"WARNING: USE MAY RESULT IN CRUEL AND UNUSUAL PUNISHMENT": HOW ADMINISTRATIVE LAW AND ADEQUATE WARNING LABELS CAN BRING ABOUT THE DEMISE OF LETHAL INJECTION

Abstract: Lethal injection, although currently the preferred method of execution in the United States, causes more botched executions than any other method. Despite recorded instances of extreme pain and suffering, the United States Food and Drug Administration ("FDA") does not regulate lethal injection drugs for safety and effectiveness because their use occurs "off-label" and thus outside of the purview of the FDA's regulatory scope. Challengers to the FDA's lack of regulation have thus far been unsuccessful in the courts due to the deference that the courts give to agency decisions. This Note discusses the ways in which administrative law can be used to bring about the demise of lethal injection. Existing FDA regulations require warning labels when a specific use of a drug causes harm. This Note proposes that concerned parties should file a citizen's petition under Administrative Procedure Act § 553(e) to compel the FDA to require drug manufacturers to update the labels to warn of the harms of using the drugs for execution. These warning labels can then be used to support Eighth Amendment challenges to the constitutionality of lethal injection.

INTRODUCTION

Around 5:30 PM on April 29, 2014, thirty-eight year old Clayton Lockett was led to a small room deep inside the Oklahoma State Penitentiary in McAlester, Oklahoma.[1] Lockett was scheduled to be executed for a murder that he committed in 2000.[2] He had been on death row for fourteen years.[3] Lockett

[1] *See* Jeffrey Stern, *The Cruel and Unusual Execution of Clayton Locket*, THE ATLANTIC (June 2015), http://www.theatlantic.com/magazine/archive/2015/06/execution-clayton-lockett/392069/ [https://perma.cc/X96E-XFGS]. Prior to his execution, Lockett attempted to slit his wrists, overdose on pills, and hang himself with his bed sheets. *Id.* When the correctional officers came to get him from his cell, he was hiding under the sheets, almost as if he knew he would be subject to a gruesome fate. *Id*.

[2] Mark Berman, *What It Was Like Watching the Botched Oklahoma Execution*, WASH. POST (May 2, 2014), https://www.washingtonpost.com/news/post-nation/wp/2014/05/02/what-it-was-like-watching-the-botched-oklahoma-execution/?utm_term=.b68c27302648 [https://perma.cc/EL8R-Y48F] (detailing that Lockett was sentenced to death in 2000 for, among other things, the kidnapping of nineteen-year-old Stephanie Neiman, whom he later shot and buried alive).

[3] *See id.* (establishing that it had been fourteen years since Lockett was convicted of murder).

was strapped onto a gurney with his arms extended to either side.[4] The technicians administering the execution attempted to locate a vein in Lockett's body to insert the IV that would deliver the lethal drugs.[5] The technicians, who were not medical professionals, had to insert the IV into Lockett over eighteen times before they were eventually able to find a suitable vein in his groin.[6]

At 6:23 PM, prison officials raised the beige blinds to the viewing area. Select people were allowed to view the execution, including reporters, the family of the inmate, and the victim's family.[7] Many reporters chose to attend Lockett's execution, as Oklahoma would be using a new lethal injection drug for the first time.[8] It was uncertain how this new drug, midazolam—a sedative that is used to induce unconsciousness for anesthetic purposes—would work for executions.[9]

Now well behind schedule, the technicians inserted the dose of midazolam into the IV and the execution process began.[10] Ten minutes later, the technicians announced that Lockett was unconscious, something that was not the usual practice and surprised the longtime media members who had witnessed many executions.[11] A short time later, the foot of the supposedly unconscious Lockett began to shake, his body nearly jerked off the gurney, and his face showed signs of severe pain.[12] Reporters heard Lockett speak and watched as his body lurched on the table and thrashed against the restraints.[13] It was at this point that the technicians lowered the blinds, shielding the viewers from what was likely a disturbing display of the gruesome reality of what an execution is like in the United States.[14]

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[4] *See* Stern, *supra* note 1 (explaining the initial steps in the execution of Lockett).

[5] *See id.* (detailing the numerous attempts to find a viable vein on Lockett's body before finally finding one in his groin).

[6] *See id.* (explaining that finding a viable vein on Lockett's body was a long and likely very painful process).

[7] *See id*. (establishing that, although the execution was set to take place at 6:00 PM, the procedure was running twenty-three minutes behind schedule because it took so long to find a viable vein).

[8] *See* Berman, *supra* note 2; Stern *supra* note 1 (explaining that midazolam, the drug given to Lockett, is a sedative that can be used to induce unconsciousness, but it may not be able to induce a complete unconscious state that would prevent the inmate from feeling pain).

[9] *See* Stern, *supra* note 1 (noting that midazolam had only been used twice for executions before Lockett's). Midazolam had been used in other states, such as Florida, before. *Id.* Midazolam is a common anesthetic used by doctors when performing procedures. *Id.* It is used to relax the patient or sometimes induce unconsciousness, but doctors do not believe that it is a strong enough drug to fully prevent pain. *Id.*

[10] *See id.* This was the first time that Oklahoma used midazolam in an execution. *Id.*

[11] *See* Berman, *supra* note 2. One of the reporters present at the execution noted that Lockett's execution was the first he had ever seen where the technicians specifically announced to the viewers that the inmate was unconscious. *Id.* The general practice is just to announce the death. *Id.*

[12] *Id.*

[13] *See* Stern, *supra* note 1 (explaining the fact that, prior to his execution, Lockett's stepmother had told him to speak as long as he could so people would know the cruelties of the death penalty).

[14] *See* Berman, *supra* note 2. It became clear that something had gone wrong and the technicians likely did not want witnesses to their mistake. *See id*.

At 6:56 PM, less than an hour after the execution began, the Director of the Oklahoma Department of Corrections called off the execution.[15] Ten minutes later, even though the execution had been stopped, the execution staff pronounced Lockett dead from a heart attack.[16]

No outsider will ever know the exact details of what happened in the room that day, but the general feeling of those who had witnessed the events that led to Lockett's inhumane death was not relief that a rapist and murderer had been put to justice.[17] The feeling could be described as eerie and disturbing during what seemed to be an abnormal execution.[18] Botched executions like Clayton Lockett's are not isolated incidents, however, even though public opinion remains indifferent towards defendants convicted of capital crimes.[19]

The story of Lockett's execution is just one example that illustrates the major problems of lethal injection in the United States.[20] They go wrong often, more often than any other execution method, and cause severe pain and suffering.[21] They are not administered by medical professionals.[22] The drugs used do not come from major pharmaceutical companies, but rather are manufactured in largely unregulated compounding pharmacies or bought from international suppliers.[23] The United States Food and Drug Administration ("FDA")—the agency charged with protecting the public from harmful drugs—does not regulate these drugs for their use in lethal injections.[24]

The lack of FDA regulation is especially problematic given the powerful effect that proper regulations could have on the viability of their use for capital

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[15] *See* Stern, *supra* note 1.

[16] *See* Berman, *supra* note 2; Stern, *supra* note 1.

[17] *See* Berman, *supra* note 2.

[18] *See id.*

[19] *Botched Executions*, DEATH PENALTY INFO. CTR., http://www.deathpenaltyinfo.org/some-examples-post-furman-botched-executions?scid=8&did=478 [https://perma.cc/EH9V-RZQZ]; *see also Death Penalty*, GALLUP, http://www.gallup.com/poll/1606/death-penalty.aspx [https://perma.cc/NZM3-RQPL]. When asked "[a]re you in favor of the death penalty for someone convicted of murder?," sixty percent of respondents in the United States were in favor as of October 2016. *Death Penalty*, *supra*.

[20] *See, e.g.*, Berman, *supra* note 2; Stern, *supra* note 1 (noting other botched executions).

[21] *Botched Executions*, *supra* note 19 (emphasizing that although lethal injection is supposedly the most humane execution method, it has the highest rate of error).

[22] Jonathan Groner, *The Hippocratic Paradox: The Role of the Medical Profession in Capital Punishment in the United States*, 35 FORDHAM URB. L.J. 883, 902–03 (2008); Stern, *supra* note 1.

[23] Erik Eckholm, *Pfizer Blocks the Use of Its Drugs in Executions*, N.Y. TIMES (May 13, 2016), https://www.nytimes.com/2016/05/14/us/pfizer-execution-drugs-lethal-injection.html?_r=0 [https://perma.cc/XEP6-DQQT]; *Compounding Pharmacies and Lethal Injection*, DEATH PENALTY INFO. CTR. (Feb. 06, 2017), http://www.deathpenaltyinfo.org/compounding-pharmacies [https://perma.cc/FLQ2-MMZW].

[24] 21 U.S.C. § 393(b) (2012); *see also id*. § 396 (preventing FDA regulation of drugs used off-label).

punishment.[25] The basis for the FDA's non-regulation is the fact that use of the drugs for execution is not their intended purpose, but rather is an "off-label" use, which is not regulated.[26] The United States Supreme Court has upheld the FDA's decision not to regulate lethal injection as a valid exercise of agency discretion.[27]

In the absence of FDA regulation, challengers to the constitutionality of lethal injections have failed in the courts.[28] Indeed, the Supreme Court has ruled that lethal injection does not violate the Eighth Amendment's prohibition of cruel and unusual punishment.[29] Whether capital punishment should be abolished in the United States is an interesting constitutional question because of possible Eighth Amendment violations[30] Those potential violations have been debated in courts across the country.[31]

This Note examines the ways in which administrative law can be used to bring about the demise of lethal injection where other attempts have failed.[32] Specifically, this Note argues that a citizen's petition under section 553(e) of the Administrative Procedure Act ("APA") to compel the FDA to require up-

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[25] *See infra* notes 303−320 and accompanying text (arguing that updated warning labels could lead to the end of lethal injection).

[26] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780; 21 U.S.C. § 396; Rose Carmen Goldberg, *Safe and Effective for Human Executions?* Glossip v. Gross *and the Eighth Amendment Bar Against Off-Label Drug Lethal Injection*, 68 STAN. L. REV. ONLINE 1, 1 (2015), https://www.stanfordlawreview.org/wp-content/uploads/sites/3/2015/05/68_Stan_L_Rev_Online_1_RoseCGoldberg.pdf [https://perma.cc/G72Y-4X7R].

[27] *See* Heckler v. Chaney, 470 U.S. 821, 830−38 (1985).

[28] *See e.g.*, Glossip v. Gross, 135 S. Ct. 2726, 2733–34 (2015) (holding that the use of midazolam in lethal injections does not violate the Eighth Amendment); Baze v. Rees, 553 U.S. 35, 56 (2008) (holding that lethal injection does not violate the Eighth Amendment).

[29] *Baze*, 553 U.S. at 56.

[30] *See* U.S. CONST. amend. V, VIII (establishing the right to due process and protecting against cruel and unusual punishment, respectively); *see also* Greg Taposci, *Three Steps to Death: The Use of the Drug Pavulon in the Lethal Injection Protocol Utilized Today Violates the Eight Amendment's Protection Against Cruel and Unusual Punishment*, 35 OHIO N.U. L. REV. 425, 443 (2009) (concluding that the use of the drug Pavulon prolongs executions and causes unneeded pain and suffering and arguing that lethal injection execution procedures that use Pavulon violate the Eighth Amendment).

[31] *See, e.g.*, Kennedy v. Louisiana, 554 US. 407, 446−47 (2008) (explaining that the death penalty must be used sparingly and only for the worst crimes imaginable, like homicides); Roper v. Simmons, 543 U.S. 551, 570, 578 (2005) (holding that people under the age of eighteen lack maturity and cannot be classified among the worst offenders, and therefore executing them violates the Eighth and Fourteenth Amendments); Atkins v. Virginia, 536 U.S. 304, 321 (2002) (holding that the mentally disabled cannot be executed because it violates the Eighth Amendment despite its previous holding regarding people with cognitive disabilities); Gregg v. Georgia, 428 U.S. 153, 171 (1974) (emphasizing that Eighth Amendment protections are not limited to historic, barbarous methods of execution); Furman v. Georgia, 408 U.S. 238, 239−40 (1972) (per curiam) (holding that the death penalty did violate the Eighth and Fourteenth Amendments in the way the state used it at the time, but that the justices could not agree on exactly why it was cruel and unusual); Trop v. Dulles, 356 U.S. 86, 100−01 (1958) (explaining that cruel and unusual punishment should be evaluated based on the evolving standards of decency in the United States).

