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

Matthew C. Bergs*

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

I. INTRODUCTION & BACKGROUND .................................................. 762
   A. HISTORY OF LEthal Injection AS A Method OF EXECUTION... 763
   B. DEVELOPMENT OF THE LEthal INJECTION DRUG SHORTAGE.....765

II. ASSESSMENT OF THE D.C. CIRCUIT’S DECISION IN COOK V. FDA...768
   A. EXPLANATION OF THE SUPREME COURT’S DECISION IN
      HECKLER v. CHANEY ............................................................. 769
   B. ANALYSIS OF THE D.C. CIRCUIT’S DECISION IN COOK V. FDA ... 770
   C. WHY COOK V. FDA WAS WRONGLY DECIDED.........................771

* M.H.A. candidate, The University of Iowa College of Public Health, 2018; J.D. candidate, The University of Iowa College of Law, 2017; B.A., Marquette University, 2013. I would like to thank Professor Todd Pettys and Dr. Ben Gillig for their invaluable comments on earlier drafts of this Note. I would also like to thank the Iowa Law Review Volume 102 Editorial Board for its assistance in preparing this Note for publication. Finally, I would like to thank my parents, Dr. Joe and Carrie Bergs, to whom I am deeply indebted, both literally and figuratively.
III. RESPONSES TO THE D.C. CIRCUIT’S DECISION IN *COOK v. FDA* .... 772
   A. EXPERIMENTING WITH ALTERNATIVE DRUGS ......................... 773
   B. ENGAGING WITH COMPOUNDING PHARMACIES ........................ 776
   C. RETURNING TO PAST METHODS OF EXECUTION .......................... 779
   D. IGNORING THE FDA’S RESTRICTIONS ................................... 783

IV. POTENTIAL SOLUTIONS TO THE D.C. CIRCUIT’S DECISION IN *COOK v. FDA* .................................................. 786
   A. ADHERE TO THE FDA’S REGULATIONS .................................. 786
   B. LITIGATE THE FDA’S REGULATIONS ..................................... 788

V. CONCLUSION ........................................................................... 790

I. INTRODUCTION & BACKGROUND

“I’ve heard everything from using heroin to using nitrogen to going back to the electric chair. That’s a debate that probably we need to have.”

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

5. *Cook v. FDA*, 733 F.3d 1, 3 (D.C. Cir. 2013).
7. See infra Part III.
penalty is still a justifiable form of punishment. As a result, it has become very
difficult for states to carry out court ordered executions. The current situation
has exasperated correctional officials, prompting Arkansas Attorney General
Dustin McDaniel to remark: “I’ve done everything I can do to carry out the
executions that have been ordered in my state, and if somebody has an idea
of how we can do that, I’d like to hear it.”

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

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

Lethal injection was first adopted as a method of execution by Oklahoma
in 1977. Dr. Jay Chapman, Oklahoma’s chief medical examiner at the time,
created the lethal injection protocol at the request of former Oklahoma state
legislator Bill Wiseman. According to Mr. Wiseman, he originally supported the adoption of lethal injection
as a method of execution because he hoped to “make executions more humane.” Vince Beiser,
2005/09/guilty-man?page=1. Prior to the adoption of lethal injection, Oklahoma executed
prisoners by electric chair. Id.

Dr. Chapman’s protocol called for the administration
of three different drugs via a saline drip: (1) sodium thiopental, an anesthetic
that induces deep unconsciousness; (2) pancuronium bromide, a muscle
relaxant that causes paralysis and suffocation; and (3) potassium chloride, a
chemical compound that triggers cardiac arrest. Convinced that lethal
injection was a more humane—not to mention cheaper—method of capital
punishment compared to previous methods, Oklahoma legislators passed the

8.  *See infra* Part III.
11.  Id. According to Mr. Wiseman, he originally supported the adoption of lethal injection
as a method of execution because he hoped to “make executions more humane.” Vince Beiser,
2005/09/guilty-man?page=1. Prior to the adoption of lethal injection, Oklahoma executed
prisoners by electric chair. Id.
(2014).
As Wiseman recalled, lethal injection offered “the following benefits[:] . . . ‘[n]o pain, no spasms, no smells or sounds—just sleep, then death.’”

