocols are intended to be administered with physicians overseeing the process. Given the considerable controversy over physician participation in executions by lethal injection,¹⁸⁷ it is not clear these protocols can be directly translated for use in American executions.

Alternatively, states could conduct preclinical laboratory and animal testing of drugs that have not been used to cause death, and develop some of the evidence needed to be able to justify the use of these drugs in humans. Statistical methods are necessary to determine how large trials should be to evaluate the safety and efficacy of lethal injection protocols, and whether a particular design (e.g., a control arm) is necessary. This option would require the assistance of individuals with expertise in conducting clinical research and could not be done by members of state departments of corrections alone.

However, there may be other barriers that prevent states from moving to protocols that are based in evidence from animal euthanasia. For example, one-drug protocols may be difficult to implement in some states that are having difficulty obtaining certain drugs. Leaving aside the relatively recent drug shortages and embargoes, it is puzzling why state departments of corrections have not been systematic and careful in attempting to improve such a controversial procedure. One charitable interpretation is that prison officials may be unaware of scientific methods, and the many constraints on the participation of medical personnel in executions have prevented states from obtaining good advice. Another possibility is that the lack of any systematic oversight by courts on lethal injection procedures, at least until fairly recently, has encouraged states to be as conservative as possible and stick to the three-drug protocol in an effort to avoid further litigation that might be prompted by changes to protocols. The least charitable interpretation may be that those involved in developing execution procedures, much like the researchers who first began experimenting on prisoners, place little value on how they treat someone who has been sentenced to be

186. Pieter V. Admiraal, [The responsible performance of euthanasia; observations on the discussion of the subject] [Article in Dutch], 127 *Ned Tijdschr Geneesk*, 964, 964 (May 28, 1983); see also Personal Communication with Annemieke Horikx, Royal Dutch Society of Pharmacy (KNMP) (May 12, 2014).

187. Compare Robert D. Truog, I. Glenn Cohen, & Mark A. Rockoff, *Physicians, Medical Ethics, and Execution by Lethal Injection*, 311 *J. AM. MED. ASS'N* 2375 (2014), with Lawrence Nelson & Brandon Ashby, *Rethinking the Ethics of Physician Participation in Lethal Injection Execution*, *HASTINGS CTR. REP.*, May–June 2011, at 28–29.

executed. State departments of corrections therefore may have little incentive to proceed cautiously, except in the sense that executions do not appear inhumane and disturbing to the general public.

B. Lethal Injection as Involving Research

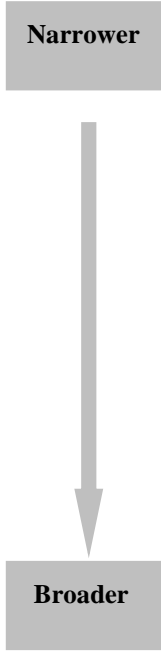
In this Section, I analyze the extent to which current approaches involve medical research. When lethal injections expose inmates to uncertain risks of drugs that lack solid evidence for use in executions, this activity is a type of research that is neither well designed nor systematic. Rather, it is conducted in an attempt to learn how to conduct future executions on other death row inmates. All states conducting executions have inmates on death row, borrow and learn from one another's experiences, and tend to change their protocols by adopting the same new drugs around the same time.¹⁸⁸ This suggests that states are making modifications and experimenting with the goal of producing knowledge from each individual execution to improve future executions.

There are several different regulatory definitions of medical research, ranging from more to less restrictive.¹⁸⁹ The narrowest definitions, like the definition used in the Department of Health and Human Services Regulations,¹⁹⁰ fail to capture experimentation that is poorly designed and not systematic. The broader definitions, like those used in the FDA's investigational new drug regulations and in state statutes and department of corrections policies, more clearly apply to many different types of research, including experimental execution. I argue below that FDA regulations are the most appropriate to apply, but also that there are barriers to enforcing any of these regulations.

188. Denno, *Lethal Injection Chaos Post-Baze*, *supra* note 27, at 1341 chart 1, 1358 chart 3.

189. *See infra* tbl.2.

190. 45 C.F.R. § 46.102(d) (2014). *But see* 21 C.F.R. § 56.102(c) (2014) (defining "clinical investigation," which the FDA considers to be synonymous with research, as "any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA . . . or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit").

Table 2: Regulatory, Statutory & Policy Definitions of Research


Statute/Regulation/ Policy	Definition of Research
DHHS Regulations, Bureau of Prisons Regulations	“[A] systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”
FDA IND Regulations	Any use of a drug, except for the use of a marketed drug in the course of medical practice, in which a drug is administered to one or more human subjects
State Statutes & Department of Corrections Policies	Much variation; many simply prohibit “the use of inmates for medical, pharmaceutical, or cosmetic experimentation”

Although no court has directly addressed this issue, several different regulations governing research might apply to execution by lethal injection: (1) the Department of Health and Human Services (DHHS) regulations governing research on prisoners; (2) the research regulations of the Bureau of Prisons; (3) state departments of corrections regulations governing research on prisoners; and (4) the FDA’s Investigational New Drug (IND) regulations. I discuss these regulations in turn, and conclude that the three types of regulations that are most applicable are state, Bureau of Prisons, and FDA regulations. Bureau of Prisons and state regulations may impose helpful safeguards, but may also make it difficult to conduct experimental execution at all if certain provisions are

applied according to a plain text reading. Finally, the FDA regulations are probably the most appropriate for regulating lethal injection experimentation, but the FDA may be reluctant to participate in review of lethal injection executions, and it would be difficult for courts to compel the agency to act.

First, both the DHHS regulations governing research on prisoners and the Bureau of Prisons regulations would likely not apply to lethal injection experimentation. The DHHS regulations apply only to research funded by the federal agencies that have signed on to those regulations.¹⁹¹ However, some states do reference the DHHS regulations in their state regulations governing research on prisoners.¹⁹² Those states may have difficulty continuing lethal injection research without addressing the safeguards discussed in Part VI, below. Additionally, the DHHS regulations define research narrowly as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”¹⁹³ To the extent that lethal injection executions are not systematically conducted, they may not fit this definition. Significantly, the regulations require that the research risks must be “commensurate with risks that would be accepted by nonprisoner volunteers”—which makes it hard to imagine that lethal injection research could be approved under these regulations, even if they did apply.¹⁹⁴

As I have argued elsewhere, state and department of corrections regulations in several states could severely restrict or prohibit current approaches to executions by lethal injection.¹⁹⁵ The Bureau of Prisons regulations apply to research conducted within the Bureau of Prisons, either by external researchers or by employees of the bureau.¹⁹⁶ These Bureau of Prisons regulations refer to the definition used in the DHHS

191. *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/commonrule/> (last visited Jan. 5, 2015). Institutions that receive federal funding for research typically are required to sign Federal Wide Assurances (FWAs), in which they promise that all research conducted by their institution will abide by the protections in the DHHS regulations. If a State's Departments of Corrections has an FWA, then it is possible that the DHHS regulations should be applied to lethal injection experimentation, and that the Office for Human Research Protection has the authority to enforce deviations from those regulations.