[32] *See infra* notes 37−320 and accompanying text.

dated warning labels expressing the harms associated with using drugs for lethal injection can provide lethal injection challengers with the evidence needed to succeed in their Eighth Amendment claims.[33] Part I discusses the misuse of lethal injection drugs and the cause of that misuse.[34] Part II examines the current state of the FDA's regulation of drugs used in lethal injections and the basis for expanded regulation.[35] Part III argues that the addition of warning labels to drugs can end their use for capital punishment.[36]

I. THE MISUSE OF LETHAL INJECTION DRUGS AND THE CAUSES OF THAT MISUSE

This part establishes the ways in which lethal injection drugs are misused and the corrupt practices used to obtain those drugs.[37] Section A of this part explores the history of botched execution in the United States.[38] Section B addresses the current problems with lethal injection and the current involvement, or lack thereof, of the medical community in executions.[39] Section C discusses the current status of lethal injection in the Supreme Court and how the Court has been unwilling to reject the practice thus far.[40]

A. The Cruel and Usual History of Botched Executions in the United States

The death penalty has been used in the United States since the founding of this country.[41] Lethal injection, the modern method of execution, was first used in the United States in Texas in 1982 and has become the preferred method of capital punishment since then.[42] Previously, electrocution had been a common method of capital punishment, and often had violent results, such as inmates

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[33] *See infra* notes 257−320 and accompanying text.
[34] *See infra* notes 37−158 and accompanying text.
[35] *See infra* notes 159−256 and accompanying text.
[36] *See infra* notes 257−320 and accompanying text.
[37] *See infra* notes 37−158 and accompanying text.
[38] *See infra* notes 41−66 and accompanying text.
[39] *See infra* notes 67−142 and accompanying text.
[40] *See infra* notes 143−158 and accompanying text.
[41] *Part I: History of the Death Penalty*, DEATH PENALTY INFO. CTR., http://www.deathpenaltyinfo.org/part-i-history-death-penalty#intro [https://perma.cc/9RNS-8EUG]. European settlers brought their execution methods with them when they colonized the United States. *Id.*
[42] Kate Pickert, *A Brief History of Lethal Injection*, TIME (Nov. 10, 2009), http://content.time.com/time/nation/article/0,8599,1815535,00.html [https://perma.cc/J8Y8-5C2U] (outlining the origins of lethal injection in the United States). Jay Chapman, the Oklahoma medical examiner who proposed the three-drug lethal injection cocktail, did not have much experience with pharmacology. *Id.* In recent years, Chapman has noted that maybe it is time for a change based on all the problems arising from his lethal injection method. Chris Fisher, *Evolution of Execution*, 21 CBA REC. 40, 41 (2007). Chapman went as far as to suggest bringing back the guillotine. *Id.*

screaming through their deaths or igniting into flames.[43] It is also easier for witnesses, including family members watching the execution, to watch a silent death, rather than watching the possibly violent physical reaction to an electrocution.[44] Regardless of the bleak outcome, lethal injection is considered to be more humane in spite of the facts that the misuse of an off-label drug to kill has had inhumane consequences and more executions are botched using lethal injection than any other method.[45]

Over four thousand people have been executed in the United States by electrocution, totaling about half of all domestic executions.[46] This method did not come without its own consequences that resulted in questions as to whether death by electric shock violated the cruel and unusual punishment clause of the Eighth Amendment.[47] Those potential violations are evidenced by the electrocution of Jesse Tafero.[48]

In 1976, Jesse Tafero shot and killed two police officers in Florida.[49] During his execution, improper use of materials caused him to suffer a great deal of pain.[50] His executioners used a synthetic sponge for the electric chair's headpiece instead of a sea sponge.[51] Synthetic sponges catch fire when too much electricity is introduced.[52] Not only did the sponge catch fire, but so too did Tafero's head.[53] The executioners had to electrocute Tafero three times before he eventually died.[54] Tafero's execution was not an isolated incident when it comes to pain and suffering during executions by electrocution.[55] More than twenty years later, flames engulfed the head of convicted murderer Pedro Medina before he died during a botched electrocution.[56]

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[43] *See* Pickert, *supra* note 42 (providing an explanation for why executions by electrocution lost favor).

[44] *Id.*

[45] *See* Fisher, *supra* note 42, at 40; *Botched Executions*, *supra* note 19. Lethal injection has been controversial since its introduction. Fisher, *supra* note 42, at 40.

[46] *Botched Executions*, *supra* note 19.

[47] *See infra* notes 41–56 (outlining specific examples where executions by electrocution caused particularly gory and inhumane results); *see also* U.S. CONST. amend. XIII. The Eighth Amendment protects against cruel and unusual punishment. *Id.*

[48] Jennifer Latson, *A Gruesome Historical Argument Against the Death Penalty*, TIME (May 4, 2015), http://time.com/3840368/1990-botched-execution/ [https://perma.cc/R8EG-RDXW].

[49] *Id.*

[50] *Id.*

[51] *Id.* The executioner had to go get the sponge from a general store, as there is no specific place to buy items needed for an execution. *Id.*

[52] *Id.*

[53] *Id.*

[54] *See* Latson, *supra* note 48 (establishing that because the first shock did not kill Tafero, he likely experienced a significant amount of pain); *Botched Executions*, *supra* note 19 (establishing that 1.92% of all electrocutions in the United States were botched).

[55] *See id.* (describing events almost identical to the execution of Jesse Tafero).

[56] *Id.* Medina was executed in 1997. *Id.* Florida switched to lethal injection three years later. *Id.*

As a result of these incidents, states across the country began to ban the use of electrocution and eventually, all states had abolished the practice.[57] In 2008, Nebraska became the last state to outlaw the use of electrocution based on evidence that the practice causes immense suffering.[58] Although it may seem obvious that electrocution would cause an inmate to suffer because it causes death by running an electric current through the body, the most prevalent and supposedly painless form of execution in the United States today—lethal injection—has statistically caused more botched executions than any other method.[59]

Although statistics are difficult to accurately identify, it is estimated that out of a total of 8776 recorded executions in U.S. history—including all execution methods—276 (3.15%) have been mishandled in one way or another.[60] Some botched executions cause minor problems, such as, in the case of lethal injection, the inability to properly administer the drugs intravenously due to the lack of viable veins.[61] These small "botches" may increase the length of the execution, but may not cause any additional pain.[62]

Alternatively, however, other types of botched executions lead to immense pain and suffering, rather than simply taking too long.[63] Lethal injection has the highest rate of botched executions at 7.12%, or seventy-five out of 1054 people.[64] Accordingly, about seven out of every hundred people put to death by lethal injection suffer through a botched execution, often involving the misuse or failed administration of the chemical substances used in the execution protocol.[65] Although the rate of pain and suffering caused by botched executions may be lower than 7.12%, these

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[57] *See* Adam Liptak, *Electrocution Is Banned in the Last State to Rely on It*, N.Y. TIMES (Feb. 9, 2008), http://www.nytimes.com/2008/02/09/us/09penalty.html [https://perma.cc/X486-T8FX]. The Supreme Court of Nebraska, the last state to continue using the electric chair, declared the practice to be cruel and unusual punishment. State v. Mata, 745 N.W.2d 229, 279 (Neb. 2008) (holding electrocution to be cruel and unusual punishment because it presents an unnecessary risk of substantial pain, is physically violent, and can mutilate the prisoner).

[58] *Mata*, 745 N.W.2d at 279; *see also* Liptak, *supra* note 57. Nebraska's sole execution method was electrocution, causing the death penalty in Nebraska to be virtually discontinued. Liptak, *supra* note 57.

[59] *See infra* notes 60−62 (establishing that lethal injections are botched at a rate almost double that of executions in general).

[60] *See Botched Executions*, *supra* note 19. More than three out of every one hundred people put to death experience some form of malfunction during their executions. *Id.*

[61] *See* Stern, *supra* note 1. Lockett was stuck more than a dozen times with a needle before the paramedic and on-call doctor were able to find a viable vein in his groin. *Id.*

[62] *See Botched Executions*, *supra* note 19. In 1985 in Texas, it took approximately forty-five minutes for the individuals carrying out the execution of an inmate to find a viable vein. *Id.*

[63] *See supra* notes 1−19 (describing the brutal death of Clayton Lockett who was put to death in 2014).

[64] *Botched Executions*, *supra* note 19 (emphasizing that, although lethal injection is supposedly the most humane execution method, it has the highest rate of error).

[65] *See id*. For example, in 1990, Charles Walker of Illinois suffered immense pain during his execution due to equipment failure and human error. *Id.*

drugs are often improperly administered, which has led to pain and suffering in an unacceptable amount of cases.[66]

B. The Problems of Lethal Injection

1. Lethal Injection Methods

Most lethal injection methods follow a three-drug protocol that begins with an injection of an anesthetic, then a paralytic, and then finally a drug that induces cardiac arrest.[67] Generally, this method includes sodium thiopental and later pentobarbital (an anesthetic), pancuronium bromide (a paralytic), and potassium chloride (used to induce cardiac arrest).[68] The anesthetic is administered first to prevent the pain caused by the following two drugs.[69]

Though lethal injection is a fairly new practice that began in the late 1970s, the method was first suggested in the late 1800s as an alternative to hanging.[70] The idea was discarded amid concerns that the new invention of the hypodermic needle used by doctors would be associated with death.[71] World War II failed to alleviate public concern about lethal injection as the Nazi's used the practice to dispose of sick and injured prisoners during the war.[72] The method was again suggested in the 1950s in the United Kingdom, but was opposed by the medical community and never came into practice.[73]

The practice was proposed once again in 1977 by Jay Chapman, an Oklahoma medical examiner.[74] A method using only an anesthetic drug to kill the inmate was suggested, but was summarily rejected as it was believed that the American people would not support a method to kill humans that was so similar to how animals are killed.[75] Chapman suggested a three-drug method like the

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[66] *See id*.

[67] *State by State Lethal Injection*, DEATH PENALTY INFO. CTR., http://www.deathpenaltyinfo.org/state-lethal-injection [https://perma.cc/WWV9-AVRF]; Eric Berger, *Lethal Injection Secrecy and Eighth Amendment Due Process*, 55 B.C. L. REV. 1367, 1376 (2014).

[68] *See State by State Lethal Injection*, *supra* note 67.

[69] David Kroll, *The Drugs Used in Execution by Lethal Injection*, FORBES (May 1, 2014), https://www.forbes.com/sites/davidkroll/2014/05/01/the-pharmacology-and-toxicology-of-execution-by-lethal-injection/#219d79d17103 [https://perma.cc/76JA-49YW].

[70] Pickert, *supra* note 42.

[71] *Id.*

[72] *Id.* (in addition to firing squad and the gas chamber).

[73] *Id.* The practice of lethal injection is still opposed by the medical community today as evidenced by the oath taken by doctors when they are sworn into the practice of medicine, and by the guidelines promulgated by the American Medical Association ("AMA") that prohibit participation in executions by doctors. *See* Groner, *supra* note 22, at 902–03; *see also Code of Medical Ethics Opinion 9.7.3*, AM. MED. ASS'N, https://www.ama-assn.org/delivering-care/capital-punishment [https://perma.cc/Z9MH-XZAD].

[74] Pickert, *supra* note 42.

