Executive Summary

The FDA has long had a policy of not applying the limitations in the Food, Drug, and Cosmetic Act to drugs used for lethal injection, and the Supreme Court upheld its discretion to do so as to domestic drugs in 1985. However, changes in the drug market required importation of drugs, and the D.C. Circuit held in 2013 that states could not import sodium thiopental. As a result, states have turned to midazolam, a drug that some experts believe is unsuited for this purpose and cannot guarantee a painless execution, although that is disputed by other experts. All agree, though, that thiopental is preferable, but imports from willing sellers in Asia remain blocked by the D.C. Circuit decision. The Supreme Court affirmed a decision rejecting a challenge to midazolam at the end of June. The decision does not, however, preclude any further challenges to midazolam.

This leaves us in a situation where executions are going forward with a second-choice drug but litigation continues, often conducted at the last minute before a scheduled execution. This state of affairs is not good for anyone concerned.

Congress can and should simply exempt acquisition, possession, and use of lethal injection drugs by states from the drug law. The intense judicial scrutiny of executions makes administrative oversight unnecessary. With the first-choice drugs available, executions can be conducted with confidence they will be painless, and litigation can be quickly terminated.

Introduction

Veterinarians use lethal injection to painlessly euthanize animals every day. It is not difficult or complicated. Most of these procedures use sodium pentobarbital, a barbiturate. States have used the same drug or another drug in the same class, sodium thiopental, for lethal injection to execute sentences of death. Texas has performed over forty executions since switching to the single-barbiturate method, and an independent press witness has not reported a significant difficulty with a single one.1

Yet there has been great controversy over the use of a different drug, midazolam. A court case challenging use of this drug went to the United States Supreme Court, and litigation continues despite that decision, as of the date of this paper. Critics contend that midazolam is insufficient as an anesthetic, and other drugs used in the three-drug method might cause extreme pain.
Why, one might ask, does any state use the controversial drug when other drugs are clearly effective and painless? Why take any risk of inflicting severe pain when an indisputably painless method is available, and why incur the costs and delays of litigation? The answers lie in a combination of the globalization of the drug market, anti-death-penalty pressures from Europe, and a dubious decision of the Court of Appeals for the D.C. Circuit that applied the Food, Drug, and Cosmetic Act to regulate an area that it was never intended to regulate.

**Lethal Injection, the FDA, and Heckler v. Chaney**

At the time the United States was founded, the death penalty was generally executed by hanging. Near the end of the nineteenth century, states began to substitute other methods, motivated by a desire to find methods that were more humane and less painful. Electrocution and lethal gas became the predominant methods. As concerns developed over these methods, lethal injection was adopted by many states.

By 1992, lethal injection was the primary method in 22 of the 36 states with the death penalty. In that year, the U.S. Court of Appeals issued a stay of execution for a California inmate who was to be executed by lethal gas. The U.S. Supreme Court vacated the stay on the ground that the inmate had abusively withheld a known claim to the last minute, but Justices Stevens and Blackmun dissented on the theory that cyanide gas was unnecessarily cruel given the availability of a “more humane and less violent method[].” lethal injection. Spurred by the additional incentive of avoiding litigation and stays of their judgments, almost all the states had adopted lethal injection as the primary method by 2000.

In the early 1980s, as lethal injection was just beginning to be used, it was nearly derailed by an improper interpretation of the Food, Drug, and Cosmetic Act (FDCA) and the Administrative Procedure Act (APA). The FDCA was enacted in 1938. The purpose of the drug portion of the act is to ensure safe and effective drugs for medical treatment. In *Chaney v. Heckler*, a group of death row inmates sought an injunction to force the FDA to take action against the use of drugs for lethal injection, claiming that this use rendered the drugs “misbranded” for the purpose of 21 U.S.C. §352(f). A divided panel of the Court of Appeals for the D.C. Circuit held that this use did bring lethal injection under FDA jurisdiction through the “misbranding” provision and, further, that the FDA nonenforcement decision was subject to judicial review.

Circuit Judge Antonin Scalia, who would be appointed to the Supreme Court three years later, dissented on both points.

The majority converts a law designed to protect consumers against drugs that are unsafe or ineffective for their represented use into a law not only permitting but mandating federal supervision of the manner of state executions. This implausible result is achieved by rewriting the law with regard to enforcement discretion and ignoring it with regard to FDA jurisdiction. I dissent from what seems to me a clear intrusion upon
powers that belong to Congress, the Executive Branch and the states. I would affirm for the reasons set forth in the district court's opinion.\textsuperscript{12}