192. *See, e.g., Research Guidelines*, N.C. DEP'T OF CORR. (Jan. 21, 2015), <https://www.ncdps.gov/Index2.cfm?a=000003,002391,002412,002456>.

193. 45 C.F.R. § 46.102(d).

194. 45 C.F.R. § 46.305(a)(3)–(4).

195. *See* Shah, *supra* note 32.

196. 28 C.F.R. § 512.10 (2014).

regulations governing research that was previously mentioned, and also prohibit “medical experimentation, cosmetic research, or pharmaceutical testing.”¹⁹⁷ Although the definition of research referenced in these regulations is relatively narrow, the prohibition of medical experimentation is much broader. As I argued in a previous paper, in the absence of creative statutory interpretation, broad prohibitions on medical experimentation or pharmaceutical testing would seem to rule out lethal injection experimentation altogether.¹⁹⁸ The additional restrictions in the Bureau of Prisons regulations include that risks to subjects have to be minimized, the risks must be “reasonable in relation to anticipated benefits,” “the selection of subjects within any one institution must be equitable,” and informed consent is generally required to be obtained and documented.¹⁹⁹ One problem with applying these regulations to executions is that the Bureau of Prisons may not be amenable to such a reading of their regulations, and may be more sympathetic to arguments that executions do not involve the conduct of experimentation or research.

A recent paper argues that the FDA’s regulatory authority likely extends to reviewing executions by lethal injection.²⁰⁰ The FDA has authority to review new drugs and protect patients and research subjects through its Investigational New Drug (IND) regulations.²⁰¹ The IND regulations apply broadly to the use of interventions without a solid evidence base, and use the following definition of research: “*Clinical investigation* means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.”²⁰² As an example of the broad reach of these regulations, the FDA has previously asserted that the IND regulations would cover human cloning.²⁰³ The

197. 28 C.F.R. § 512.11(a)(3).

198. Shah, *supra* note 32, at 1111.

199. 28 C.F.R. § 512.11(a)(4).

200. See JOHNS HOPKINS CLINIC FOR PUB. HEALTH L. & POL’Y, *supra* note 32, at 1–3. The authors note that there are jurisdictional challenges because actions to enforce the Food, Drug & Cosmetic Act (FDCA) must be brought by the government, but argue that death row inmates may be able to argue for enforcement on the basis of their Fourteenth Amendment due process rights or as an Eighth Amendment challenge. *Id.* at 3–4.

201. Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 HOUS. J. HEALTH L. & POL’Y 1, 5 (“The protection of study subjects is a central objective of the law that permits FDA to approve INDs and of the Agency’s own standards and procedures.”).

202. 21 C.F.R. § 312.3(b) (2014).

203. Rick Weiss, *Human Clone Research Will Be Regulated: FDA Asserts It Has Statutory*

definition of research in the IND regulations is much more expansive than the definition used in the DHHS regulations.²⁰⁴ It would seem to require that states either define their activities as medical practice or submit an IND application to the FDA. As noted earlier, many states expressly define their activities as outside the scope of medical practice. Even for states that do not define lethal injection executions as outside the practice of medicine, to the extent they are conducting medical *research*, they are clearly operating not engaged in the *practice* of medicine.

Under the IND regulations, sponsors and researchers have to submit an application of their research protocol to the FDA for prior review of safety, efficacy, and scientific merit. The FDA would have the authority to insist upon review by an institutional review board (IRB) or to suspend the activity by placing the investigation on what is known as a “clinical hold.”²⁰⁵ Under the regulations, if a state submitted a proposed protocol to the FDA and fulfilled the regulatory requirements thirty days before an execution, and the FDA failed to act, then the state could proceed with the execution.²⁰⁶

The FDA might be reluctant to take on this review. First, there is lack of clarity about the right standard of review and how the FDA would apply its own statutory authority to executions. Another problem is that the FDA is required to determine whether drugs are safe and effective under the Federal Food, Drug, and Cosmetic Act,²⁰⁷ which may be an impossible standard for executions to meet. In *FDA v. Brown & Williamson Tobacco Corporation*,²⁰⁸ the Supreme Court held that the FDA could not assert its authority over tobacco products because the FDA’s requirement to ensure drugs and devices are safe simply could

Authority to Regulate Attempts at Human Cloning, WASH. POST, Jan. 20, 1998, at A1. (quoting the Lead Deputy Commissioner Michael Friedman’s claim that the FDA had the authority to regulate cloning through the IND regulations based on “serious health and safety issues” for the mother and cloned fetus).

204. 21 U.S.C. § 355 (2012).

205. 21 U.S.C. § 355(i)(3)(A).

206. JOHNS HOPKINS CLINIC FOR PUB. HEALTH L. & POL’Y, *supra* note 32, at 12.

207. 21 C.F.R. § 312.22(a) (2014) (“FDA’s primary objectives in reviewing an IND are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phase 2 and 3, to help assure that the quality of the scientific evaluation of drugs is adequate to permit an evaluation of the drug’s effectiveness and safety. Therefore, although FDA’s review of Phase 1 submissions will focus on assessing the safety of Phase 1 investigations, FDA’s review of Phases 2 and 3 submissions will also include an assessment of the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval.”).

208. 529 U.S. 120 (2000)

not be met by regulating tobacco products—the FDA would have to take them off the market.²⁰⁹ Because Congress had “foreclosed the removal of tobacco products from the market,” the Court found that FDA regulation of tobacco products would “plainly contradict Congressional policy.”²¹⁰ Although one could argue that executions cannot be conducted in a safe manner since the goal of an execution is to cause death, what the FDA regulates depends on how the clinical investigation is defined. To the extent that the goal of clinical investigations in executions would be to determine whether the use of certain drugs within executions could decrease the risks of suffering, the FDA could presumably approve that research. Precluding the use of some drugs as unacceptably risky would also not clearly contradict Congressional or state policy. Therefore, the FDA does have room to regulate executions without banning them altogether, and would not necessarily have to contradict federal or state policy to do so.

Additionally, the FDA routinely judges the safety of drugs where those drugs pose both risks and benefits to the individuals who are taking them. But there is no clear benefit to inmates to undergo executions, so the risks and benefits would have to be evaluated in some other way. Given that the Supreme Court has not settled on one standard for determining when the risks associated with lethal injection would be unconstitutional,²¹¹ it may be very difficult for the FDA to assess whether the risks associated with lethal injection are acceptable. Yet, as I argue below, the research regulations do provide clear guidance on the need to minimize risks, which is one area where the FDA’s considerable expertise could be invaluable.