[75] *Id.*

contemporary model.[76] Little testing was done on the initial three-drug protocol before it was implemented and subsequently spread across thirty-seven states beyond its initial administration in Texas in 1982 during the execution of Charles Brooks.[77] Although Chapman's expertise was in forensic pathology, not pharmacology, his proposal was still approved the same year it was proposed despite his lack of expertise in the subject matter.[78] Although other methods of execution are still technically legal in some states, lethal injection is used in almost every circumstance.[79]

Although the three-drug method is the most common method of lethal injection, drug shortages have forced states to seek out alternative methods.[80] One alternative method involves injecting lethal doses of only the anesthetic, which, if injected in high enough doses, has a deadly effect.[81] Most recently, states have started using midazolam, the drug used in Clayton Lockett's execution, as the first of the three drugs.[82] Doctors have expressed concern with the use of midazolam because it does not last as long as sodium thiopental or pentobarbital and it cannot induce a permanent coma, causing concern that midazolam does not completely dull the pain of the other execution drugs.[83] There is no one perfect lethal injection method and the lack of consensus as to the best method indicates that there may not be one.[84]

2. The Medical Profession's Lack of Participation in Executions

Lethal injection has a higher rate of botched executions than any other execution method.[85] Like in Clayton Lockett's case, many other executed inmates

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[76] *Id.*

[77] *Id.* (noting that Brooks was executed for murdering a mechanic named David Gregory).

[78] *Id.*

[79] *Id.* In states where more than one method of execution is available, such as firing squad, gas chamber, or hanging, inmates have the option to choose the method that kills them. *Id.* Although the inmates in these states have this option, the vast majority of them choose lethal injection. *Id.* Pickert noted that 936 of the 1107 people executed since 1997 have died by lethal injection. *Id.* Only sixteen have chosen a different method between 2000 and 2009. *Id.*

[80] *State by State Lethal Injection*, *supra* note 67; *see also* Eckholm, *supra* note 23 (explaining that Pfizer was the last major pharmaceutical company to provide states with drugs used for lethal injection).

[81] *See State by State Lethal Injection*, *supra* note 67.

[82] *Id.*

[83] *See* Ed Cara, *What Is Midazolam: Why Are Doctors Worried the Lethal Injection Drug Won't Sedate Death Row Inmates?*, MED. DAILY (June 29, 2015), http://www.medicaldaily.com/what-midazolam-why-are-doctors-worried-lethal-injection-drug-wont-sedate-death-row-340468 [https://web.archive.org/web/20170312210523/http://www.medicaldaily.com/what-midazolam-why-are-doctors-worried-lethal-injection-drug-wont-sedate-death-row-340468] (explaining why doctors are concerned about the use of midazolam for lethal injections from a medical perspective).

[84] *See State by State Lethal Injection*, *supra* note 67. Though there are commonalities between them, the states that carry out the death penalty do not have identical procedures. *Id.*

[85] *Botched Executions*, *supra* note 19.

experienced excruciating pain from the use of the drugs, generally from failure to properly administer the anesthetic.[86] Improper administration of lethal injection drugs likely stems from the lack of participation of medical doctors based on ethical obligations to save lives rather than participate in executions.[87] Furthermore, highly trained medical professionals generally do not participate in executions, leaving the fairly complex execution procedures to lesser-trained personnel.[88] In Lockett's case, a paramedic with no experience carrying out executions using midazolam attempted to administer the drugs.[89] The paramedic noted that much of the equipment, including the types of needles and tubing, was incorrect.[90] When the paramedic could not properly secure the IV, a doctor stepped in.[91] This doctor never thought he would have to participate in administering the drugs.[92] He thought he would only have to pronounce Lockett dead.[93] Instead, the doctor ended up securing the IV.[94]

Medical doctors have the most experience when it comes to the use of the drugs used in lethal injections, as they are trained professionals.[95] Though the

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[86] *See* Berger, *supra* note 67, at 1377–78; *supra* notes 1–19 and accompanying text (discussing Clayton Lockett's execution). Successful, painless executions depend on the proper administration of the anesthetic. *Botched Executions*, *supra* note 19. If the anesthetic does not properly render the inmate unconscious, the inmate would be conscious for the administration of the paralytic, which may cause a feeling of suffocation, and conscious while the executioners induce cardiac arrest. Berger, *supra* note 67, at 1377. An inmate in Florida, Angel Diaz, spent thirty-four minutes in pain before he finally died. *Id.* at 1377–78. In Missouri, a dyslexic executioner admitted he did not know how much anesthetic he used. *Id.* at 1377.

[87] *See* Groner, *supra* note 22, at 902–03 (explaining that doctors swear to "do no harm" and that many medical associations specifically condemn the participation of medical professionals in executions); Stern, *supra* note 1 (explaining that the doctor who assisted in the execution of Clayton Lockett never intended to do anything other than declare him dead); Peter Tyson, *The Hippocratic Oath Today*, PBS (Mar. 27, 2001), http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html [https://perma.cc/GM9S-QRQK] (discussing the oath that doctors are required to swear to before beginning the licensed practice of medicine).

[88] *See* Stern, *supra* note 1 (explaining that sometimes the person selecting the drugs to be used is an attorney).

[89] *Id.* The prison warden oversaw Lockett's execution. *Id.* When the execution started to go wrong, the warden communicated with the director of the Oklahoma Department of Corrections, Robert Patton, who in turn reached out to the General Counsel in the governor's office, who told the director he had the authority to stop the execution. *Id.* By the time Patton instructed the warden to stop the execution, it was too late, and Lockett was soon pronounced dead of a heart attack. *Id.*

[90] *Id.*

[91] *Id.*

[92] *See id.*

[93] *Id.*

[94] Stern, *supra* note 1.

[95] *See* Ty Alper, *Doctors Can and Do Participate in Executions*, N.Y. TIMES (May 1, 2014, 9:42 AM), http://www.nytimes.com/roomfordebate/2014/04/30/doctors-in-the-death-chamber/doctors-can-and-do-participate-in-executions [https://perma.cc/4VYW-JX64] (explaining that doctors are trained professionals that have participated in hundreds of executions and can help ensure that executions are painless). There is no record of medical professionals ever having been punished for participating in executions, as national medical boards only provide practice guidelines *Id.* Some states even have

doctor in Lockett's case participated in the execution, medical doctors swear to do no harm.[96] Though it is not expressly prohibited, many medical organizations across the globe agree that doctors should not participate in executions.[97] For instance, the most prominent organization of medical doctors in the United States, the American Medical Association ("AMA"), has condemned lethal injection in its ethics guidelines to physicians.[98] Although the AMA does not have any legal enforcement authority, its influence has been far reaching as lethal injection procedures do not require medical professionals, and many medical professionals choose not to participate.[99] State medical boards, some of which follow the AMA guidelines, solely possess the enforcement authority of medical ethics guidelines, meaning that only they have the ability to punish medical professionals for participating in executions.[100] Although doctors may participate in executions, their ethical guidelines clearly state that they should not, and many do not.[101]

3. The Suspicious and Secret Sources of Lethal Injection Drugs

Not only is there a high degree of difficulty in administering drugs during executions, there is also mystery surrounding precise lethal injection methods across the states.[102] Drugs used for the purpose of lethal injection have become increasingly more difficult to obtain; as a result, states have turned to disreputable and suspect sources to continue carrying out executions.[103] To mask the dubious nature of the sources, states have enacted secrecy laws that prevent citizens from knowing where exactly those drugs came from.[104] This lack of infor-

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laws that prohibit doctors from being punished for participating. *Id.* Some even go as far as to say that courts should require the participation of a medical professional during executions, but leave it up to the individual to decide whether or not they are morally opposed to participating. *Id.*

[96] Groner, *supra* note 22, at 902; Tyson, *supra* note 87. The Hippocratic Oath, in one of its many versions, is the oath that doctors swear to before beginning practice in the medical field. Tyson, *supra* note 87.

[97] Groner, *supra* note 22, at 902–03 (explaining that national medical associations do not have enforcement power).

[98] *Id.* at 903.

[99] *Id.*

[100] *Id.* The AMA guidelines, much like ethical guidelines for lawyers, are a set of guidelines doctors are obligated to follow. *Id.*; *see also Code of Medical Ethics Opinion 9.7.3*, *supra* note 73 (establishing the AMA's position that "physicians must not participate in a legally authorized execution").

[101] *Id.*; *see also* Stern, *supra* note 1 (describing a situation where a doctor did not expect to participate in an execution, but ultimately had to after the lesser trained individual could not secure the IV).

[102] Nathaniel Crider, *What You Don't Know Will Kill You: A First Amendment Challenge to Lethal Injection Secrecy*, 48 COLUM. J.L. & SOC. PROBS. 1, 5 (2014).

[103] *See id.* at 46 (explaining that many states are considering reverting to old methods of execution, such as the gas chamber or the electric chair, because lethal injections are becoming increasingly difficult to carry out).

[104] *See id.* at 5. These state secrecy laws impede prisoners from learning virtually anything about their execution process, including information relating to where the drugs came from or the qualifica-

mation about lethal injection protocols creates significant obstacles for individuals challenging the legality of their executions due to an inability to obtain the information that could save them.[105]

Lethal injection drugs have become increasingly hard to obtain because domestic pharmaceutical companies have stopped providing drugs for use in executions.[106] States have to be more creative, and therefore secretive, as to the origins of these lethal drugs because often times the drugs are coming from disreputable sources.[107] Executions are deeply rooted in the history of the United States and states continue to look for ways to carry them out, even if it means providing little to no information about them to the public.[108] The criminal justice system as it operates today will seek out all viable options to continue the practice, even if those options skirt the boundaries of the legal system.[109]

Oklahoma passed a law in 2011 that made lethal injection practices a state secret.[110] When journalist Katie Fretland wanted to know exactly where the drugs were coming from, she had to follow the money trail, eventually discovering that the drugs were paid for in cash, with more than $50,000 spent on pentobarbital, a drug used during the first step of the lethal injection process.[111] Many

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tions of those who administer the drugs. *Id.*; *see also* GA. CODE. ANN. § 42-5-36 (West 2017) ("The identifying information of any person or entity who participates in or administers the execution of a death sentence and the identifying information of any person or entity that manufactures, supplies, compounds, or prescribes the drugs, medical supplies, or medical equipment utilized in the execution of a death sentence shall be confidential and shall not be subject to disclosure under Article 4 of Chapter 18 of Title 50 or under judicial process. Such information shall be classified as a confidential state secret.").

[105] *See infra* notes 130–138 and accompanying text (discussing state secrecy laws).

[106] Eckholm, *supra* note 23 (explaining that drug companies do not want their products used in executions because it is bad for business).

[107] *See* Berger, *supra* note 67, at 1388 (explaining that execution procedures have become less and less consistent, relying more and more on under-regulated compounding pharmacies to secure lethal injection drugs).

[108] *See id.*; *Part I: History of the Death Penalty*, *supra* note 41 (establishing the long history of executions in the United States).

[109] *See* Stern, *supra* note 1 (establishing that to carry out the death penalty, states seek alternative means to obtain drugs for lethal injection, such as soliciting sale from international companies under false pretenses).

[110] OKLA. STAT. ANN. tit. 22, § 1015(B) (West 2011). The Oklahoma state secrecy law surrounding lethal injection hides the identities of all people who participate in executions, including those who actually administer the drugs. *Id.* The law also prevents people from finding out who provided those drugs, including supplies and equipment, and are non-discoverable in both civil and criminal proceedings. *Id.*

[111] *See* Stern, *supra* note 1. Fretland had a source in the prison system that allowed her to find out where the drugs were coming from. *Id.; see also Pentobarbital*, U.S. NAT'L LIBR. MED. (Dec. 1, 2017), https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0011665/?report=details#how_to_use [https://perma.cc/X99K-AW3J] (describing pentobarbital). Pentobarbital is a barbiturate used to relieve tension, anxiety, nervousness, insomnia, and to assist in relaxing a patient before a medical procedure. *Id.* Pentobarbital can also be used to treat seizures. *Id.*

of these drugs are obtained from compounding pharmacies that are minimally regulated by the FDA.[112]

Given the difficulty of obtaining lethal injection drugs from traditional manufactures, states have increasingly turned to compounding pharmacies to obtain the drugs used for executions.[113] Compounding pharmacies are generally used to alter drugs so they are effective for specific patients.[114] These facilities often alter drugs to take out certain inactive ingredients so that a person who is allergic to that ingredient may take that drug.[115] Often time, compounding pharmacies operate like traditional pharmacies in that they make almost identical drugs in large quantities, but this is not always the case.[116] For instance, a correctional facility in Mississippi allegedly received raw materials from a compounding pharmacy that the correctional facility had to mix itself.[117]

Before 2013, compounding pharmacies were largely unregulated by the FDA.[118] At the end of 2013, Congress passed the Drug Quality and Security Act in response to a meningitis outbreak stemming from contaminated steroid injections provided by the New England Compounding Center, a compounding pharmacy.[119] The Drug Quality and Security Act requires large-scale compounding pharmacies to register as outsourcing facilities subject to FDA regulations.[120] These large-scale facilities may now be subject to regulation under the FDA; however small-scale distribution of drugs and prescriptions to individuals can still occur without governmental oversight.[121] Small-scale compounding phar-

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[112] *Compounding Pharmacies and Lethal Injection*, *supra* note 23. Compounding pharmacies generally alter the chemical makeup of drugs to be more effective for specific patients. *Id.* These compounding pharmacies are generally not regulated by the FDA unless those pharmacies are producing large scale quantities of those drugs at which time the FDA will require the pharmacy to register as an outsourcing facility that will be regulated by the FDA. *Id.*; *see also* Stern, *supra* note 1 (discussing compounding pharmacies). In 2013, the FDA inspected thirty compounding pharmacies and discovered that twenty-nine of them were unsanitary. Stern, *supra* note 1. Compounding pharmacies operate as both a drug manufacturer and a pharmacy with little FDA oversight. *Id.*

[113] *See* Berger, *supra* note 67, at 1382. Compounding pharmacies have been known to mislabel their drugs. *Id.* at 1383.