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

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

15. Fellner & Tofte, supra note 13.
18. Denno, supra note 12, at 1342 chart 1.
19. Id.
20. Id. at 1342 (footnote omitted).
22. Id. at 41. The prisoners acknowledged that, if performed properly, Kentucky’s lethal injection protocol would not constitute cruel and unusual punishment. Id.
23. Id. at 52 (quoting Farmer v. Brennan, 511 U.S. 825, 842 (1994)).
substantial risk of serious harm as “compared to the known and available alternatives.”

B. DEVELOPMENT OF THE LETHAL INJECTION DRUG SHORTAGE

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

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

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


26. Id.


31. David W. Freeman, Pentobarbital, Euthanasia Drug, Used in Oklahoma Execution: Was It
pentobarbital used in the United States is Lundbeck, a company headquartered in Denmark. In July 2011, facing significant external pressures, Lundbeck took steps to prevent correctional facilities in the United States from acquiring pentobarbital.

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

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

---


33. Fan, supra note 32, at 440.


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

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

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

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

---

38. Beaty, 853 F. Supp. 2d at 35.
40. Id. The FDA also made clear “that while it will permit thiopental imports it . . . will not vet or vouch for the ‘safety, effectiveness, purity, or any other characteristics’ of thiopental shipments.” Id.
44. Judson Berger, Justice Department Pursues ‘Strange’ Probe of Execution Drug, FOX NEWS (May 8, 2011), http://www.foxnews.com/politics/2011/05/08/justice-department-pursues-strange-probe-execution-drug. It is unclear why California’s sodium thiopental shipment was never seized. Some commentators argue that the DOJ’s purpose in seizing the imported sodium thiopental was to “slow the pace of executions,” a purpose which was not served by seizing California’s shipment because California “had executions on hold anyway and just announced it was delaying executions for at least another year.” Id.
Department of Health and Human Services, and various government officials. In *Beaty v. FDA*, the prisoners alleged that the FDA, in releasing Dream’s shipments of sodium thiopental, had improperly allowed the importation “of a misbranded and unapproved new drug” thereby violating several provisions of the Federal Food, Drug, and Cosmetic Act (“FDCA”), and requiring refusal of admission. The FDA argued it had discretion over whether to reject misbranded and unapproved sodium thiopental, but the court disagreed and found that the language of the FDCA required the FDA to reject such drugs. The court then permanently enjoined the FDA from permitting the importation of “apparently misbranded or unapproved” sodium thiopental.

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

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

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

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

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

---

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

46. *Id.* at 37.

47. *Id.* at 40.

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


50. *Id.*

51. *Id.*

52. *Cook*, 733 F.3d at 12 (holding that “[t]he FDA acted in derogation of [its] duties by permitting the importation of thiopental, a concededly misbranded and unapproved new drug, and by declaring that it would not in the future sample and examine foreign shipments of the drug despite knowing they may have been prepared in an unregistered establishment”).
which provides background and exposition on the governing law utilized in
Cook. Part II.B then analyzes the Cook decision. Finally, Part II.C argues that,
in light of the Supreme Court’s ruling in Heckler v. Chaney, Cook v. FDA was
wrongly decided.