If the FDA decides not to enforce the IND regulations, whether the agency can be compelled to act is not settled. It depends on whether the agency’s decision was discretionary or mandatory. In *Heckler v. Chaney*,²¹² the U.S. Supreme Court reviewed the FDA’s decision not to exercise its authority under the Food, Drug, and Cosmetic Act²¹³ to perform enforcement actions such as reviewing the safety and efficacy of lethal injection drugs being distributed in interstate commerce, affixing warning labels to the drugs, and seizing drugs that were to be used in executions.²¹⁴ The Supreme Court has explained that under the

209. *Id.* at 135.

210. *Id.* at 137–39.

211. *Baze v. Reese*, 553 U.S. 35, 52 (2008).

212. 470 U.S. 821, 824 (1985).

213. 21 U.S.C. § 355 (2012).

214. *Heckler*, 470 U.S. at 824.

Administrative Procedures Act, if an agency elects not to pursue that action and exercise its coercive power, the action is “presumptively unreviewable” by the courts.²¹⁵ The particular decision to enforce the FDCA was committed to agency discretion by law, and the Court concluded that the presumption was not overcome in that case. Deference to the FDA was warranted.²¹⁶ On the other hand, in *Cook v. FDA*,²¹⁷ the D.C. Circuit held that the FDA’s jurisdiction over the regulation of importation of lethal injection drugs into the country was not discretionary, but mandatory. The FDA was therefore required to inspect the importation of drugs and refuse admission to drugs that were adulterated, misbranded, or unapproved for use in the United States.²¹⁸

Importantly, the IND regulations require the sponsor of the research to submit an application to the FDA,²¹⁹ suggesting that this may not be an action subject to discretion on the part of the sponsor of the research at least. This requirement on sponsors does not necessarily imply, however, that the FDA is required to enforce these regulations against departments of corrections who are failing to comply.²²⁰ Additionally, though the FDA can grant exemptions to IND requirements, to meet these exemptions, states would have to receive approval from an IRB and would also have to ensure that the way the drugs are being administered does not “significantly increase the risks” or “decrease the acceptability of the risks.”²²¹ There is no indication that any of the states conducting lethal injection have received IRB approval, and it would be hard to argue that administration of anesthetic and paralytic drugs by non-medically trained prison officials could do anything but significantly increase the risks involved.

There are, additionally, policy reasons why the FDA may be reluctant to regulate experimental executions and courts may find these reasons persuasive. For instance, in *Heckler v. Chaney*,²²² the FDA Commissioner explained that the FDA decided not to exercise jurisdiction over lethal injection drugs because its jurisdiction over these

215. *Id.* at 828–32.

216. *Id.* at 837.

217. 733 F.3d 1 (D.C. Cir. 2013).

218. *Id.* at 10 (citing 21 U.S.C. § 381(a) (2012)).

219. 21 C.F.R. § 312.1(a) (2014).

220. 21 U.S.C. § 355(i) (2012). Note that citizens could petition the FDA to ask why the FDA is not enforcing IND regulations or failing to respond to a protocol submitted by a state department of correction under 21 U.S.C. § 10.30 (2012).

221. 21 C.F.R. § 312.2(b)(iii).

222. 470 U.S. 821 (1985).

drugs was not clear and capital punishment is a matter of criminal justice with which it should not interfere.²²³ He further stated that:

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 State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions²²⁴

The court in *Cook v. FDA* also took into account policy considerations that might give reason to respect an FDA decision not to act. The court noted that as a matter of statutory interpretation, courts can depart from the plain text if it would lead to an “absurd” result.²²⁵ In *Cook*, the court considered the FDA’s arguments that the agency was best positioned to determine how to allocate its scarce resources under this authority.²²⁶ But the FDA’s inability to regulate every article imported into the country did not convince the court that the FDA should not examine the subset of drugs at issue in lethal injection executions. In sum, the FDA’s regulations are the most applicable, but there are several barriers to enforcing these regulations, particularly if the FDA is not willing to do so itself. State regulations, department of corrections policies, and the Bureau of Prisons regulations would also apply, though it would be difficult to approve experimental execution under these regulations.

C. *Lethal Injection as Involving Quality Improvement*

State departments of corrections explicitly indicate in some cases that their activities are a form of quality improvement or quality control. As I will argue below, the distinction between quality improvement and research does not have much normative significance, and I will not rely on it heavily in my analysis of what should be done about experimental executions. Nevertheless, it is worth explaining what aspects of executions might count as quality improvement to forestall potential

223. *Id.* at 824.

224. *Id.* at 824–25.

225. *Cook v. FDA*, 733 F.3d 1, 9 (D.C. Cir. 2013) (citing *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 494 (D.C. Cir. 2004)).

226. *Id.* at 9.

objections.

As an example of a state describing lethal injection modifications and the related data collection as quality control, Ohio explicitly labels a section of its protocol with the subtitle “Quality Assurance,” and has a designated Special Assistant for Execution Policy and Procedures. The Ohio protocol provides: “The Special Assistant shall evaluate the performance of the Execution Team, review the conduct of court-ordered executions and report to the Director of the Department. His or her duties will consist of reviewing documentation, training, and professional qualifications, to ensure compliance with the written policy directive.”²²⁷ Quality control “is designed to bring about the immediate improvement of care in local settings,”²²⁸ typically by applying existing knowledge of practices that are within the standard of care. These modifications can happen at just one institution or several. The line between research and quality control typically turns on whether the results of the investigation are intended to improve local practice or to be disseminated more broadly—quality improvement is often characterized by the quick feedback of the findings into the same setting that was making the changes and studying them.²²⁹ Even if the State of Ohio is right to see its lethal injection experimentation as a form of quality assurance or quality control, whether it should have increased ethical safeguards depends on the level of risk.

To the extent that these quality control activities involve high risks, the distinction between research and quality control is a distinction without a difference. Furthermore, scholarship on research ethics and regulations has begun to recognize that the classic distinctions between treatment, research, and quality control are eroding as data collection is increasingly a part of every medical encounter, and the important normative questions therefore are about the level of risk involved for the subjects of the data collection.²³⁰ As quality control activities involve increasing amounts of risk, the ethical restrictions on quality control activities come closer to those governing research, and informed consent is typically required.²³¹ Since the normative value of distinguishing

227. STATE OF OHIO DEP’T OF REHAB. & CORR., *supra* note 168.

228. Mary A. Baily et al., *The Ethics of Using QI Methods to Improve Health Care Quality and Safety*, HASTINGS CTR. REP., July–Aug. 2006, at S1, S29.

229. *Id.* at S34.

230. Nancy E. Kass et al., *The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight*, HASTINGS CTR. REP., Jan.–Feb. 2013, at S4, S5; Emily A. Largent, Steven Joffe, & Franklin G. Miller, *Can Research and Care Be Ethically Integrated?*, HASTINGS CTR. REP., July–Aug. 2011, at 3738.