[114] *See Compounding Pharmacies and Lethal Injection*, *supra* note 23.

[115] *Id.*

[116] *See id.*

[117] *See* Berger, *supra* note 67, at 1384.

[118] *See Compounding Pharmacies and Lethal Injection*, *supra* note 23.

[119] Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 588 (2013); *see* Michael Gabay, *The Drug Quality and Security Act*, 49 HOSP. PHARMACY 615, 615 (2014). The meningitis outbreak led to sixty-three deaths. *Compounding Pharmacies and Lethal Injection*, *supra* note 23.

[120] *See Compounding Pharmacies and Lethal Injection*, *supra* note 23; *see also Outsourcing Facilities*, FOOD & DRUG ADMIN. https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm393571.htm [https://perma.cc/SJV8-26GS] (explaining that outsourcing facilities are compounding pharmacies that can register to qualify for exemptions from certain FDA approval requirements such as label requirements but not "current good manufacturing practices").

[121] *See Compounding Pharmacies and Lethal Injection*, *supra* note 23 (noting that unregistered compounding pharmacies still distribute small amounts of drugs for specific patients).

macies are prime targets for states to obtain their lethal injection drugs because of this largely unregulated status.[122]

In addition to compounding pharmacies, states have also looked outside the United States to obtain lethal injection drugs.[123] In 2016, Pfizer became the last American pharmaceutical company to stop providing states with drugs used for lethal injection.[124] With the shortage of lethal injection drugs already slowing down capital punishment procedures across the country, states have turned to foreign companies.[125] One such company, Dream Pharma, operated out of London inside of a driving school and had an office that consisted of two desks and a single cabinet.[126] Dream Pharma supplied these drugs to the Arizona Department of Corrections for €4528.25 in 2010.[127] Many countries outside of the United States, including the United Kingdom, have outlawed the death penalty; when the British government discovered that Dream Pharma was supplying state governments in the United States with drugs for lethal injection, it quickly cracked down to prevent the sales.[128] The United Kingdom stopped exporting sodium thiopental and the United States Court of Appeals for the D.C. Circuit blocked the import of sodium thiopental from international suppliers.[129]

As states have turned to unregulated and sometimes illegal sources for lethal injection drugs, they have enacted secrecy laws that attempt to hide the information from the public.[130] Although the purpose of these state secrecy laws is difficult to discern, their effect is not.[131] The Oklahoma secrecy law prevents the identities of the drug suppliers and the people who participate in the executions from being made public.[132] A similar secrecy law in Georgia states that participants, manufacturers, and supplies used in lethal injections are not subject to

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[122] *Id.*

[123] Eckholm, *supra* note 23.

[124] *Id*.

[125] Stern, *supra* note 1.

[126] *Id.*

[127] *Unmasked: The Briton Accused of Supplying Drugs to US Death Row*, INDEPENDENT (Jan. 7, 2011), http://www.independent.co.uk/news/uk/home-news/unmasked-the-briton-accused-of-supplying-drugs-to-us-death-row-2178137.html [https://perma.cc/34RB-XX4B].

[128] Lincoln Caplan, *The End of the Open Market for Lethal-Injection* Drugs, NEW YORKER (May 21, 2016), http://www.newyorker.com/news/news-desk/the-end-of-the-open-market-for-lethal-injection-drugs [https://perma.cc/8BV6-5J8X]; *see also United Kingdom Marks 50th Anniversary of Death Penalty Abolition*, DEATH PENALTY INFO. CTR, https://deathpenaltyinfo.org/node/6296 [https://perma.cc/CY7T-LCZH] (establishing that the United Kingdom abolished capital punishment in 1965, and in Northern Ireland in 1963).

[129] *See* Cook v. FDA, 733 F.3d 1, 3, 10–11 (D.C. Cir. 2013) (enjoining the FDA from allowing foreign drugs, specifically sodium thiopental, from being allowed into the United States markets); Caplan, *supra* note 128.

[130] GA. CODE. ANN., § 42-5-36(d)(2) (West 2017); OKLA. STAT. ANN. tit. 22, § 1015(B) (West 2011); S.D. CODIFIED LAWS § 23A-27A-31.2 (2013).

[131] *See* Eckholm, *supra* note 23.

[132] OKLA. STAT. ANN. tit. 22, § 1015(B).

disclosure through judicial process.[133] In South Dakota, making these lethal injection procedures known is a criminal offense.[134] States like Texas claim that the secrecy laws are in place to protect drug manufacturers from backlash stemming from death penalty opponents.[135] These laws, however, are more likely designed to protect states from lawsuits when executions go awry.[136] For example, after Oklahoma botched Lockett's execution, his estate brought a case seeking injunctive relief and damages after his painful execution.[137] Keeping execution participants a secret prevents lawsuits from being filed, likely because potential plaintiffs do not know who to sue.[138]

In the case of Michael Taylor in 2014, Missouri declined to provide Taylor with details about the execution process, including details about the origins of the drugs used.[139] Taylor based his arguments on the likelihood of risks of serious pain in violation of the Eighth Amendment.[140] Courts all the way to the United States Supreme Court denied Taylor's request for a stay of execution.[141] Had Taylor been able to access the information about the source of the drugs, it's possible he may have prevailed in his appeals; instead on February 25, 2014 he became the fourth person executed in Missouri in as many months.[142]

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[133] GA. CODE. ANN., § 42-5-36(d)(2).

[134] Crider, *supra* note 102, at 22; *see also* S.D. CODIFIED LAWS § 23A-27A-31.2 (establishing that the identity and qualifications of those who supply and those who administer intravenous substances are confidential).

[135] Crider, *supra* note 102, at 23; Eckholm, *supra* note 23.

[136] Crider, *supra* note 102, at 23.

[137] *See id.* at 24–25. The United States Court of Appeals for the Tenth Circuit ruled in 2016 that the execution of Clayton Lockett did not violate the Eighth Amendment's protections against cruel and unusual punishment as "'[s]ome risk of pain is inherent in any method of execution—no matter how humane.'" Estate of Lockett v. Fallin, 841 F.3d 1098, 1109 (10th Cir. 2016), *cert. denied sub nom.* Lockett v. Fallin, 137 S. Ct. 2298 (2017) (quoting *Baze*, 553 U.S. at 47).

[138] *See* Crider, *supra* note 102, at 25 (explaining that secrecy laws are likely implemented to encourage the participation of physicians and pharmaceutical companies, as identifying tortfeasors would be an arduous task).

[139] *See* Berger, *supra* note 67, at 1369. Taylor sued the shop that was supposed to provide the lethal injection drugs, arguing that pentobarbital made by compounding pharmacies creates a substantial risk that the execution will cause immense pain and suffering. *Id.* Wanting to avoid litigation, the shop decided not to supply the state of Missouri with the drugs. *Id.*

[140] *Id.*

[141] *Id.* at 1370.

[142] Tony Rizzo, *Missouri Executes Michael A. Taylor for 1989 Murder of Teenager*, KAN. CITY STAR (Feb. 25, 2014, 12:54 PM), http://www.kansascity.com/news/politics-government/article340107/Missouri-executes-Michael-A.-Taylor-for-1989-murder-of-teenager.html [https://perma.cc/GF48-WBPE]. Taylor was sentenced to death for kidnapping, raping, and stabbing fifteen-year-old Ann Harrison fifteen times. *Id.* It took thirty-six hours to recover Harrison's body, and three months to identify Taylor as one of two assailants. *Id.* Taylor was finally executed almost twenty-five years after the murder, and after one stay of execution in 2008 where he came within hours of meeting his demise. *Id.*

C. The Supreme Court and the Death Penalty

The Eighth Amendment to the United States Constitution prohibits the infliction of cruel and unusual punishment.[143] This Amendment is vague, and courts have struggled to clearly define what constitutes cruel and unusual punishment.[144] In the 1958 landmark case *Trop v. Dulles*, the United States Supreme Court defined cruel and unusual with vague language, holding that cruel and unusual punishment should be evaluated based on society's "evolving standards of decency."[145] In the 2002 case *Atkins v. Virginia*, the Court concluded that evolving standards of decency are not judged by the standards that prevailed when the laws were written.[146] These standards of decency have been difficult to determine, especially when those standards involve capital punishment, though the general consensus amongst the states and the Supreme Court is that the lethal injection of adult inmates does not necessarily violate those standards.[147]

The Court has been busy dealing with death penalty issues over the last fifteen years and has handed down important decisions regarding lethal injection.[148] In the 2008 case *Baze v. Rees*, the Court held that the three-drug lethal injection method used in Kentucky did not violate the Eighth Amendment.[149] Kentucky state inmates on death row had brought the case, claiming that the three-drug lethal injection method poses a great risk of significant pain.[150] The Court found that the death row inmates failed to show the risk of significant harm in violation of the Eighth Amendment and also failed to provide tried and tested alternatives.[151] The Court seemed to indicate that because there is no better option to carry out the death penalty, lethal injection is appropriate for executions.[152]

Seven years later, in 2015, in *Glossip v. Gross*, the Court once again decided a case on the issue of whether or not lethal injection violated the Eighth

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[143] U.S. CONST. amend. VIII.

[144] *See id.*; *Furman*, 408 U.S. at 281 (Brennan, J., concurring). The punishment is cruel and unusual if it "is unusually severe, if there is a strong probability that it is inflicted arbitrarily, if it is substantially rejected by contemporary society, and if there is no reason to believe that it serves any penal purpose more effectively than some less severe punishment." *Id.* at 282. *Furman* briefly outlawed the death penalty, but was overturned in 1976 by *Gregg v. Georgia*. *See* 428 U.S. at 207 (holding that Georgia's capital punishment statutory scheme did not violate the Constitution); *Furman*, 408 U.S. at 239–40 (per curiam).

[145] *Trop*, 366 U.S. at 101.

[146] *Atkins*, 536 U.S. at 311.

[147] *Glossip*, 135 S. Ct. at 2731; *Baze*, 553 U.S. at 56; *see State by State Lethal Injection*, *supra* note 67 and accompanying text (listing over thirty states that use lethal injection).

[148] *See, e.g.*, *Glossip*, 135 S. Ct. at 2731; *Baze*, 553 U.S. at 56.

[149] *Baze*, 553 U.S. at 56.

[150] *Id.* at 40–41.

[151] *Id.* at 62.

[152] *See id*. at 61.