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

In Heckler v. Chaney, the United States Supreme Court considered “the
extent to which a decision of an administrative agency to exercise its
‘discretion’ not to undertake certain enforcement actions is subject to judicial
review.”53 Prisoners facing execution by lethal injection in Texas and
Oklahoma argued that under the FDCA, the use of sodium thiopental for
executions made it a “misbrand[ed]” and “new” drug pursuant to sections
352 and 355 respectively.54 They further argued that the sodium thiopental
required FDA approval “as ‘safe and effective’ for human execution.”55

Previously, the FDA had declined to take such action, arguing its jurisdiction
to interfere with the states’ criminal justice systems was questionable.56

The FDA also argued that the alleged dangers to the inmates did not constitute “a
serious danger to the public health or a blatant scheme to defraud,” so its
exercise of enforcement discretion was proper.57 The Court, after declining
to “address the thorny question of the FDA’s jurisdiction,”58 held that the
decision was unreviewable because, in the FDCA, Congress “commit[ted]
complete discretion to the [FDA] to decide how and when [enforcement
provisions] should be exercised.”59

The Court premised its holding in Heckler on the FDCA’s general
enforcement provision, which is contained in section 372.60 Section 372
provides that “[t]he [FDA] is authorized to conduct examinations and
investigations.”61 With no other “law to apply,” i.e., provisions that “withd[ra]w
discretion from the agency and provide[] guidelines for exercise of its
enforcement power,” the Court found that the language of section 372 clearly

55. Id. at 824 (quoting 21 U.S.C. § 355).
56. Id. at 824–25 (“Were FDA clearly to have jurisdiction in the area, moreover, we believe
we would be authorized to decline to exercise it under our inherent discretion to decline to
pursue certain enforcement matters. The unapproved use of approved drugs is an area in which
the case law is far from uniform. Generally, enforcement proceedings in this area are initiated
only when there is a serious danger to the public health or a blatant scheme to defraud. We
cannot conclude that those dangers are present under [s]tate lethal injection laws, which are
duly authorized statutory enactments in furtherance of proper [s]tate functions. . . .”).
57. Id.
58. Id. at 828.
59. Id. at 835.
60. Id. at 823–24 (quoting 21 U.S.C. § 352 (2012)).
evinced Congress’s intent to grant the FDA enforcement discretion.\(^{62}\) Significantly, the Court did not consider “the [FDCA’s] substantive prohibitions of ‘misbranding’ and the introduction of ‘new drugs’ absent agency approval” to constitute “law to apply.”\(^ {63}\) Instead, it found the provisions to be “simply irrelevant to the agency’s discretion to refuse to initiate proceedings.”\(^ {64}\) The Court came to this conclusion despite the fact that both provisions use the word “shall,” with section 352 stating “[a] drug . . . shall be deemed to be misbranded,”\(^ {65}\) and section 355 stating “no person shall introduce . . . into interstate commerce any new drug.”\(^ {66}\) It is also important to note that at the end of its decision the Court declared: “The fact that the drugs involved in this case are ultimately to be used in imposing the death penalty must not lead this Court or other courts to import profound differences of opinion over the meaning of the Eighth Amendment . . . into the domain of administrative law.”\(^ {67}\)

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

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

\(^{62}\) *Heckler*, 823 U.S. at 834–37.

\(^{63}\) *Id.* at 835–36.

\(^{64}\) *Id.* at 836.

\(^{65}\) 21 U.S.C. § 352(a) (emphasis added).

\(^{66}\) *Id.* § 355(a) (emphasis added).

\(^{67}\) *Heckler*, 823 U.S. at 838.

\(^{68}\) *Cook v. FDA*, 733 F.3d 1, 5 (D.C. Cir. 2013) (first alteration in original).

\(^{69}\) 21 U.S.C. § 381(a) (emphasis added).

\(^{70}\) *Id.* (emphasis added).

\(^{71}\) *Cook*, 733 F.3d at 8.
drug despite knowing they may have been prepared in an unregistered establishment.”

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

C. Why Cook v. FDA Was Wrongly Decided

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

72.  Id. at 12.
73.  Id. at 9.
74.  Id. (quoting Executive Summary: A Review of FDA’s Approach to Medical Product Shortages, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm277744.htm (last updated Nov. 3, 2012)).
75.  Id. at 10.
76.  Id. at 4 (first alteration in original) (emphasis added).
77.  See supra notes 62–64 and accompanying text.
78.  See supra notes 63–64 and accompanying text.
In addition, even if the FDA does not have enforcement discretion to collect drugs and refuse admission if they are found to violate section 381(a), it is unclear whether this also means the FDA does not have enforcement discretion to determine whether a drug actually violates section 381(a) in the first place. The D.C. Circuit held that “[t]he clear implication [of its ruling] is the FDA must examine the samples that it must request and determine whether they appear to violate [section 381(a)].” The D.C. Circuit justified this inference arguing that “it would make no sense for the Congress to mandate the collection, but not the examination, of samples of drugs.”