231. *See* Kass et al., *supra* note 230, at S6–7.

lethal injection practices that might be appropriately considered quality control activities from those that have aspects of medical research is not clear, I will not rely on this distinction in this analysis.

If the evidence that seven percent of all executions by lethal injection have been botched in some way is accurate, and if the risks associated with error involve excruciating pain and suffering, it seems likely the risks involved in execution by lethal injection are more than minimal and deserve increased ethical protections (namely, informed consent and independent review of the protocols). It is also relevant that prison officials who have difficulty obtaining the drugs needed for executions are turning to compounding pharmacies, given the extra risks associated with the drugs produced in compounding pharmacies.²³²

In sum, by using untested drugs, drug combinations, and doses, executions by lethal injection involve poorly designed research. The regulations that most clearly apply to executions by lethal injection are FDA IND regulations, Bureau of Prisons regulations, and state laws and department of corrections policies that have expansive definitions of research. There may be significant barriers facing those who seek to enforce these regulations as they apply to experimental executions, as I have suggested above. However, the regulations do converge on several protections that have interesting implications for experimental executions. In the next section, I demonstrate how the safeguards that are common across the regulations would apply to lethal injection experimentation.

IV. SPECIFIC ETHICAL AND REGULATORY SAFEGUARDS FOR LETHAL INJECTION EXECUTION

There are three requirements common to all of the regulations described above that should be applied to experimental execution: (1) independent oversight, (2) risk minimization, and (3) informed consent.²³³

A. *Independent Oversight*

Perhaps the most important of the research protections, and the way to

232. Jesse M. Boodoo, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 AM. J.L. & MED. 220, 221 (2010).

233. See 45 C.F.R. § 46, subpart C (2014); 21 C.F.R. § 50 (2014); 28 C.F.R. § 512.10 (2014); Ezekiel J. Emanuel, David Wendler, & Christine Grady, *What Makes Clinical Research Ethical?* 283 J. AM. MED. ASS'N 2701, 2701 (2000).

ensure that the other requirements are met, is independent expert review. Independent oversight of research helps ensure that research is sound, likely to yield generalizable results, and not unacceptably risky. A critical component of rigorous oversight is having relevant expertise. Prison officials cannot be allowed the discretion to experiment with biomedical interventions on prisoners without oversight. Officials devising execution protocols seek execution methods that courts will not view as involving cruel and unusual punishment and that do not raise public concern, but not necessarily methods that reduce risks as far as possible. One of the difficulties with the current system, as I will argue below, is that courts lack sufficient expertise to evaluate protocols and develop appropriate safeguards.

There are at least four possible places where independent review of lethal injection protocols could be performed: (1) Institutional Review Boards (IRBs), (2) courts, (3) the FDA, and (4) a quality control panel set up specifically at the prison. Some commentators have argued that IRBs should review lethal injection protocols.²³⁴ IRBs are required to have at least five members, with at least one member whose expertise is scientific and at least one member from non-scientific background, and one member who is not affiliated with the institution.²³⁵ The research ethics literature is replete with criticism of IRBs for being overprotective and focused on informed consent above all else.²³⁶ Given how conservative IRBs are about the risks of research,²³⁷ it is safe to assume that no IRBs in the United States have experience reviewing research designed to result in death. Nevertheless, IRBs do have far more experience reviewing research than the courts, and the regulatory requirements are meant to ensure some degree of relevant expertise and independence from the institution. Thus, if there are IRBs that have extensive experience reviewing research that takes place in correctional settings, these IRBs might have the general expertise to evaluate lethal

234. Koniaris et al., *supra* note 32.

235. 45 C.F.R. § 46.107.

236. Carol A. Heimer & JuLeigh Petty, *Bureaucratic Ethics: IRBs and the Legal Regulation of Human Subjects Research*, 6 ANN. REV. L. SOCIAL SCI. 601, 605–06 (2010) (“[M]uch of the literature on human subjects regulation asserts that IRBs have failed at the task of regulating human subjects research.”); Taimur Saleem & Umair Khalid, *Institutional Review Boards—a Mixed Blessing*, 4 INT’L ARCHIVES MED. 19, 20 (2011) (commenting that IRBs “represent an intrusion of bureaucracy and excessive red tape into medicine to the extent of being ‘frustrating’, ‘consternating’ and ‘paternalistic for the researchers’”); see also Beth Azar, *Ethics at the Cost of Research?*, MONITOR ON PSYCHOL., Feb. 2002, at 38, 38.

237. See Seema Shah et al., *How Do Institutional Review Boards Apply the Federal Risk and Benefit Standards for Pediatric Research?*, 291 J. AM. MED. ASS’N 476 (2004).

injection experimentation. Additionally, IRBs do sometimes use ad hoc subject matter experts in situations where the complexity of a research study requires additional input.

Courts have, of course, already been involved in the process of evaluating lethal injection protocols. One problem with having courts review lethal injection protocols as research or quality control projects is they typically have less expertise in evaluating research. Some of the most prominent cases in which courts have made judgments pertaining to research studies have been criticized for the limited understanding of the justifications for and constraints on research.²³⁸ The limitations faced by courts are illustrated by the transcript of a hearing in the recent Arizona execution of Mr. Wood discussed in the introduction. Although the judge demonstrated impartiality and competence in running the proceedings, because he did not know or have ready access to information that brain death is incompatible with spontaneous breathing, or whether stopping the execution would minimize the amount of pain the inmate may have been suffering, the court's ability to provide adequate oversight over the execution was compromised.²³⁹

There are legal procedures for hearing and evaluating scientific evidence and expert testimony, including ensuring there is a zealous advocate to present and vet the appropriate evidence. But the current level of secrecy that many states are using with respect to their execution procedures and suppliers is incompatible with robust independent review of the research on lethal injection. If courts are not weighing evidence on whether a particular compounding pharmacy has sufficient quality control, or about the risks of the specific drugs that are being used, they cannot conduct rigorous independent scrutiny of lethal injection research. This secrecy has been justified based on concerns that death penalty opponents will protest or harass those involved with executions, but makes it difficult to feel confident that courts are providing sufficient oversight.²⁴⁰

Another possibility, as discussed in Part III above, would be for the FDA to review executions by lethal injection. Under the FDA

238. See, e.g., Jack Schwartz, *The Kennedy Krieger Case: Judicial Anger and the Research Enterprise*, 6 J. HEALTH CARE L. & POL'Y 148, 152–53 (citing *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001)).

239. See generally Transcript of Telephonic Motion for Emergency Stay of Execution, *Wood v. Ryan*, No. CV 14-1447-PHX-NVW (D. Ariz. July 23, 2014), available at <http://www.scribd.com/doc/234993495/Transcript-related-to-Joseph-Wood-execution>.