Amendment.[153] State death row inmates from Oklahoma brought the same action as in *Baze*, though the specific action in *Glossip* stemmed from the use of the drug midazolam.[154] The State of Oklahoma had been unable to obtain other popular anesthetics for executions, but was able to obtain midazolam.[155] Writing for the Court, Justice Samuel Alito concluded that the fact that death penalty abolitionists had made it so hard for prisons to obtain drugs that caused little pain—by putting pressure on drug manufacturers to stop providing those drugs to the prisons—had forced prison authorities to resort to the use of midazolam.[156]

The crux of the Court's reasoning in both *Glossip* and *Baze* was that the death penalty must be enforced, with *Glossip* finding that there is no better alternative than midazolam under the circumstances, and *Baze* finding no better alternative than lethal injection in general, and both concluding that the use of lethal injection should be upheld.[157] Because the death penalty is so deeply rooted in our history, lawmakers and judicial figures have been hesitant to abolish the use of lethal injection, finding no better alternative, and have been willing to overlook the very real risks of significant pain inflicted by the use of lethal injection drugs.[158]

II. THE FDA'S REGULATORY AUTHORITY

The FDA regulates drugs that are used for purposes listed on their labels.[159] Laws prevent the FDA from regulating drugs used for off-label purposes.[160] Drugs used for lethal injection fall precisely into the category of drugs that that are used off-label and therefore they are not substantially regulated.[161] The Supreme Court, citing the administrative law principle that gives great deference to agency decisions, has upheld the agency's decision not to regulate lethal injection drugs.[162] The FDA has the authority, however, to require warning la-

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[153] *Glossip*, 135 S. Ct. at 2731.

[154] *Id.*

[155] *Id.* at 2734.

[156] *Id*. at 2733–34.

[157] *Id.* at 2738; *Baze*, 553 U.S. at 56.

[158] *See Glossip*, 135 S. Ct. at 2731; *Baze*, 553 U.S. at 56; Stern, *supra* note 1; *Botched Executions*, *supra* note 19; *Part I: History of the Death Penalty*, *supra* note 41. The petitioners did provide an alternative lethal injection method, but that alternative was not shown to be effective and was not used in any other state. *Baze*, 553 U.S. at 56–57. The State of Kentucky was not obligated to adopt this method. *Id.*

[159] 21 U.S.C. § 396 (2012).

[160] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

[161] *See* Goldberg, *supra* note 26, at 1.

[162] *See* Heckler v. Chaney, 470 U.S. 821, 837–38 (1985) (holding that the FDA is not required to regulate drugs used for off label purposes, and the judiciary must defer to the administrative agency).

bels when there is reasonable evidence of a connection between the off-label use of a drug and a serious hazard.[163]

Section A of this part discusses the sources, scope, and purpose of the FDA's authority to regulate drugs generally and, more specifically, the decision to only regulate drugs for their on-label purpose[164] Section B explains the FDA's limited regulation of lethal injection drugs.[165] Section C discusses the deference courts afford the FDA.[166] Finally, Section D identifies the possible basis under the APA for using administrative avenues to compel the FDA to require warning labels and therefore regulate lethal injection drugs. [167]

A. The FDA's Authority to Regulate Drugs

The first Congressional statute that mandated controls to ensure the safety of food and drugs was passed in the United States in 1906 under Congress' power to regulate interstate commerce.[168] After a marketed sulfanilamide (antibiotic) formulation manufactured with toxic solvents caused more than one hundred deaths, Congress passed the Food, Drug and Cosmetic Act of 1938 ("FDCA") which required, for the first time, that drug products be demonstrated to be safe before they were marketed.[169] A further amendment to the FDCA in 1962 added the requirement that all new drugs be shown to be both safe and effective prior to marketing.[170]

Congress delegated enforcement of the FDCA to the FDA. The FDA's primary purpose is to protect and promote public health by controlling and supervising food, drugs, and many other items that impact human health.[171] Although the FDA is administratively within the Department of Health and Human Services, the administrator of the FDA is the Commissioner of Food and Drugs,

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[163] *See* 21 C.F.R. § 201.80(e) (2017) (regulating the Food, Drug and Cosmetic Act's ("FDCA") requirements for labeling); *see also* Wyeth v. Levine, 555 U.S. 555, 571 (2009) (requiring manufacturers to adequately warn of product hazards).

[164] *See infra* notes 168–177 and accompanying text.

[165] *See infra* notes 178–202 and accompanying text.

[166] *See infra* notes 203–225 and accompanying text.

[167] *See infra* notes 226–256 and accompanying text.

[168] An Act of June 30, 1906, ch. 3915, § 1, 34 Stat. 768, 768. The act made it illegal to manufacture tainted or misbranded food or drugs in the United States. *Id.*

[169] Federal Food, Drug, and Cosmetic Act, ch. 675, § 1, 52 Stat. 1040, 1040 (1938). Food and drugs must be safe and effective before they are allowed to be marketed. *Id.*; Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG. (June 1981), https://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/ucm2007257.htm [https://perma.cc/4XRB-K98H].

[170] Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781.

[171] *See* 21 U.S.C. § 393(b) (listing the different missions of the FDA); *see also What We Do*, FOOD & DRUG ADMIN., http://www.fda.gov/aboutfda/whatwedo/ [https://perma.cc/5DG6-8YW2] (providing an overview of the functions of the FDA).

appointed by the President with the advice and consent of the Senate.[172] The FDCA gives the FDA the responsibility and authority to ensure that drugs, food, and cosmetics are safe and effective for human use.[173]

In 1962, Congress enacted a series of amendments to the FDCA including, among other things, the principle that the government would not interfere with the off-label use of lawfully available drugs by the medical community.[174] The FDA does not regulate drugs when they are used for purposes other than those for which they were approved, such uses are referred to as off-label.[175] Under the FDCA, physicians can use lawfully available drugs for any purpose deemed appropriate.[176] Under this doctrine of off-label use of lawfully available drugs, the boundaries of acceptable prescription drug use are set by peer-reviewed medical publications, by habits of use of the local medical communities, and by state boards of medical licensing.[177]

B. Limited Regulation of Lethal Injection Drugs

Although it is within the FDA's power to regulate drugs, the FDA's authority over lethal injection is vague, as it can regulate the drugs that are later used in lethal injection for their on-label purpose, such as anesthesia during surgery, but not for their off-label use—executing humans.[178] Drugs used in executions are not just used for lethal injection but have historical usage for specific medical purposes, such as anesthesia to render a patient unconscious before surgery.[179]

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[172] 21 U.S.C. § 393(a), (d). The Department of Health and Human Services ("HHS") was established in 1953 under 42 U.S.C. § 3501. 42 U.S.C. § 3501. The mission of HHS is to "enhance and protect the health and well-being of all Americans" by "providing for effective health and human services and fostering advances in medicine, public heath, and social services." *About HHS*, HHS.GOV, https://www.hhs.gov/about/index.html [https://perma.cc/L5AG-J6L2].

[173] 21 U.S.C. § 393(b).

[174] *See generally* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780; 21 U.S.C. § 396.

[175] 21 U.S.C. § 396.

[176] *See id.* (preventing the FDA from regulating the off-label use of drugs).

[177] Gregory Conko, *Hidden Truth: The Perils and Protection of Off-Label Drug and Medical Device Promotion*, 21 HEALTH MATRIX 149, 153 (2011) (explaining that off-label usage of drugs is regulated by state licensing authorities and medical professional standards); Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 481 (2009) (establishing that peer-reviewed medical journals provide support for off-label drug use); Dayna Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud,* 40 U. MICH. J.L. REFORM 281, 327 (2007) (explaining that, although off-label drugs are regulated by state common law, courts often rely on medical professionals and state licensing authorities, presumably as they are the experts on medical issues); *see also* Sigma-Tau Pharm., Inc. v. Schwetz, 288 F.3d 141, 146–47 (2002) (noting that it is not Congress's intent to allow the FDA to interfere with the use of certain drugs for other uses than provided on the label, as this interference will hinder their ability to adequately treat patients).

[178] *See* 21 U.S.C. § 396 (establishing that the FDA cannot stand between a health care practitioner's medical judgment to prescribe certain drugs for off-label uses to their patients).

[179] *See Midazolam (Injection Route)*, MAYO CLINIC (Mar. 1, 2017), http://www.mayoclinic.org/drugs-supplements/midazolam-injection-route/description/drg-20064813 [https://perma.cc/ETK4-

The FDA regulates the drugs for those purposes, requiring them to be safe and effective for medical use.[180] When it comes to governmental executions of criminals, the FDA does not regulate the safety or effectiveness of the drugs, as they as they are being used off-label.[181]

This is not to say that the FDA does not regulate lethal injection drugs at all.[182] In December 2016, the Texas Department of Criminal Justice sued the FDA for impounding drugs used for lethal injection.[183] Texas believed that the FDA must make a decision concerning whether drugs from that particular supplier could be used, and the timeframe for that decision must be reasonable.[184] In April of 2017, the FDA determined that the drugs had to be exported or destroyed because they were either unapproved of misbranded.[185] This decision took the FDA almost two years to make.[186]

In *Cook v. FDA*, the United States Court of Appeals for the D.C. Circuit held that the FDA is required to regulate all foreign imports of lethal injection drugs and to stop the imports if the drugs do not meet agency standards.[187] Inmates from Arizona, California, and Tennessee sued the FDA for allowing the use of sodium thiopental in executions, as they believed that the drug was misbranded and unapproved.[188] The D.C. Circuit found that the FDA must sample all foreign drugs provided by an unregistered facility, which the FDA had not done in this case.[189]

Because lethal injection drugs are becoming increasingly harder to obtain, states are seeking alternative means to carry out the death penalty.[190] The

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9XWQ]. Midazolam, one of the drugs currently being used for lethal injection is used to cause loss of consciousness before surgery, as well as relieve stress before surgery, or just cause drowsiness. *Id.*

[180] *See What We Do*, *supra* note 171 (summarizing the function of the FDA when it comes to pharmaceutical regulation).

[181] Raymond Bonner, *FDA's Immoral Stance on Lethal Injection Drugs*, BLOOMBERG (July 29, 2012, 6:30 PM), https://www.bloomberg.com/view/articles/2012-07-29/fda-s-immoral-stance-on-lethal-injection-drugs [https://web.archive.org/web/20170331165715/https://www.bloomberg.com/view/articles/2012-07-29/fda-s-immoral-stance-on-lethal-injection-drugs].

[182] AnneClaire Stapleton & Elliot C. McLaughlin, *Texas Sues FDA Over Impounded Execution Drugs*, CNN (Jan. 4, 2017, 9:28 AM), http://www.cnn.com/2017/01/04/health/texas-lethal-injection-drugs-fda-lawsuit/ [https://perma.cc/5UEM-3Z7N].

[183] *Id.*

[184] *Id.*

[185] Jolie McCullough, *FDA Officially Bans Texas' Attempted Import of Execution Drugs*, TEX. TRIB. (Apr. 20, 2017, 4:00 PM), https://www.texastribune.org/2017/04/20/fda-rules-texas-attempted-import-execution-drugs/ [https://perma.cc/E8B2-XX8R].

[186] *Id.*

[187] *Cook*, 733 F.3d at 12.

[188] *Id.* at 3.

[189] *Id.* at 10–11.

[190] *See* Caplan, *supra* note 128. States have been known to mislead pharmaceutical companies in order to get drugs for lethal injection. *Id.* In 2011, Ohio was trying to obtain pentobarbital and tried to mislead the company Lundbeck into selling the drug to the Ohio Department of Mental Health when the drugs would really be used for lethal injections. *Id.*

FDA-regulated pharmaceutical companies who produce quality drugs and carry out their sales through legal means have stopped selling drugs for the purpose of lethal injection altogether.[191] Although the FDA has no authority to regulate the use of approved drugs for lethal injections in executions, they do attempt to prevent foreign drugs from entering the domestic market.[192] Unfortunately for the FDA, pursuant to the FDCA, it cannot regulate lethal injection drugs manufactured domestically because they are being administered for an off-label use and they can only regulate them for their on-label use.[193]

Similar to regulating foreign drugs, but not domestic, the FDA regulates drugs used to kill animals, but not humans. The FDA has a strict set of regulations for drugs used on animals through the Center for Veterinary Medicine ("CVM"), with new drugs used on animals approved through a New Animal Drug Application ("NADA").[194] The CVM stipulates that new animal drugs must be humane and cannot cause any pain when used as instructed on the drug label.[195] For a new animal drug to be approved, a sponsor, also known as the applicant, accumulates information about the safety and effectiveness of that drug and then submits the NADA to the CVM.[196] After extensive review, the group of reviewers from the CVM either approve or deny the sale of the drug.[197]

The FDA provides compliance policy guides specifying criteria for labeling drugs used for animal euthanasia based on input from the CVM.[198] New drugs

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[191] *See* Eckholm, *supra* note 23. No FDA-regulated pharmaceutical company provides drugs for the purpose of lethal injection, likely because providing those drugs hurts business as drug companies are supposed to be in the business of helping people, not hurting people. *See id*.