Thus, the D.C. Circuit concluded that if the FDA is given drug samples it must, pursuant to section 381(a), determine if they are misbranded according to section 355 and refuse admission accordingly. This conclusion, however, also contradicts the Supreme Court’s interpretation of the FDCA because in Heckler the Court expressly noted that the FDA has enforcement discretion under section 372 to determine whether a drug is misbranded under section 355.

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

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

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

79. Cook, 733 F.3d at 8 (emphasis added).
80. Id.
81. Id.
82. See supra note 59 and accompanying text.
83. See supra notes 74–75 and accompanying text.
84. Id. at 4.
pentobarbital. Part III.C then considers several states’ return to past methods of execution as backups. Finally, Part III.D evaluates some states’ decisions to ignore the FDA’s regulations.

A. EXPERIMENTING WITH ALTERNATIVE DRUGS

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

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

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

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

---

95. Id.
96. Id.
100. Id. at 2733.
101. See supra notes 23–24 and accompanying text.
102. Glossip, 135 S. Ct at 2737 (alteration in original) (quoting Baze v. Rees, 553 U.S. 35, 52 (2008)).
to identify either and held that states’ use of midazolam did not violate the Eighth Amendment. 103

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

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

---

103. Id. at 2731.
105. See supra notes 26–28 and accompanying text.
110. Denno, supra note 12, at 1335; see also Lincoln Caplan, The End of the Open Market for Lethal-Injection Drugs, NEW YORKER (May 21, 2016), http://www.newyorker.com/news/newdesk/the-end-of-the-open-market-for-lethal-injection-drugs (*In 2012, Missouri replaced its three-drug protocol for lethal injections with a one-drug protocol, using propofol. Within a year,
this dangerous cycle will eventually end with states running out of new lethal injection drugs to try, the consequences of allowing that process to play out would be even more undesirable. As Justice Sotomayor argued in her dissenting opinion in *Glossip*, “[t]he execution protocols [s]tates hurriedly devise as they scramble to locate new and untested drugs are all the more likely to be cruel and unusual—presumably, these drugs would have been the [s]tates’ first choice were they in fact more effective.” Thus, the use of alternative lethal injections drugs is not a viable solution to the *Cook* decision.

**B. ENGAGING WITH COMPOUNDING PHARMACIES**

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

---


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


117. *Id.* at 1382. To qualify for exemption compounding pharmacies must meet certain conditions such as having an “individual physician’s prescription and a requirement that the compounds are not copies of commercially available drugs.” Ellen Killoran, *Arizona Botched Lethal Injection: Secrecy, Compounding Pharmacies and the Eighth Amendment*, INT’L BUS. TIMES (July 26, 2014, 2:13 PM), http://www.ibtimes.com/arizona-botched-lethal-injection-secrecy-compounding-pharmacies-
The lack of oversight and regulation of compounding pharmacies has, in the past, had deadly consequences. In 2012, New England Compounding Center of Framingham (“NECC”), illegally manufactured a large batch of injectable steroids. The steroids were prepared in a room with a “leaky boiler [that] stood in a pool of stagnant water; powder hoods [that] were covered with dirt and fuzz; and [an] air intake [that] came from vents that were about 30 yards from a dust-spewing recycling plant.” Due to the unsterile conditions, many of the steroids were contaminated during the manufacturing process with lethal fungal spores. NECC ultimately manufactured over 17,000 vials of the steroids and distributed them to more than 20 states. What followed was “the country’s worst compounded drug crisis,” as the steroids “infected more than 800 people with fungal meningitis in 2012, 64 of whom died.” The incident prompted a massive FDA investigation of dozens of compounding pharmacies all over the country, which revealed “objectionable conditions at more than sixty facilities.”