240. Michael Graczyk, *Texas Agency Pushes to Keep Execution Drug Source Secret*, NEWSOK (Apr. 2, 2014), <http://newsok.com/texas-pushes-to-keep-execution-drug-source-secret/article/3949442>.

regulations, the FDA would review an IND application and would require that an IRB review the research at the same time.²⁴¹ The FDA may be reluctant to review executions, particularly without a clear sense of what risk standard to apply. Unlike the courts, however, the FDA has expertise in reviewing research, medical practice, and non-validated uses of drugs and devices. The FDA has considerable scientific expertise and is likely to be the body that is best informed about how the drugs being used for lethal injection work and what risks are associated with them. It is likely that the depth of expertise available at the FDA far surpasses what an individual court can bring to bear on the questions surrounding lethal injection. The FDA might be well situated to review lethal injection experimentation.

Finally, it is possible that special institutional bodies could be set up to review the quality control activities of various prisons. This approach has the advantage of ensuring that people who have the relevant expertise would be the ones reviewing the activities. Such a board might include scientists who conduct research, former prisoners, lawyers, and ethicists. One concern about this board is that it might be subject to capture by advocates from either side of the death penalty debate. It might therefore be advisable that some independent institution, such as the judicial branch, be involved in vetting the board members, analogously to the judicial use and oversight of special masters in consent decrees.²⁴²

Given the special expertise, authority, and independence of the FDA, it seems clear that the FDA is at this time best positioned to review experimentation in executions by lethal injection. A specially constituted institutional board that has relevant expertise may be an alternative or an addition to FDA review.

B. *Minimizing Risk*

Both research and quality control activities are subject to the requirement to minimize risk. Judging the risk level of research on methods of execution by lethal injection requires comparing an

241. 21 C.F.R. § 312.66 (2014).

242. Wayne D. Brazil, *Special Masters in Complex Cases: Extending the Judiciary or Reshaping Adjudication?*, 53 U. CHI. L. REV. 394, 394–95 (1986) (“Courts appoint special masters as a means of addressing three overlapping categories of problems: judicial limitations, shortcomings of the traditional adjudicatory system, and shortcomings of parties and counsel. Judicial limitations include time constraints; lack of expertise in esoteric or technologically sophisticated areas; lack of skill in certain roles, such as the facilitation of settlement negotiations; and limitations that stem from the proprieties of judicial conduct, at least for the judge who will try the case.”).

experimental execution to a standard execution. The risk of death is therefore not a risk of the research—death is actually, in this case, the desired outcome. The benefits might have to do with having shorter executions that are more likely to be humane (perhaps analogous to the benefits in palliative care research conducted at the end of life). Those individuals who are being experimented upon should not be exposed to any unnecessary risk that could easily be eliminated. The risk that seems most relevant in analyzing executions by lethal injection is the risk of pain and suffering before death, both in terms of its severity and its duration. In other words, a long, drawn-out execution with significant pain might be as concerning as a shorter execution that subjected an inmate to pain of greater intensity.

In the case of *In re Kemmler*, the Court clarified that to violate the Eighth Amendment, there must be “something inhuman and barbarous, something more than the mere extinguishment of life.”²⁴³ Although it is clear that torture is beyond the pale, what degree of risk of a torturous death the Eighth Amendment will tolerate is an open question. The standards for weighing acceptable risks in research are similar, in some respects, to the approach the Supreme Court has taken in defining what risks of pain and suffering would be unconstitutional. As the Court explained in *Francis v. Resweber*,²⁴⁴ “The traditional humanity of modern Anglo-American law forbids the infliction of unnecessary pain in the execution of the death sentence. Prohibition against the wanton infliction of pain has come into our law from the Bill of Rights of 1688. The identical words appear in our Eighth Amendment.”²⁴⁵ It has also been recognized that an Eighth Amendment analysis requires analyzing the objective risk of harm, and if that risk is significant enough, prison officials cannot claim that they were “subjectively blameless” for harm that would otherwise violate the Eighth Amendment.²⁴⁶

However, how a court should weigh the objective risk of harm became somewhat muddled in *Baze v. Rees*. There, a plurality of the Court noted that the Supreme Court has shied away from providing a precise definition of the Eighth Amendment’s prohibition on cruel and unusual punishment. The plurality approvingly quoted a case from 1879, which noted that difficulty would attend the effort to define “with exactness the extent of the constitutional provision which provides that

243. 136 U.S. 436, 447 (1890).

244. *Louisiana ex rel. Francis v. Resweber*, 329 U.S. 459 (1947).

245. *Id.* at 463.

246. *Farmer v. Brennan*, 511 U.S. 825, 842, 846 n.9 (1994).

cruel and unusual punishments shall not be inflicted;” but “it is safe to affirm that punishments of torture, . . . and all others in the same line of unnecessary cruelty, are forbidden” by that amendment to the Constitution.²⁴⁷ As Deborah Denno has argued, “the Court lacks a coherent constitutional standard for assessing pain. Although the gratuitous infliction of pain is definitely impermissible, far less clear is the constitutionally allowable amount of pain that can exist for an execution and the penological theory that might justify such pain.”²⁴⁸

In *Baze*, the different opinions argued for different standards: (1) the plurality indicated that a lethal injection protocol is not “cruel and unusual” unless it involves a “substantial risk of serious harm” or an “objectively intolerable risk of harm” and there are alternatives that effectively address this risk;²⁴⁹ (2) Justice Thomas argued that executions violate the Eighth Amendment only when protocols are “deliberately designed to inflict the pain”—thereby arguing for a focus only on the subjective prong of an Eighth Amendment analysis; and (3) Justice Ginsburg’s dissent (joined by Justice Souter) argued for a standard that rules out an “untoward, readily avoidable risk of inflicting severe and unnecessary pain.”²⁵⁰ Justice Ginsburg’s dissent requiring that there be no “untoward risk”²⁵¹ was the only standard that was consistent with the obligation to minimize risks in research or quality control activities. Thirty-six cases have cited Justice Ginsburg’s dissent in an attempt to establish that, even under the strictest standard laid out in *Baze*, the protocol in question would be considered constitutional.²⁵² Noting the Court’s inability to agree on a particular standard, as well as the considerable changes that have been made to lethal injection protocols (even the Kentucky protocol approved in *Baze* has been changed to a one-drug protocol), Denno has argued that the precedent set in *Baze* is largely moot.²⁵³

Practically, risk minimization likely puts extra scrutiny on particular aspects of execution by lethal injection. For instance, risk minimization may require Departments of Corrections to stop using the drug

247. *Baze v. Rees*, 553 U.S. 35, 48 (2008) (quoting *Wilkerson v. Utah*, 99 U.S. 130, 136 (1879)).

248. Deborah W. Denno, *Getting to Death: Are Executions Constitutional?*, 82 IOWA L. REV. 319, 326 (1997).

249. *Baze*, 553 U.S. at 50, 52.