[192] *See* Stapleton, *supra* note 182. The FDA seized internationally manufactured lethal injection drugs that were to be used in Texas executions. *Id.*

[193] 21 U.S.C. § 396.

[194] *Id.* § 321(v) (2012 & Supp. IV 2016). A new animal drug is any drug used on non-humans that is not generally recognized as safe and effective for its recommended use. *Id.*; 21 U.S.C. § 360b (2012 & Supp. IV 2016) (defining the ways in which a new animal drug can be deemed unsafe for use on animals); *About the Center for Veterinary Medicine*, FOOD & DRUG ADMIN., https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm [https://perma.cc/6U5S-48W7] (noting the mission of the Center for Veterinary Medicine ("CVM"), and listing the ways in which that mission can be achieved, including ensuring that animal drugs are safe before they are used).

[195] 21 U.S.C. § 393(b); *CPG Sec. 650.100 Animal Drugs for Euthanasia*, FOOD & DRUG ADMIN., https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074715.htm [https://perma.cc/J3CX-BNC5] [hereinafter Animal Drugs for Euthanasia].

[196] *See* 21 U.S.C. § 360b; *see also About the Center for Veterinary Medicine*, *supra* note 194; *From an Idea to the Marketplace: The Journey of an Animal Drug Through the Approval Process*, FOOD & DRUG ADMIN., https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm#A_Brief_Summary_of_the_Drug_Approval_Process [https://perma.cc/H3QS-L7R6] (providing a general overview of the New Animal Drug approval process that describes the steps followed to get new animal drugs approved).

[197] *From an Idea to the Marketplace*, *supra* note 196.

[198] *CPG Sec. 605.100—Use of Statements Regarding NADA Approval by FDA in Labeling and Advertising of New Animal Drugs*, FOOD & DRUG ADMIN., https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074651.htm [https://perma.cc/KR5X-97T4] [hereinafter NADA Approval].

that are intended to be used for animal euthanasia under the FDA guidelines can only be sold for that purpose upon being approved after filing a NADA.[199] In order to be marketable, drugs used to euthanize animals must be shown to be humane and painless when used properly.[200] Since there appears to have been no application ever submitted to the FDA seeking approval for the use of drugs for human euthanasia, the FDA has neither reviewed the safety and effectiveness of human drugs for such purpose, nor has it ever approved human drugs for the purpose of euthanasia.[201] Unlike drugs used for human execution, the drugs used for animal euthanasia are strictly regulated.[202]

C. Agency Deference Under the Administrative Procedure Act

The FDA is an executive agency whose regulatory authority is delegated by Congress under the FDCA.[203] After Congress enacts laws, executive agencies such as the FDA regulate the implementation of those laws.[204] This allows for expediency as those agencies are better equipped to handle their specific problems than a third party, such as the courts.[205] Specific administrative agencies have expertise in those areas of law that the courts do not.[206]

Because power is delegated to administrative agencies, such as the FDA under the APA, different standards under § 706 determine whether or not a court will determine an agency decision to be unlawful, leaving greater discretion to the agencies.[207] Courts have considered the degree of agency care, consistency, formality, expertness, and persuasiveness to determine agency deference.[208] These standards also include *Chevron* deference, which, in short, re-

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[199] *Id.*

[200] Animal Drugs for Euthanasia, *supra* note 195.

[201] *See Heckler*, 470 U.S. at 823. The litigation in *Heckler* arose out of the FDA's decision not to take enforcement action as requested by the petitioner based on the theory that lethal injection drugs violated the FDCA. *Id.*

[202] *See* 21 U.S.C. § 360b (outlining extensively all the ways in which new animal drugs are regulated by the FDA and the CVM); *see also Heckler*, 470 U.S. at 823.

[203] 21 U.S.C. § 393.

[204] Administrative Procedure Act, 5 U.S.C. §§ 551–559 (2012 & Supp. IV 2016) (codifying agency rulemaking procedures).

[205] Chevron, U.S.A., Inc. v. Nat'l Res. Def. Council, Inc., 467 U.S. 837, 865 (1984) (explaining that administrative agencies are likely more equipped to deal with specific matters based on their expertise in those areas).

[206] Bradley Lipton, Note, *Accountability, Deference, and the Skidmore Doctrine*, 119 YALE L.J. 2096, 2121 (2010); *see* SEC v. Chenery Corp., 332 U.S. 194, 209 (1947). Administrative decisions should be given the most weight because they are the product of expertise. *Chenery Corp.*, 332 U.S. at 209.

[207] *See* 5 U.S.C. § 706 ; United States v. Mead Corp., 533 U.S. 218, 228 (2001).

[208] *Mead*, 533 U.S. at 228.

quires the courts to defer to the decisions of administrative agencies unless Congress has spoken directly on the issue at hand.[209]

The FDA's authority and obligation to regulate lethal injection drugs came to a head before the United States Supreme Court in 1985, in *Heckler v. Chaney*.[210] The case arose out of the claims brought by inmates in Oklahoma and Texas who were sentenced to death by lethal injection.[211] The inmates petitioned the FDA, claiming that the lethal injection drugs violated the FDCA as they were approved for medical use, but not for use in executions.[212] The question before the Court was whether or not courts can review an administrative decision under the APA.[213] Under the APA, individuals have the right to judicial review when they have been harmed by agency action or inaction.[214] After the inmates petitioned the FDA to enforce their claims, the FDA did not act, and the inmates sought judicial review of that refusal to act.[215]

The *Heckler* court ruled against the inmates.[216] Section 701 of the APA states that judicial review of agency decisions should not occur if courts cannot meaningfully interpret the law in question that has already been interpreted by the administrative agency, such as the enforcement provisions of the FDCA.[217] Therefore, the Court held, the enforcement of the law should be left to the administrative agency.[218] Agency decisions cannot be reviewed unless Congress

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[209] *Chevron*, 467 U.S. at 866. If Congress has not directly spoken on the matter, the challenge brought before the court will be unsuccessful. *Id.* The Administrative Procedure Act ("APA") provides avenues for those affected by administrative decisions to petition for change, stating that interested people have the right to petition the issuance, amendment, or repeal of an administrative rule. 5 U.S.C. § 553(e) (allowing individuals to petition the government to change the regulations implemented by federal agencies). In order to have judicial review of an agency decision, the aggrieved party must establish standing. U.S. CONST. art. III, § 2, cl. 1; Lujan v. Defs. of Wildlife, 504 U.S. 555, 557–58 (1992). Construing Article III of the United States Constitution, the United States Supreme Court has outlined a three-part test to determine standing: whether (1) a legally protected interest has been violated, (2) whether there is a causal connection between the protected interest and the actions, and (3) whether the injury can be redressed. *Lujan*, 504 U.S. at 560−61. After constitutional standing is established, standing must also be established under the APA, which requires that an injury be inflicted by a federal agency. 5 U.S.C. § 702. Standing under the APA is achieved when an individual suffers from a legal wrong by an administrative agency under the relevant statute. *See id.* (providing individuals with an avenue to sue the government for legal wrongs inflicted upon them). That legal wrong must stem from a final agency action. *See* 5 U.S.C. § 704 (providing that agency actions are not reviewable if they are preliminary or intermediate in nature). To be final, the action must result from the end of the agency decision-making process, and it must determine rights and obligations, or have legal consequences. Bennett v. Spear, 520 U.S. 154, 177−78 (1997).

[210] *See Heckler*, 470 U.S. at 823.

[211] *Id.*

[212] *Id.*

[213] *Id.*

[214] *See* 5 U.S.C. § 702 (explaining the right of review under the APA).

[215] *Heckler*, 470 U.S. at 823.

[216] *Id.* at 837.

[217] *Id.* at 830.

[218] *Id.*

specifically provides for review under particular statutes.[219] The enforcement provisions of the FDCA, meaning the provisions that allow the FDA to regulate drugs for on label use, do not "overcome" APA § 701.[220] The FDA could have chosen to act, but because they did not, the judiciary has no authority to review that decision.[221] The Court found that the FDA had discretion, and legally chose not to use it.[222]

The deference courts afford under administrative law means that attempts to compel the FDA to regulate lethal injection drugs on the basis that they are harmful and thus violate the FDCA will likely not succeed in the court system given the vast deference afforded to the FDA.[223] Moreover, these cases show that the FDA is not willing to regulate the drugs on their own accord.[224] Although administrative law effectively closes the courts as avenue for reform, it also creates an opportunity to bypass the courts and force the FDA to regulate drugs for safety and effectiveness.[225]

D. Warning Labels as a Basis for the Regulation of Drugs

As discussed *supra*, the purpose of the FDA is to protect individuals from harm that can be inflicted by many substances and to balance the risks posed by medications with the benefits of those drugs.[226] One way the FDA works to achieve that goal is through the use of warning labels.[227] FDA regulations require drug manufacturers to have warning labels listing the potential hazards and harmful effects of the drug.[228] Manufactures are usually only required to address harms that occur for the on-label uses of the drug; they are not required to list the harms that arise from off-label use.[229]

Currently, because the drugs for lethal injections are used for an off-label purpose, the FDA does not require them to have warning labels that would in-

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[219] *Id.*

[220] *Id.* at 837.

[221] *Id.* at 837–38.

[222] *See id.*

[223] *See id.* (establishing the broad authority of the FDA to establish and enforce certain regulations that are not expressly instituted by Congress or obvious congressional intent).

[224] *See id.*

[225] *See* 5 U.S.C. § 553(e) (creating an avenue for private citizens to petition administrative decisions that those individuals or groups of individuals believe will have adverse consequences).

[226] *See What We Do*, *supra* note 171.

[227] *See* 21 C.F.R. § 201.80(e) (regulating the FDCA requirements for labeling).

[228] *See id.*; *see also Wyeth*, 555 U.S. at 571 (requiring manufacturers to adequately warn of product hazards). Federal law controls when determining whether warning labels on drugs are adequate, and as a federal agency, the FDA's authority trumps state authority. Pliva, Inc. v. Mensing, 564 U.S. 604, 624 (2011) (holding that federal law preempts any claim brought under state law alleging that a generic drug was accompanied by inadequate warnings).

[229] *See* 21 C.F.R. § 201.80(e) (explaining when warning labels must be updated to reflect certain hazards).

form the user of the possible adverse reactions that could be experienced the user—such as those experienced by Clayton Lockett.[230]

Though the FDA is not allowed to regulate off-label uses of drugs, the FDCA regulations state that manufacturers are legally responsible for the warning labels that they create for their drugs and further require that those warning labels must be adequate.[231] Adequate warning labels must be updated if there is reasonable evidence of a connection between the drug and a serious hazard.[232] Manufacturers must revise their labels when there is evidence of a serious hazard.[233] Thus, the FDA has legal authority to require manufacturers to re-label their drugs when new evidence of risks arises.[234]

Fortunately for opponents of the death penalty, the 2009 Supreme Court case *Wyeth v. Levine* has opened the door to force manufacturers to adequately label their drugs in order to prevent misuse.[235] The *Wyeth* court held that manufacturers bear the responsibility to adequately label and include warnings on their drugs while the drug is on the market.[236] The FDA has the authority to require manufacturers to update their labels if those drugs are being misused.[237] These changes may be required if the FDA determines that a certain drug is commonly used for a purpose that may cause a serious bodily injury that is not already warned against on the label.[238] These warnings must articulate that certain uses of that drug are not effective and can be harmful.[239]

Pursuant to the FDCA, the Code of Federal Regulations outlines different times where the FDA must order manufacturers to re-label drugs.[240] Drugs may be manufactured for specific uses, but often times, those same drugs are used for a completely different purpose.[241] Similarly, if there is a common use for a certain drug, the FDA may require specific labeling that informs the user that the drug for that use is not effective.[242] The label may also list contraindications,

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[230] *See* 21 U.S.C. § 396 (preventing FDA regulation of drugs used off-label).

[231] *Wyeth*, 555 U.S. at 570–71.