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

---


120. Jaslow, supra note 119.


124. Goldman, supra note 114, at 3.

It was later discovered that the pentobarbital used to execute Robert was contaminated with fungus. It was later discovered that the pentobarbital used to execute Robert was contaminated with fungus. In January 2014, Oklahoma also experienced problems with compounded pentobarbital when it executed Michael Lee Wilson. Shortly after being injected Wilson declared, “I feel my whole body burning.” While it was never discovered whether the compounded pentobarbital used in Wilson’s execution was contaminated, his “reaction was consistent with contaminated pentobarbital, which experts explain creates the excruciating sensation of sandpaper scraping the insides of a person’s veins.”

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

---

129. Id.
131. Goldman, supra note 114, at 3.
132. Crider, supra note 122, at 18.
134. See Killoran, supra note 117 (noting that “[a]s long as these pharmacies are getting prescriptions, even though it’s not pursuant to the medical needs of the patient, they are still sort of working within the framework that was set up by Congress”); Ross Levitt & Deborah Feyerick, Death Penalty States Scramble for Lethal Injection Drugs, CNN (Nov. 16, 2013, 1:44 PM), http://www.cnn.com/2013/11/15/justice/states-lethal-injection-drugs (discussing a federal civil complaint filed in Texas that alleged officials from the Texas Department of Criminal Justice falsified prescriptions to obtain pentobarbital).
Due to their limitations and lack of oversight, traditional compounding pharmacies cannot be relied upon to produce safe lethal injection drugs. Once again, however, the issue may soon be moot due to significant external pressures. In February 2014, attorneys for Michael Taylor, an inmate on death row in Missouri, filed a lawsuit against The Apothecary Shoppe, an Oklahoma compounding pharmacy, for supplying drugs across state lines to Missouri’s Department of Corrections. As one commentator noted, such litigation “is a shot across the bow of compounding pharmacies . . . [If] they’re doing things across state lines that they don’t have full permission for, if they’re not fully licensed, [or] if they have had some sanctions in the past . . . those things are going to come out.” Then, in March 2015, both the International Academy of Compounding Pharmacists and the American Pharmacist Association publicly discouraged their members from compounding drugs for executions. Thus, in light of these problems and external pressures, the use of lethal injection drugs manufactured by compounding pharmacies is not a viable solution to the Cook decision.

C. RETURNING TO PAST METHODS OF EXECUTION

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


136. Sullivan, supra note 135.


139. Bever, supra note 138.

140. Niraj Chokshi, Map: How Each State Chooses to Execute Its Death Row Inmates, WASH. POST
mandate the use of a sanctioned alternative if lethal injection became impossible.\textsuperscript{141} The main sponsor of the law, state Senator Ken Yager, said it was necessary due to "a real concern that we could find ourselves in a position that if the chemicals were unavailable to us that we would not be able to carry out the sentence."\textsuperscript{142} Alabama and Virginia considered a similar mandate, though neither state ultimately passed it into law.\textsuperscript{143}

Since Tennessee’s electric chair mandate, several states have considered statutes requiring execution by firing squad if lethal injection drugs become unavailable. In September 2014, legislators in Wyoming debated passing a firing squad mandate, with one of the leading proponents arguing that, "[i]f we are going to continue to have the death penalty, then we are going to have to have an available secondary form of execution."\textsuperscript{144} The legislative session ended, however, before any action could be taken.\textsuperscript{145} Arkansas, South Carolina, and Missouri also briefly considered such a mandate.\textsuperscript{146} In March 2015, Utah became the first state to pass a firing squad mandate.\textsuperscript{147} (Apr. 30, 2014), https://www.washingtonpost.com/blogs/govbeat/wp/2014/04/30/map-how-each-state-chooses-to-execute-its-death-row-inmates ("Prisoners can choose between injection or sanctioned alternatives in six states—Alabama, California, Florida, South Carolina, Virginia and Washington. In California, the alternative is lethal gas and in Washington it’s hanging. In the rest, it’s electrocution.").