250. *Id.* at 52 (plurality opinion); *id.* at 94 (Thomas, J., concurring); *id.* at 123 (Ginsburg, J., dissenting).

251. *Id.* at 123 (Ginsburg, J., dissenting).

252. Denno, *supra* note 27, at 1353.

253. *Id.* at 1346.

midazolam (which was implicated in three of the four botched executions that occurred in 2014),²⁵⁴ intramuscular injections, paralytic agents, and compounding pharmacies. Additionally, securing the involvement of physicians would be an important way to minimize the risks to which inmates are exposed.

Some state protocols permit intramuscular injection, which is also unnecessarily risky.²⁵⁵ Individuals who receive intramuscular injections may experience wide variation in how quickly the drug is taken up by their bodies, and may therefore suffer extended executions and increased exposure to painful side effects.²⁵⁶ Given the possibility of faster-acting intravenous injection, this risk may not be necessary. The use of compounding pharmacies adds to the risk, since it is possible that incorrect drugs or dosages will be used, or that the drugs will be contaminated. Finally, despite the controversy it would raise, it seems likely that the involvement of medically trained professionals may also decrease the risks associated with lethal injection.²⁵⁷

The use of paralytic agents fails scrutiny under a standard requiring

254. See *Missouri Used Controversial Execution Drug Midazolam, Report Finds*, THE GUARDIAN (Sept. 3, 2014, 4:15 PM), <http://www.theguardian.com/world/2014/sep/03/missouri-execution-drug-sedative-midazolam-report>.

255. See, e.g., STATE OF OHIO DEP'T OF REHAB. & CORR., *supra* note 168.

256. Declaration of Mark J.S. Heath, M.D. at 6–9, *Cooey (Biros) v. Strickland*, No. 2:04cv1156-GLF-MRA (S.D. Ohio. Dec. 3, 2009).

257. The American Medical Association has an ethical prohibition on physician involvement in executions, and there is considerable debate over whether physicians should participate in executions by lethal injection in the scholarly literature. See, e.g., AM. MED. ASS'N, CODE OF ETHICS OPINION 2.06 – CAPITAL PUNISHMENT (2005); Ty Alper, *The Role of State Medical Boards in Regulating Physician Participation in Executions*, 95 J. MED. LICENSURE & DISCIPLINE (2009), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1544623; Linda L. Emanuel, *Letter: Physicians and Executions*, HASTINGS CTR. REP. Mar.–Apr. 2012, at 4; Lawrence Nelson & Brandon Ashby, *Rethinking the Ethics of Physician Participation in Lethal Injection Execution*, HASTINGS CTR. REP., May–June 2011, at 28, 29; Robert D. Truog & Troyen A. Brennan, *Participation of Physicians in Capital Punishment*, 329 NEW ENG. J. MED. 1346, 1348 (1993); Robert D. Truog, I. Glenn Cohen, & Mark A. Rockoff, *Physicians, Medical Ethics, and Execution by Lethal Injection*, 311 J. AM. MED. ASS'N 2375 (2014); Robert M. Veatch, *The Impossibility of a Morality Internal to Medicine*, 26 J. MED. & PHIL. 621, 634 (2001); David Waisel, *Physician Participation in Capital Punishment*, 82 MAYO CLINIC PROC. 1073, 1079 (2007). Notwithstanding this debate, some physicians clearly do participate in executions without fear of legal sanction. See, e.g., Ty Alper, *The Role of State Medical Boards in Regulating Physician Participation in Executions*, 95 J. MED. LICENSURE & DISCIPLINE 1, 3 (2008) (noting that states have indicated that physicians were involved in overseeing executions and have even taken more active roles, and that legal prohibitions are unlikely to be enforced); Denno, *supra* note 99, at 65–70 (explaining that physicians have been involved in executions since the creation of the first lethal injection protocol in Oklahoma); Atul Gawande, *When Law and Ethics Collide—Why Physicians Participate in Executions*, 354 NEW ENG. J. MED. 1221, 1223–28 (2006) (interviewing physicians who indicated that they have participated in executions for various reasons).

risk minimization. These agents mask any movements or distress by the inmate, making it impossible to tell if the inmate has not been properly anesthetized. The justification for a paralytic agent is to further the state's interest in dignity by maintaining an appearance of a peaceful death. Although the state might have some reason to modify executions to make them seem more dignified, there should be a limit on the level of risk involved. For instance, the use of blankets to cover an inmate's limbs might be one way a state could make an execution appear more dignified without increasing risk. On the other hand, if a state were to argue that having to submit to lethal injection challenges in the courts and share information about executions publicly limits the dignity of the procedure, this would seem to give the interest in dignity far too much weight. Because it could pose significant risk, the use of a paralytic agent does not seem justifiable by an interest in dignity, and therefore fails to fulfill the obligation to minimize risks in research.

C. *Informed Consent*

Another requirement for the ethical conduct of research is informed consent. Valid informed consent would require disclosure of the drugs and procedures being used, the risks involved, and the available alternatives. Obtaining informed consent helps ensure that people are not subjected to experimentation unknowingly or against their will and that they are able to protect their own interests.²⁵⁸ Asking for informed consent from inmates could also help ensure that lethal injection protocols are not excessively risky for particular inmates with special conditions. For instance, Russell Bucklew's execution has been placed on hold by the Supreme Court because he has a unique medical condition, referred to as cavernous hemangioma, which causes him to have clumps of malformed blood vessels that would greatly increase the risks of a prolonged and painful execution.²⁵⁹

As the Institute of Medicine's Committee on Ethical Considerations for Protection of Prisoners Involved in Research stated, "ethical research involves ensuring, as a prerequisite for research, that the standard of medical health care available in the correctional setting permits the inmate to have a meaningful choice between the existing care that is available and the experimental intervention."²⁶⁰ Inmates do not, of

258. Emanuel, Wendler & Grady, *supra* note 233, at 2706.

259. John Eligon, *Supreme Court Halts Missouri Execution and Sends Case Back to Appeals Court*, N.Y. TIMES, May 22, 2014, at A16.

260. ETHICAL CONSIDERATIONS, *supra* note 93, at 22.

course, have the right to give informed consent to being executed—that decision is for a jury to make. Instead, just as some inmates might be given a choice to participate in research conducted by the state testing a new medication for treating HIV, so too should inmates be asked for their consent to participate in *research* about how they should be killed. As previously discussed, consent is required for quality control procedures that involve more than minimal risk, and is typically required for many categories of research.