[232] 21 C.F.R. § 201.80(e).

[233] *Id.*

[234] *Id.*

[235] *See Wyeth*, 555 U.S. at 570–71 (concluding that manufacturers are responsible for the adequacy of their warning labels under 21 C.F.R. § 201.80(e)).

[236] 21 C.F.R. § 201.80(e); *Wyeth*, 555 U.S. at 570–71.

[237] 21 C.F.R. § 201.80(c).

[238] *Id.*

[239] *Id.*

[240] *Id.* § 201.80(c)–(e).

[241] *Id.* § 201.80(e); *Understanding Unapproved Use of Approved Drugs "Off-Label,"* FOOD & DRUG ADMIN. (June 2, 2016), https://www.fda.gov/ForPatients/Other/OffLabel/ucm20041767.htm [https://perma.cc/2M63-2RFK]. For example, bupropion, an anti-depressant most commonly used to treat depression, is also prescribed to treat ADHD. *See* Timothy Berigan, Letter to the Editor, *The Many Uses of Bupropion and Bupropion Sustained Release (SR) in Adults*, 4 PRIMARY CARE COMPANION J. CLINICAL PSYCHOL. 30, 30 (2002) (explaining the uses of burpropion).

[242] 21 C.F.R. § 201.80(c).

specifically for particular uses where using that drug is far more detrimental than beneficial.[243]

The FDA may require these warnings for off-label usage.[244] If there is a relationship between a serious hazard and a specific use of that drug, a warning may be necessary.[245] A hazard warning of death or serious injury may have to be placed prominently on a box.[246] If this warning is required, specific adverse reactions must be listed.[247] For example, cigarettes require a boxed warning where Federal law requires at least one of a number of warnings to be on the packaging.[248] These warnings include, among others, an advisory that cigarettes can cause death, are addictive, and can cause harm to babies during pregnancy.[249]

Considering that there are now a growing number of public reports of misuse of drugs used for human execution, there are arguably grounds to request that the FDA require manufacturers to warn users of the hazards of those drugs.[250] Individuals may file citizen petitions to federal agencies, including the FDA, to require the re-labeling of drugs used for lethal injections to include warnings against misuse that may lead to suffering and painful deaths.[251] The FDA provides direction to individuals who want regulations changed.[252] The citizen petition must include the action requested, a statement of grounds, the environmental and economic impact, and certification.[253]

Drugs are misused off-label for the purpose of lethal injection, sometimes resulting in pain and suffering.[254] Those adversely affected by lethal injection could attack the safety and effectiveness of drugs used off-label for the purpose of human euthanasia in the criminal justice system by petitioning the FDA to require manufacturers to re-label the misused drugs.[255] A citizen's petition can be a way to encourage the FDA to update warning labels on the drugs, and those

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[243] *Id.* These contraindications should be known hazards and not theoretical possibilities, meaning that there must be some evidence in place that shows the drugs have adverse effects. *Id.*

[244] 21 C.F.R. § 201.80(c), (e).

[245] *Id.* § 201.80(e).

[246] *Id.*

[247] *Id.*

[248] 15 U.S.C. § 1333(a) (2012).

[249] *Id.*

[250] *See, e.g.*, 21 C.F.R. § 10.30 (2017); *id.* § 201.80(c)–(e); *supra* notes 240–249 and accompanying text.

[251] 5 U.S.C. § 553(e); 21 C.F.R. § 10.30.

[252] 21 C.F.R. § 10.30. The Code of Federal Regulations ("CFR") provides guidelines for filing a citizen petition. *Id.* The CFR provides a format for petition submissions, which should include the action requested, a statement of grounds, environmental impact, economic impact, and finally a certification of, among other things, that the information provided includes information that may be unfavorable to the petitioner. *Id.*

[253] *Id.* § 10.30(b).

[254] *See* Goldberg, *supra* note 26, at 1.

[255] 5 U.S.C. § 553(e); *see* 21 C.F.R. § 201.80(c)–(e).

warning labels could provide a way to successfully challenge the constitutionality of lethal injection.[256]

III. How the Addition of Adequate Warning Labels on Lethal Injection Drugs Could End Their Use for Capital Punishment in the United States

There is overwhelming evidence that lethal injection drugs used for the purpose of capital punishment are unsafe and can cause substantial pain when misused.[257] Lethal injections have led to botched executions at a current rate of about seven percent—higher than any other method of execution.[258] For comparison, the rate of botched executions in general is around three percent.[259] Whether that is due to the misuse of the drugs by executioners, the general ineffectiveness of the specific drugs, or both, is unclear.[260] What is clear, however, is that more than seven percent of the time, something goes wrong with the lethal injection and substantial pain and suffering can result.[261]

The ineffectiveness of certain drugs in lethal injection executions is highlighted not only by the high rate of botched executions, but also by pharmaceutical companies' collective unwillingness to provide those drugs for that use.[262] Currently, no domestic pharmaceutical company provides drugs to be used for lethal injection executions.[263] Accordingly, prisons have had to resort to compounding pharmacies, that, until 2013, saw little or no FDA regulation.[264]

Not only does the FDA not regulate the compounding pharmacies that source the drugs, but neither do they regulate the drugs themselves.[265] Because the use of these drugs for lethal injection occurs for an off-label purpose, the FDA does not regulate the drugs for safety and effectiveness.[266] The United

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[256] U.S. CONST. amend. VIII; 5 U.S.C. § 553(e). If a petition were successful, attorneys would have concrete evidence to present before the judge and jury establishing the possibility to cruel and unusual punishment due to immense pain and suffering. *See infra* notes 315–316 and accompanying text (arguing that updated labels could lead to a court refusing to impose the death penalty).

[257] *See* Goldberg, *supra* note 26, at 3*;* Stern, *supra* note 1; *Botched Executions*, *supra* note 19.

[258] *Botched Executions*, *supra* note 19.

[259] *Id.*

[260] *See* Stern, *supra* note 1 (highlighting an instance where the executioner could not properly administer the drugs); *see also* Cara, *supra* note 83 (explaining hesitancy from the medical community to use midazolam because it is short acting and often fails to put the patient or prisoner in a full coma).

[261] *See Botched Executions*, *supra* note 19.

[262] *See* Eckholm, *supra* note 23; Stern, *supra* note 1 (indicating times in which executions did not go smoothly and explaining that no major FDA-regulated pharmaceutical company provides certain drugs for use in lethal injections).

[263] Eckholm, *supra* note 23.

[264] *See Compounding Pharmacies and Lethal Injection*, *supra* note 23. Compounding pharmacies are generally not regulated when it comes to the manufacture of lethal injection drugs. *Id.*

[265] *See Compounding Pharmacies and Lethal Injection*, *supra* note 23.

[266] 21 U.S.C. § 396 (2012).

States Supreme Court has upheld the FDA decision to regulate lethal injection drugs as a valid exercise of agency discretion.[267]

In the absence of regulation, there are no ways to ensure the safety and effectiveness of the lethal injection process; thus botched executions will continue.[268] The evidence shows that seven out of every one hundred lethal injections are botched, often causing pain and suffering for the inmate.[269] Thus far, however, the courts have determined that these botched executions do not violate the Eighth Amendment's prohibition against cruel and unusual punishment.[270] The Supreme Court has found that petitioning capital defendants have not been able to provide a feasible and better alternative to lethal injection, thereby effectively stopping Eighth Amendment arguments before they can really begin.[271] If the FDA were to require warning labels for these off-label uses, however, the new warnings could provide a future petitioner with the evidence needed to sustain a constitutional challenge under the Eight Amendment to the use of the drugs for capital punishment, even if there is currently no better alternative.[272]

Section A of this part argues why the FDA has the authority to regulate drugs used for lethal injection.[273] Section B examines how citizens can use administrative law to compel the FDA to put warning labels on the drugs used in lethal injections.[274] Finally, section C explains how the warning labels can provide a basis to prevail on Eighth Amendment claims in the court systems.[275]

A. Why the FDA Should, and Ultimately Does, Have Authority to Regulate Drugs Used in Executions

Although the FDA's mission is to protect individuals from exposure to harmful drugs, its regulatory authority only extends as far as Congress has delegated.[276] Congress explicitly stated in the 1962 Amendments to the FDCA that

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[267] Heckler v. Chaney, 470 U.S. 821, 837–38 (1985).

[268] *See* 21 U.S.C. § 396 (preventing the government from interfering with physicians); *Heckler*, 470 U.S. at 837–38 (declaring that the FDA did not have to regulate drugs used off-label); *Compounding Pharmacies and Lethal Injection*, *supra* note 23 (explaining compounding pharmacies in the United States).

[269] *See Botched Executions*, *supra* note 19 (showing statistical rates of botched executions among different execution methods).

[270] *Compare* U.S. CONST. amend. VIII (prohibiting cruel and unusual punishment), *with* Glossip v. Gross, 135 S. Ct. 2726, 2731 (2015) (upholding the constitutionality of lethal injection), *and* Baze v. Rees, 553 U.S. 35, 56 (2008) (same).

[271] *See Glossip*, 135 S. Ct. at 2731, *Baze*, 553 U.S. at 56.

[272] *See* Trop v. Dulles, 356 U.S. 86, 100–01 (1958). Use of drugs with clear warnings for the risk of pain and suffering in off-label use in executions could constitute a violation of "evolving standards of decency" by which the Court has judged Eighth Amendment jurisprudence. *See id.*

[273] *See infra* notes 276–291 and accompanying text.

[274] *See infra* notes 292–302 and accompanying text.

[275] *See infra* notes 303–320 and accompanying text.

[276] *See* 21 U.S.C. § 393(b) (2012) (outlining the purpose of the FDA); *What We Do*, *supra* note 171 (establishing the mission of the FDA).

the FDA does not have the authority to regulate off-label uses of drugs.[277] If the FDA's goal is to keep people safe from unsafe drugs, using an off-label prescription is a convenient way to circumvent that goal.[278]

Thus far, the FDA has not had to make any decisions regarding the safety and effectiveness of lethal injection drugs because they were not manufactured for that purpose.[279] The United States Supreme Court determined in *Heckler v. Chaney* that courts are not equipped to decide this question and that it should be left up to the expertise of the administrative agency.[280] There is no language in the FDCA stating that the FDA is obligated to regulate drugs used for executions; therefore, as the law stands today, drugs used in lethal injections are considered to be used off-label and are not regulated for that purpose.[281]

Although the FDA does not regulate lethal injection drugs for safety and effectiveness, they do engage in limited forms of regulations.[282] The United States Court of Appeals for the D.C. Circuit determined that the FDA must closely monitor foreign imports of drugs used for the purpose of lethal injection.[283] In *Cook v. FDA*, the D.C. Circuit found that FDA's policy of ignoring foreign imports of lethal injection drugs for state-level executions violated its statutory obligations and prohibited the practice.[284] If drugs from foreign manufacturers should be regulated, so too should the same domestically produced drugs used for off-label purposes.[285] Likewise, if drugs used for euthanizing animals must be proven to be humane, safe, and effective before the FDA authorizes their use, so too should drugs used on humans.[286]

Moreover, the FDA's decision not to regulate drugs in light of the FDCA, although ruled to be a valid exercise of agency discretion by the Supreme Court, is better considered an abdication of duty.[287] The purpose of the FDA is to protect the public from harmful food and drugs.[288] By any measure of common-

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[277] 21 U.S.C. § 396.

[278] *Id*. §§ 393(b), 396.

[279] *See Heckler*, 470 U.S. at 837–38.

[280] *Id.*

[281] *See id.*

[282] *See Compounding Pharmacies and Lethal Injection*, *supra* note 23 (explaining that the FDA does regulate large scale drug production from compounding pharmacies); Stapleton, *supra* note 182 (establishing FDA regulation of internationally imported drugs).

[283] Cook v. FDA, 733 F.3d 1, 10–11 (D.C. Cir. 2013).

[284] *Id.*

[285] *See id.*

[286] Animal Drugs for Euthanasia, *supra* note 195 (regulating the drugs for euthanizing animals, providing that they must cause a humane in painless death in order to gain FDA approval).

[287] *Heckler*, 470 U.S. at 830−38; *see also* 21 U.S.C. § 393(b) (establishing the mission of the FDA).