\textsuperscript{143} Kim Bellware & Willa Frej, \textit{Virginia Governor Scraps Electric Chair Law}, \textsc{Huffington Post} (Apr. 10 2016, 8:18 PM), http://www.huffingtonpost.com/entry/virginia-electric-chair-law-decision_us_5702ba2e9b885fb50d5d9b2b; Brian Lyman, \textit{Electric Chair Won’t Come Back to Alabama}, \textsc{Montgomery Advertiser} (June 4, 2015, 12:28 AM), http://www.montgomeryadvertiser.com/story/news/politics/southunionstreet/2015/06/03/electric-chair-come-back-alabama/28412699.

\textsuperscript{144} Dan Frosch, \textit{Wyoming Considers Firing Squad as Death-Row Backup}, \textsc{Wall Street J.} (Jan. 25, 2015, 8:00 PM), http://www.wsj.com/articles/wyoming-considers-firing-squad-as-death-row-backup-142223096.

\textsuperscript{145} Dan Frosch, \textit{Utah Passes Bill Allowing Execution by Firing Squad}, \textsc{Wall Street J.} (Mar. 11, 2015, 12:04 PM), http://www.wsj.com/articles/utah-lawmakers-pass-bill-allowing-firing-squads-for-executions-1426033376.


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

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

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

\textsuperscript{148} Utah Code Ann. § 77-18-5.5(4) (Supp. 2015).
\textsuperscript{152} Oklahoma Governor Signs ‘Foolproof’ Nitrogen Gas Execution Method, supra note 151.
\textsuperscript{153} Maurice Chammah et al., After Lethal Injection, MARSHALL PROJECT (June 1, 2015, 7:15 AM), https://www.themarshallproject.org/2015/06/01/after-lethal-injection.
\textsuperscript{154} See supra notes 10–13 and accompanying text.
\textsuperscript{157} Oklahoma Governor Signs ‘Foolproof’ Nitrogen Gas Execution Method, supra note 151.
\textsuperscript{158} Id.
chair, firing squad, or gas chamber. In addition, many experts argue that, in light of the recent botched executions, these alternate methods may actually be more humane than lethal injection. Indeed, when Oklahoma adopted nitrogen hypoxia as its primary backup to lethal injection, Christian cited these two benefits, availability and humaneness, as the primary justifications for the switch. While no one has seriously argued that the electric chair is a more humane method of execution than lethal injection, many commentators contend that death by firing squad is perhaps the most humane form of execution. As Fordham Law School professor and death penalty expert Deborah Denno writes, "there is only one method of execution


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


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

[El]ectrichair deaths are some sort of combination of asphyxiation and cardiac arrest, and the nervous system is usually paralyzed. The body tenses up—sometimes violently—and inmates often defecate. Smoke and steam rise out of the body probably because the inmate’s blood is boiling. The inmate’s temperature become so hot, flesh falls off if someone touches the body, and the inmate usually receives third and fourth-degree burns under the electrode cap. . . . “Sometimes the eyeballs can pop out.” . . . The body can also bleed because of the pressure of the expanding tissue. . . . “It’s horrible, but it’s really like the body is cooking.” Grace Wyler, This Is How You Die in an Electric Chair, VICE (May 25, 2014), http://www.vice.com/read/how-you-die-in-an-electric-chair.