States seeking to modify their lethal injection protocols would have to ask inmates whether they prefer the modified or unmodified version of the protocol or could offer inmates a choice of a different method of execution altogether. This is not a wholly unprecedented suggestion. Great Britain's Royal Commission on Capital Punishment reviewed lethal injection in the middle of the twentieth century and noted that, although lethal injection raised too many concerns for them to recommend its immediate adoption, an anesthetist testifying before the Royal Commission suggested that: "It should be offered as an alternative, pleasanter, method of execution, and should be used only when it has been willingly accepted."²⁶¹ The Royal Commission was concerned that inmates might have a hard time making such a decision, and also believed that it was the State's responsibility to select the best method of execution available and carry it out with "dignity, solemnity, speed, and certainty."²⁶²

Nevertheless, some states do offer inmates a choice between different methods of execution. Florida's statute provides that a person sentenced to death will undergo lethal injection, unless he or she "affirmatively elects to be executed by electrocution."²⁶³ Missouri permits execution

261. ROYAL COMM'N ON CAPITAL PUNISHMENT, *supra* note 124, at 259.

262. *Id.*

263. FLA. STAT. § 922.105(1) (West, Westlaw through Ch. 255 (End) of 2014 2d Reg. Sess. & Sp. "A" Sess. of 23d legislature); *see also* South Carolina: "A person convicted of a capital crime and having imposed upon him the sentence of death shall suffer the penalty by electrocution or, at the election of the person, lethal injection under the direction of the Director of the Department of Corrections. The election for death by electrocution or lethal injection must be made in writing fourteen days before the execution date or it is waived. If the person waives the right of election, then the penalty must be administered by lethal injection." S.C. CODE ANN. § 24-3-530(A) (Westlaw through end of 2014 Reg. Sess.); Tennessee: noting that if other methods become unavailable for some reason, an inmate no longer has the right to choose and "all persons sentenced to death for a capital crime shall be executed by any constitutional method of execution," TENN. CODE ANN. § 40-23-114 (Westlaw through end of 2014 2d Reg. Sess.); Utah: allowing some inmates to opt for death by firing squad, UTAH CODE ANN. § 77-18-5.5 (Westlaw through 2014 General Sess.); Virginia: "The Director, or the assistants appointed by him, shall at the time named in the sentence, unless a suspension of execution is ordered, cause the prisoner under sentence of death to be electrocuted or injected with a lethal substance, until he is dead. The method of

either by lethal injection or in a gas chamber.²⁶⁴ By contrast, in twenty-one states, lethal injection is the only execution method allowed.²⁶⁵ Some states could reinstate older methods of execution to offer alternatives.²⁶⁶ Of course, alternative approaches to execution may not be available if they have been ruled unconstitutional, so the only alternative in such jurisdictions would be an unmodified lethal injection protocol.²⁶⁷ If there are states where there are truly no alternative options, it may still be worthwhile to provide inmates with the information about the protocol to see if there are any particular risks that can be minimized—for instance, if a larger dose of the anesthetic might be needed for an inmate who previously suffered from drug addiction. Simply informing inmates about what they will be given may be an important protection for inmates who have special medical conditions that make the planned doses or drugs especially risky for them.²⁶⁸ Significantly, inmates are likely to give consent to at least some

execution shall be chosen by the prisoner. In the event the prisoner refuses to make a choice at least fifteen days prior to the scheduled execution, the method of execution shall be by lethal injection. Execution by lethal injection shall be permitted in accordance with procedures developed by the Department.” VA. CODE ANN. § 53.1-234 (Westlaw through end of 2014 Reg. Sess. & includes cc. 1 to 5 from the 2014 Sp. S. I.); Washington: “The punishment of death shall be supervised by the superintendent of the penitentiary and shall be inflicted by intravenous injection of a substance or substances in a lethal quantity sufficient to cause death and until the defendant is dead, or, at the election of the defendant, by hanging by the neck until the defendant is dead. In any case, death shall be pronounced by a licensed physician.” WASH. REV. CODE § 10.95.180(1) (2014).

264. MO. REV. STAT. § 546.720(1) (Westlaw through end of 2014 2d Reg. Sess. of 97th General Assembly). In an analysis of different methods of execution conducted in the mid-twentieth century, Great Britain’s Royal Commission on Capital Punishment dismissed lethal gas as an option because of the “highly unpleasant historical associations” with lethal gas that might render this method of execution unpalatable to the public. ROYAL COMM’N ON CAPITAL PUNISHMENT, *supra* note 124, at 257.

265. Denno, *supra* note 27, at 1342 (current information as of June 2014). *See, e.g.*, KY. STAT. ANN. § 431.220(1)(a) (Westlaw through end of 2014 legis.) (“every death sentence shall be executed by continuous intravenous injection of a substance or combination of substances sufficient to cause death”).

266. David Stout, *The Tennessee Senate Has Backed a Bill to Reinstate the Electric Chair*, TIME (Apr. 10, 2014), <http://time.com/57066/tennessee-senate-electric-chair-capital-punishment-execution/>.

267. For instance, the Ninth Circuit has ruled that gas chamber executions are unconstitutional. *See Fierro v. Gomez*, 77 F.3d 301, 309 (9th Cir. 1996).

268. *See, e.g.*, *Bucklew v. Lombardi*, 565 F. App’x 562, 564 (8th Cir. 2014) (Granting a stay of execution after agreeing that the evidence demonstrated that Bucklew “suffers a medical condition known as cavernous hemangioma involving large vascular deformities and tumors in his face and neck that cause pressure, pain, and frequent bleeding” that was likely to result in “either (1) a long, drawn-out, and painful death due to poor movement of the drug through his atypical circulatory system, or (2) death via choking and suffocation on blood released by anticipated ruptures of the weakened veins in his neck and face.”); stay subsequently granted in *Bucklew v. Lombardi*, ___ U.S. ___, 134 S. Ct. 2333 (2014).

protocols. Ohio's brief move to a one-drug protocol was what inmates had been requesting in prior litigation because it was likely to decrease risks.²⁶⁹

There is, however, an important issue to resolve in obtaining informed consent for executions. Under *Stewart v. LeGrand*,²⁷⁰ the Supreme Court held that if an inmate elects a particular method of execution, he waives his right to challenge its constitutionality.²⁷¹ In the canons of research ethics, the function of requiring informed consent in research is to ensure that individuals can protect their own interests and exercise their autonomy.²⁷² The FDA regulations and the DHHS regulations indicate that informed consent cannot serve as a waiver, stating as follows: "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."²⁷³

In the lethal injection context, informed consent can help ensure that the options that minimize risks are offered to inmates, the changes made to protocols do not increase the risks, and that inmates with particular conditions that increase the risks are identified in advance. These protective functions could be watered down if inmates were wary of electing one option over another because it foreclosed future legal challenges. Given the state of flux in lethal injection protocols, it also seems important to preserve an ongoing right to challenge a protocol when evidence emerges about new risks or better alternatives.