[288] *See* 21 U.S.C. § 393(b); *What We Do*, *supra* note 171.

sense, it is incredulous that the FDA would not regulate drugs that are intended not just to harm, but to kill members of the public.[289]

Although the FDA does not currently require the warning labels of drugs used for lethal injection to include warnings of safety and effectiveness, that does not mean that FDA cannot require them at all.[290] In fact, the FDA must require warning labels to list the harmful effects and a citizen's petition through administrative law is the way to compel them to do so.[291]

B. An Administrative Law Citizen's Petition Can Compel the FDA to Require Warning Labels for Lethal Injection Drugs

The FDA has the authority to require warning labels when drugs are used for an off-label purpose if there is a relationship between a specific use of the drug and a serious hazard.[292] Under this authority, the FDA could require manufactures to re-label the drugs used for lethal injection.[293] Given the FDA's prior unwillingness to regulate lethal injection drugs, however, it seems unlikely the FDA would do so on its own accord.[294] Fortunately for challengers of the drugs, administrative law provides a way to circumvent agency inaction and achieve their desired results: a citizen's petition.[295]

Citizens should petition the FDA to use its regulatory authority to require all manufacturers of drugs commonly used for lethal injection to update their warning labels to warn against misuse.[296] The petition should argue that the misuse of the drugs used in lethal injections carries the risk of causing severe pain and suffering, as currently the labeling of the drugs contains no warning of such harms and thus is inadequate.[297] The pain and suffering resulting from the use of the drugs for lethal injections constitutes a serious hazard.[298] Therefore, the FDA must require manufacturers to update the labels.[299] The updated label should state that these drugs are not intended for use in human euthanasia because such

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[289] *Compare* 21 U.S.C. § 396 (preventing the FDA from interfering with the physician patient relationship), *with* Animal Drugs for Euthanasia, *supra* note 195 (requiring that drugs used for animal euthanasia be painless and humane).

[290] *See* 21 C.F.R. § 201.80(c) (2017) (stating if there is evidence that off-label uses are not effective, the warning must include this fact).

[291] *See id.* § 201.80(c)-(e); *see also* 5 U.S.C. § 553(e) (2012).

[292] 21 C.F.R. § 201.80(c)-(e).

[293] *Id*.

[294] *See Heckler*, 470 U.S. at 837–38.

[295] 5 U.S.C. § 553(e).

[296] *Id.* (allowing citizens to petition for change of administrative rulings); 21 C.F.R. § 201.80(e).

[297] 5 U.S.C. § 553(e); 21 C.F.R. § 201.80(e); *Botched Executions*, *supra* note 19.

[298] *See* 21 C.F.R. § 201.80(e) (explaining that warning labels must be updated if there is evidence of a serious hazard related to the drug); Stern, *supra* note 1 (detailing the suffering of Clayton Lockett during his botched execution); *Botched Executions*, *supra* note 19 (establishing that executions by lethal injection are frequently botched).

[299] 21 C.F.R. § 201.80(e).

use may result in pain and suffering, and should provide adequate directions for effective use.[300]

Furthermore, from a policy standpoint, the FDA's regulatory authority would be severely undermined if companies were not required to accurately warn individuals of common ways that drugs are misused in a way that can lead to pain and suffering.[301] Once warning labels are in place, challengers to the constitutionality of lethal injection will have a powerful tool to use in the court system.[302]

C. How Warning Labels Can Lead to Defeating Lethal Injection in Court

To many, it may seem as though changing a warning label on a drug that has already proved to induce pain and suffering is meaningless, as considerable evidence already exists that executions by lethal injection can cause pain and suffering.[303] This point of view drastically underestimates the power that administrative procedure has in affecting the future of the death penalty.[304] The main reason why challenges to the constitutionality of lethal injection under the Eighth Amendment have failed thus far is the inability of petitioners to establish that pain and suffering of lethal injections amount to cruel and unusual punishment.[305] FDA labels warning of the risk of severe pain and suffering from the use of the drugs in lethal injections will provide the information that previous challenges have lacked.[306]

Death penalty opponents base many of their arguments on the Eighth Amendment, an amendment that has firm roots in morality.[307] Basing legal deci-

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[300] *See* 21 C.F.R. § 201.80(c), (e). The regulatory authority to require warning label updates comes from the regulations associated with the FDCA. *Id.*

[301] *See id.* § 201.80(c), (e) (establishing when the FDA can require warning labels to be updated).

[302] *See* U.S. CONST. amend. VIII; 21 C.F.R. § 201.80(e).

[303] *See Botched Executions*, *supra* note 19 (providing botched executions statistics); *see also* Eckholm, *supra* note 23 (describing problems states are having in carrying out executions); Stern, *supra* note 1 (describing an instance of immense pain and suffering).

[304] *See* 5 U.S.C. § 553(e) (establishing that individuals have a say in the ways administrative agencies carry out their rules, and those individuals may petition the agencies to change or eliminate rules).

[305] *See* U.S. CONST. amend. VIII; *see also Baze*, 553 U.S. at 56.

[306] *Glossip*, 135 S. Ct. at 2733–34; *Baze*, 553 U.S. at 56. The Supreme Court declined to find lethal injection unconstitutional under the Eighth Amendment in both landmark death penalty cases. *Glossip*, 135 S. Ct. at 2733–34; *Baze*, 553 U.S. 35 at 56.

[307] *See Trop*, 356 U.S. at 100–01. In *Trop*, the Supreme Court famously articulated that the Cruel and Unusual Punishments Clause of the Eighth Amendment is governed by the "evolving standards of decency that mark the progress of a maturing society." *Id.* at 100–01. Judicial reasoning is riddled with moral decision-making, such as through the proportionality requirements often discussed in capital cases. Michael S. Moore, *Morality in Eighth Amendment Jurisprudence*, 31 HARV. J.L. & PUB. POL'Y 47, 52 (2008). Judges often have to decide whether someone deserves to be put to death. *Id.* In 2005, in *Roper v. Simmons*, the Supreme Court had to decide if those capital offenders under the age of eighteen deserved to die if they did not have the mental capacity to fully understand their crimes.

sions on differing sets of moral codes are likely to result in dramatically different outcomes, with historically unfavorable results for death penalty opponents.[308]

Opponents of the death penalty may argue that merely changing the warning label on a drug meant to cause death to heinous criminals is an unlikely deterrent for the courts.[309] In reality, these new requirements provide an incredible opportunity for defense counsel in capital cases.[310] Lethal injection drugs have been known to cause pain and suffering.[311] If the FDA were to require an adequate label on these drugs stating that fact, defense counsel would have clear evidence to present to the judge and jury that the use of the drugs for the purpose of lethal injection causes pain and suffering.[312] A jury is less likely to allow a punishment of death when the mode of execution inflicts severe pain.[313] Many may consider that modern standards of decency, as discussed in the 1958 Supreme Court case, *Trop v. Dulles*, do not include the intentional infliction of severe pain.[314]

Updating warning labels could be invaluable to a defendant in a capital case whose only argument is that he or she is likely to suffer great pain at the hand of the government.[315] Though many might still agree that there is no better alternative for executions, it becomes less and less viable for courts to use that argument to uphold capital punishment when it is clear that the person being executed will endure pain and suffering.[316]

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543 U.S. 551, 555–56 (2005); *see* Moore, *supra*, at 52. According to the view linking punishment and morality, severity of punishment is firmly rooted in whether the offender deserves that punishment. Moore, *supra*, at 52. From this perspective, when there is talk of "moral desert," one's morality accompanies decision-making. *Id.*

[308] *See supra* note 31 (listing landmark Supreme Court cases determining what constitutes cruel and unusual punishment). No Supreme Court case since *Furman v. Georgia* in 1972 has held that capital punishment violates the Eighth Amendment. *See* 408 U.S. 238, 239–40 (1972) (per curiam) (holding the death penalty to be unconstitutional).

[309] *See* 21 C.F.R. § 201.80(e) (requiring that warning labels be updated to warn against serious harm).

[310] *See id.*

[311] *See supra* note 303 (reiterating examples of the numerous botched executions across the country since the 1980s).

[312] *See* 21 C.F.R. § 201.80(e).

[313] *See Trop*, 356 U.S. at 100–01. Based on the Court's theory of evolving standards of decency from *Trop v. Dulles*, this warning label may present an opportunity to demonstrate to a court that the current method of lethal injection has gone far beyond the standard. *See id*. If government required warning labels to state warnings of pain and suffering, execution by lethal injection may join the likes of the electric chair and the gas chamber as executions methods deemed inhumane. *See Descriptions of Execution Methods*, DEATH PENALTY INFO. CTR., https://deathpenaltyinfo.org/descriptions-execution-methods [https://perma.cc/AA34-UDDS].

[314] *See Trop*, 356 U.S. at 100–01.

[315] *See* 21 C.F.R. § 201.80(e).

[316] *See Glossip*, 135 S. Ct. at 2731 (concluding that no better alternatives have been established, and ignoring that, the lack of alternatives notwithstanding, lethal injection is not a human way to carry out the death penalty); *Baze*, 553 U.S. at 56.

It is impossible to know just what was going through Clayton Lockett's head as he lay on the table, unable to move under his restraints while poison meant to stop his heart coursed through his body.[317] What witnesses saw that day, however, was not a humane and painless death that the law currently requires for animal euthanasia.[318] They saw the undignified death of a fellow citizen whose government had failed to protect him from the very thing that the United States Constitution promised he would never have to endure.[319] For Lockett, and so many others, a proper warning label could have been all that stood between a lifetime of repenting for his crimes and a death that could have felt like being burned alive.[320]

CONCLUSION

Throughout history, states have struggled to establish execution methods that match society's "evolving standards of decency." Since its implementation in the 1980s, the execution method of lethal injection has failed to establish that it is more humane than any of its predecessors. Indeed, lethal injection has a higher rate of error than any other method of execution. Despite these rates of botched executions, the United States Supreme Court has not found lethal injection to violate the Eighth Amendment.

In recent years, large pharmaceutical companies that have traditionally manufactured the drugs used for lethal injections have stopped providing them for that use. As a result, states have turned to either largely unregulated compounding pharmacies or foreign companies. The exact source of drugs being used today is unknown, however, as states have enacted secrecy laws that prevent the disclosure of the origins of drugs. This legislation has effectively barred civil suits seeking to ban the use of these drugs and created significant obstacles for direct criminal appeals of those sentenced to die.

The FDA, the agency tasked with protecting and warning the public from harmful drugs, does not regulate lethal injection drugs for safety and effectiveness because their use occurs for an off-label purpose. Although the FDA has yet to regulate drugs for lethal injection, administrative law provides a way to

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[317] *See* Stern, *supra* note 1. The thoughts running through Lockett's mind are unknown because the drugs used prior to stopping his heart rendered him unable to speak beyond a few unintelligible words. *Id.*

[318] *Id.*; *see also* NADA Approval, *supra* note 198. (outlining veterinary euthanasia drug regulations).

[319] *See* Stern, *supra* note 1. The United States government has sworn to protect its citizens from the infliction of cruel and unusual punishment. U.S. CONST. amend. VIII. It is difficult to imagine that being awake for one's own drug-induced cardiac arrest is not cruel and unusual while the firing squad, a method that has never botched an execution, has fallen out of practice. *See Botched Executions*, *supra* note 19; *see also* Stern, *supra* note 1.

[320] *See* 21 C.F.R. § 201.80(e) (requiring that drug effects be adequately warned against); Stern, *supra* note 1.

compel the agency to do so. Pharmaceutical regulations already in place establish that the FDA must regulate warning labels for drugs, such as those used in lethal injections, that it knows are being misused.

Citizens can file an APA § 553(e) petition to initiate administrative rulemaking that would require the FDA to update its warning labels on these drugs to include warnings that the misuse of the drugs can cause severe pain and suffering. Should these petitions prevail, the long-standing history of capital punishment may see its demise in the United States. If lethal injection drugs are required to have updated warning labels cautioning that their use causes pain and suffering, courts may be hesitant to allow executions to go forward with such clear evidence that those drugs can be harmful. Indeed, what better proof is there that a drug causes cruel and unusual punishment than if it says so on the label.

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