163. See, e.g. P. Thomas DiStanislao, III, Comment, A Shot in the Dark: Why Virginia Should Adopt the Firing Squad as its Primary Method of Execution, 49 U. CHI. L. REV. 779, 797, 801 (2013) (suggesting that “the most favorable [method of execution] is firing squads” because “execution by firing squad is both more reliable and more ‘humane’”); Patrik Jonsson, Utah Firing Squad Decision: Could It Actually Make Death Penalty More Humane?, CHRISTIAN SCI. MONITOR (Mar. 11, 2015), http://www.csmonitor.com/USA/Justice/2015/0311/Utah-firing-squad-decision-Could-it-actually-make-death-penalty-more-humane-video (“People say firing squad is so brutal, but . . . it’s probably the most humane, it kills people the quickest, and it’s one we have expertise for.”); Erin McCann, Why Did Utah Bring Back the Firing Squad? How the U.S. Kills People in 2015, GUARDIAN (Mar. 24, 2015, 5:46 PM), http://www.theguardian.com/world/2015/mar/24/utah-execution-firing-squad-death-penalty (“Death by firing squad] sounds like the wild west, but it’s probably the most humane way to kill somebody.”); McCoy, supra note 147 (“[T]he firing squad . . . may even be the most humane of all methods.”).
that merits a positive rating: the firing squad. This method stands alone because it is the only one that involves experts specifically trained to kill human beings as well as a record of relative speed and certainty.\textsuperscript{164}

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

\section*{D. Ignoring the FDA’s Restrictions}

The most recent way in which states have responded to the \textit{Cook} decision is by ignoring the FDA’s restrictions. Though the \textit{Cook} decision effectively prohibited the importation of sodium thiopental, states like Nebraska and Ohio have continued to seek out foreign producers.\textsuperscript{172} On May 14, 2015,
Nebraska Governor Pete Ricketts announced that the state had purchased 1,000 vials of sodium thiopental from Harris Pharma ("Harris"), a pharmaceutical company based out of Kolkata, India. Email communications from Harris to the Nebraska Department of Correctional Services ("NDCS"), obtained by the American Civil Liberties Union of Nebraska via a Freedom of Information Act ("FOIA") request, revealed that Harris was selling the drug to "a few other states" in addition to Nebraska. Then, in June a report surfaced that the Ohio Department of Rehabilitation and Correction ("ODRC") planned to import sodium thiopental from an unidentified foreign source.

The FDA responded by sending letters to the respective heads of the NDCS and ODRC and Harris. The letters reminded all parties involved that, in Beaty, the district court had "permanently enjoined FDA from permitting the entry of, or releasing any future shipments of, foreign manufactured sodium thiopental that appears to be misbranded or an unapproved new drug" and "that there is no FDA approved application for sodium thiopental" in the United States. The DEA issued a separate statement explaining that "[t]he DEA is in sync with the FDA on the importation of barbiturate anesthetics such as sodium thiopental from foreign companies. We allow their importation if they come from an FDA-approved source." Nebraska never
received the sodium thiopental it purchased from Harris and passed a law abolishing the death penalty, though voters opted to repeal that law in November 2016. Ohio did not follow through on its plan to import sodium thiopental and announced in October 2016 that it had revised its execution protocol, switching from sodium thiopental back to midazolam.

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

---

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


183. Nashrulla et al., supra note 181.

184. Id.

185. Id.

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

The FDA will follow standard importation procedures, which allow for the importer
decision and threatened to “sue if the FDA [does] not release the drugs.”
Thus, it is clear, based on this strict enforcement, that ignoring the FDA’s regulations is not a viable solution to the \textit{Cook} decision.

\section*{IV. POTENTIAL SOLUTIONS TO THE D.C. CIRCUIT’S DECISION IN \textit{COOK V. FDA}}

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

\subsection*{A. ADHERE TO THE FDA’S REGULATIONS}

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

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

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

\begin{flushright}
\end{flushright}


\footnote{\text{Geidner \& McDaniel, supra note 186.}}

\footnote{\text{Chris McDaniel \& Chris Geidner, Former FDA Investigator Now Backing Four States’ Execution Drug Import Efforts, BUZZFEED NEWS} (Dec. 9, 2015, 6:50 PM), http://www.buzzfeed.com/chrisimdaniel/former-fda-investigator-consulting-states.}
misbranded; (4) the sodium thiopental is not adulterated; and (5) the FDA examines the shipment to determine if any of the conditions outlined in 21 U.S.C. 381(a) exist.\textsuperscript{191}

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

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


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

\textsuperscript{193} Id.