Inmates would have to be informed what drugs were being used in the modified and unmodified protocols to make an informed choice. That disclosure would violate the secrecy some states now maintain. Much of the experimentation being conducted is not transparent. A Texas appellate court recently permitted the Department of Corrections to keep secret the name of the compounding pharmacy producing the drugs they will use in an upcoming execution.²⁷⁴ The court reasoned that revealing

269. See generally *State v. Rivera*, Nos. 04CR065940, 05CR068067 (Ohio Cnty. Ct. C.P. June 10, 2008).

270. 526 U.S. 115 (1999).

271. *Id.* at 119 (1999); see also *State v. Morris*, 24 S.W.3d 788, 797 (Tenn. 2000).

272. Ezekiel J. Emanuel, David Wendler, & Christine Grady, *What Makes Clinical Research Ethical?*, 283 J. AM. MED. ASS'N 2701, 2706 (2000).

273. 21 C.F.R. § 50.20 (2014); 45 C.F.R. § 46.116 (2014) (general requirements for informed consent).

274. Michael Graczyk, *Appeals Court: Texas Execution Back On*, BIG STORY (Apr. 7, 2014), <http://bigstory.ap.org/article/appeals-court-texas-execution-back>.

the names of these pharmacies subjects them to pressure and protests from anti-death penalty groups. One Associated Press investigation found that all but four states refused to disclose the source of their lethal injection drugs.²⁷⁵ Thus, informed consent is an important protection that many states could easily incorporate, but that is incompatible with the level of secrecy in some states.

CONCLUSION

By using new drugs, novel drug combinations, and untested doses, executions by lethal injection involve medical experimentation that is neither well designed nor evidence based. Executions have not adhered to the standards of validating medical practice, which would require careful extrapolation from existing data and/or rigorous data gathering in humans to find an effective approach that does not exceed the Eighth Amendment's restrictions on risks of pain and suffering. States have also failed to take account of the principles and legal requirements governing biomedical research, including obtaining independent review, informed consent, and minimizing risks. Adherence to those principles would protect inmates against excessive and unnecessary risks.

Some readers may be concerned that these arguments are merely a cover for an abolitionist view on the death penalty. Because certain lethal injection drugs are in short supply, adherence to the principles of biomedical research may be very difficult. The logical conclusion might be to halt executions by lethal injection. While it is possible that abolitionists will find some of the arguments made here congenial to their views, it is also possible that this Article provides a framework for more humane lethal injections that may be more acceptable to courts and the general public. The goal of this paper is not to spell out better ways to perform lethal injection, but to make clear how to understand lethal injection experimentation and how to regulate it. In particular, this analysis may help ensure that the current practice of lethal injection is properly regulated so that it no longer involves scientifically questionable, disrespectful, and risky experimentation on inmates. Death penalty proponents have shown resourcefulness in responding to lethal injection challenges,²⁷⁶ as have abolitionists,²⁷⁷ and it would be

275. Andrew Welsh-Huggins & Jim Salter, *In Most States, Execution Drugs Are Surrounded By Secrecy*, HUFFINGTON POST (Apr. 5, 2014), http://www.huffingtonpost.com/2014/04/05/execution-drugs-secrecy_n_5097069.html.

276. Mark Berman, *Missouri Attorney General Wants the State to Produce its Own Lethal Injection Drugs*, WASH. POST (May 29, 2014), <http://www.washingtonpost.com/news/post-nation/wp/2014/05/29/missouri-attorney-general-wants-the-state-to-produce-its-own-lethal-injection-drugs>.

overstating the case to imagine that this Article could end the debate over executions by lethal injection one way or the other.

It is possible that challenges to lethal injection will push states to revert to other methods of execution that have been used in the past, including firing squads, hanging, electrocution, and lethal gas. Many of these options raise concerns beyond the scope of the present paper.²⁷⁸ However, it is worth noting that the FDA regulates the use of anesthetic gas, and it is sometimes used as a medical intervention.²⁷⁹ For this reason, the use of the gas chamber may be subject to FDA oversight and might face challenges similar to those I have discussed here.

Future research on experimental executions should address what causes of action might be available to prisoners to challenge lethal injection executions as involving the conduct of research. Other questions include whether families of inmates in executions gone wrong can obtain damages from the state—and whether alternatives like the use of lethal gas might raise similar concerns about the conduct of research.

My analysis has also revealed gaps in research ethics and regulation. Many scholars have noted that there are significant gaps in the regulation of research in the absence of federal funding.²⁸⁰ Less explored are gaps in regulation of poorly conducted and secretive research. If biomedical research is systematic and rigorous, it should clearly be regulated. If, however, biomedical research is poorly designed and

In addition, proposals for a new method have sometimes come from unusual quarters. See Tracy Connor, *Jack Kevoorkian's Aide Pushed Carbon Monoxide for Executions*, NBC NEWS (May 29, 2014, 11:36 AM), <http://www.nbcnews.com/storyline/lethal-injection/jack-kevoorkians-aide-pushed-carbon-monoxide-executions-n117806>.

277. Holly Williams, *Meet the Woman Behind a Shortage of Execution Drugs*, CBS NEWS, (Apr. 30, 2014, 7:31 PM), <http://www.cbsnews.com/news/meet-the-woman-behind-a-shortage-of-execution-drugs/>.

278. See Robert J. Sech, *Hang 'Em High: A Proposal for Thoroughly Evaluating the Constitutionality of Execution Methods*, 30 VAL. U.L. REV. 381 (1995). See generally Christopher Q. Cutler, *Nothing Less than the Dignity of Man: Evolving Standards, Botched Executions and Utah's Controversial Use of the Firing Squad*, 50 CLEV. ST. L. REV. 335 (2003). Chief Judge Kozinski has argued that lethal injection is a flawed enterprise because it attempts to mask the fact that executions “are brutal, savage events, and nothing the state tries to do can mask that reality. Nor should it. If we as a society want to carry out executions, we should be willing to face the fact that the state is committing a horrendous brutality on our behalf.” *Wood v. Ryan*, 759 F.3d 1076, 1103 (9th Cir. 2014) (Kozinski, J., dissenting). He ultimately settled on the firing squad as the most promising method of execution, and states: “If we, as a society, cannot stomach the splatter from an execution carried out by firing squad, then we shouldn’t be carrying out executions at all.” *Id.*

279. See *Baxter Int’l, Inc. v. Abbott Labs.*, 315 F.3d 829, 830 (7th Cir. 2003).

280. Deborah A. Zarin et al., *Federal Human Research Oversight of Clinical Trials in the United States*, 311 J. AM. MED. ASS’N 960, 960 (2014) (finding that between five to sixteen percent of clinical trials may fall into this regulatory gap).

cloaked in secrecy, it becomes much more difficult to determine how to regulate it, and even the avenues suggested here may depend on voluntary action by an agency like the FDA. This regulatory gap exists even though concerns about risks and uncertainty might increase in research that is not well designed, evidence-based, conducted by experts, or transparent. The origins of and solution to this paradox of research ethics and regulation are critically important avenues for future research.