\textsuperscript{194} Joe Duggan, Ricketts Stops Trying to Import Death Penalty Drugs for Now, OMAHA WORLD-HERALD (Dec. 7, 2015), http://www.omaha.com/news/nebraska/ricketts-stops-trying-to-import-death-penalty-drugs-for-now/article_85e2a404-9ae5-11e5-8d92-7774506a50cb.html. As noted above, voters decided to reinstate the death penalty, though it remains unclear whether Nebraska intends to renew its efforts to obtain sodium thiopental. Sanburn, supra note 179.

\textsuperscript{195} Nashrulla et al., supra note 181.

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

\textsuperscript{197} Nashrulla et al., supra note 181 (“BuzzFeed News traveled to Harris’s business locations in August and discovered the facility he registered with the FDA as a facility that manufactures or processes drugs is actually a small rented office, and that the business address he lists on Drug
United States complicates registration because the FDA has repeatedly stated “that there is no FDA approved application for sodium thiopental” in the United States. Consequently, “even if you have every permit, import license, registration, [and] everything else,” it is unlikely sodium thiopental could be legally imported because “the drug has to be approved in the U.S., and right now sodium thiopental isn’t.” Thus, adhering to the FDA’s regulations is unlikely to result in renewed access to sodium thiopental.

B. LITIGATE THE FDA’S REGULATIONS

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

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

---

198. See supra note 176 and accompanying text.
200. U.S. CONST. amend. X.
individual states. This primary authority over criminal law extends to the administration of criminal sentencing, including the death penalty. As a result, the states have historically been left to their own devices in formulating and implementing the death penalty, so long as they do not run afoul of the cruel and unusual punishment clause of the Eighth Amendment. The Supreme Court recently reaffirmed this principle in Baze v. Rees, where it noted that “determining ‘best practices’ for executions... would substantially intrude on the role of state legislatures in implementing their execution procedures—a role that by all accounts the States have fulfilled with an earnest desire to provide for a progressively more humane manner of death.”

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

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

---

207. See generally Charles E. MacLean & M. Akram Fazier, Death Penalty Jurisprudence by Tallying State Legislative Enactments: Harmonizing the Eighth and Tenth Amendments, 51 CRIM. L. BULL. 839 (Summer 2015) (discussing the interaction between the Supreme Court’s Eighth Amendment jurisprudence and its Tenth Amendment jurisprudence).
210. See supra note 58 and accompanying text.
211. See supra note 76 and accompanying text.
requires that punishment be in accordance with “the evolving standards of decency that mark the progress of a maturing society.” While the Court itself has never invalidated a method of execution under this doctrine, “society has nonetheless steadily moved to more humane methods of carrying out capital punishment.” Indeed, as the Court noted in Baze, “[t]he firing squad, hanging, the electric chair, and the gas chamber have each in turn given way to more humane methods, culminating in today’s consensus on lethal injection.” Thus, the Court has effectively delegated enforcement of the “evolving standards of decency” doctrine to the states, allowing “legislatures to tak[e] the steps they deem appropriate, in light of new developments, to ensure humane capital punishment.”

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

V. CONCLUSION

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

---

213. Baze, 553 U.S. at 48, 62 (plurality opinion).
214. Id. at 62.
215. Id.
216. See Lowes, supra note 3.
seems to be “moving backward on the evolutionary scale.” Thus, states must find a way to legally import sodium thiopental—the most reliable anesthetic available for lethal injection—from foreign suppliers in order to reverse the current trends and bring a measure of reliability back to their lethal injection protocols. The best option for accomplishing that goal is for states to file an as-applied constitutional challenge to section 381(a) of the FDCA and argue that it interferes with the states’ sovereign power over criminal law in violation of the Tenth Amendment.