On the jurisdictional point, Judge Scalia noted,

*The FDCA is directed at the sale and distribution of drugs rather than their use.* The only provision that could remotely apply here is the prohibition against “the doing of any . . . act with respect to . . . a . . . drug . . . [which] results in such article being . . . misbranded,” 21 U.S.C. § 331(k). Even if one adopts the extraordinary notion that a person causes an article to be misbranded by simply using it for a purpose not stated on the label, § 331(k) would still not apply, since -- in accordance with the Act’s focus upon sale and distribution rather than drug use -- it requires that the misbranding occur “while such article is held for sale (whether or not the first sale) after shipment in interstate commerce.” *Id.* Here the drugs are in the possession of the states’ penal authorities. Under no conceivable interpretation of the English language could they be deemed “held for sale.”\textsuperscript{13}

The government took the case to the Supreme Court, and it reversed unanimously. The opinion of the Court, joined by eight of the nine justices, said “we need not and do not address the thorny question of the FDA’s jurisdiction.”\textsuperscript{14} Instead, the high court concluded that case was controlled by a provision of the Administrative Procedure Act that there is no judicial review of “agency action ... committed to agency discretion by law.”\textsuperscript{15}

Among the arguments rejected by the Supreme Court was one based on the word “shall” in 21 U.S.C. §334. That section says that anyone who violates the substantive provisions of the law “shall be imprisoned ... or fined.” Without any “indication in case law or legislative history that such was Congress’ intention in using this language” the high court was “unwilling to attribute such sweeping meaning to” it.\textsuperscript{16}

**Imported Drugs and *Cook v. FDA***

The decision in *Heckler v. Chaney* and the FDA’s policy largely ended the tactic of trying to use the FDCA to attack capital punishment for the next two decades. Sodium thiopental continued to be used as the first component of the three-drug method in use throughout the country. When the three-drug method came under attack, Ohio developed a new protocol using thiopental alone,\textsuperscript{17} and many other states followed suit.

Just as this change seemed to be drawing execution challenges to a close, though, an unexpected development resulted from the globalization of the pharmaceutical market. The sole source of thiopental in the United States was Hospira, Inc.\textsuperscript{18}

“In early 2010, an FDA inspection had revealed problems at Hospira’s aging facility in North Carolina, where it produced thiopental, and the company decided to move production to a facility in Liscate, Italy. But when the Italian government learned that
thiopental would be manufactured in its territory, it refused to license the Liscate plant absent guarantees that the drugs made there would not be used in executions.”

At about the same time, opponents of the death penalty tried to persuade the FDA to cut off imports of thiopental altogether, claiming that importation of drugs was distinguishable from the domestic use upheld in *Heckler v. Chaney*. The FDA declined and issued a statement to the media on January 4, 2011:

The U.S. Food and Drug Administration (FDA) is charged by Congress with protecting the public health. *Ensuring the safety and effectiveness of pharmaceuticals used for medical purposes is a core part of FDA’s mission.*

*Reviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA’s explicit public health role.* FDA does not verify the identity, potency, safety, or effectiveness of substances imported for this purpose. FDA exercises similar enforcement discretion when these drugs are manufactured and purchased within the United States.

Accordingly, FDA chooses to continue to defer to law enforcement on all matters involving lethal injection, consistent with the U.S. Supreme Court’s ruling in *Heckler v. Chaney* (1985).

**Following is information that addresses the import of sodium thiopental –**

So far this year with the imports of sodium thiopental, in 2009 and 2010, FDA permitted the importation of several shipments of sodium thiopental to state Departments of Correction. In doing so, FDA deferred to law enforcement in the use of substances for lethal injection, which is consistent with the agency’s longstanding policy. The agency did not conduct any review of these products for safety, effectiveness or quality. In the context of two death penalty cases in the fall of 2010, it was suggested that FDA “approves” the importation of these drugs for use in lethal injections and/or reviews them for safety, effectiveness, and quality. In actuality, the FDA neither approves nor reviews these drugs for use in lethal injections and feels it necessary to clear up any confusion. Also, FDA reviewed its procedures for the importation of sodium thiopental in concert with CBP [Customs and Border Protection]. The agencies decided that since FDA does not conduct a review of pharmaceuticals intended for lethal injection, FDA will continue to exercise its enforcement discretion not to review these shipments and allow processing through CBP’s automated system for importations. The agencies are working together to develop a system for future shipments that avoids any confusion about whether FDA evaluates shipments of drugs intended for lethal injection.

Is the importation of unapproved sodium thiopental for lethal injection illegal?
In deferring to law enforcement on matters involving pharmaceuticals for lethal injection, FDA is exercising enforcement discretion. This approach by the agency was upheld by the Supreme Court in Heckler v. Chaney (1985). Among the reasons cited by the Court for its decision not to review FDA’s non-enforcement against lethal injection drugs is that agencies are responsible for prioritizing their enforcement resources to most effectively achieve their statutory missions. Again, FDA similarly defers to law enforcement with respect to transport of these substances within the United States.

What will happen to any shipments for correctional facilities that are currently pending?

*FDA is releasing these with the comment: “FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity, or any other characteristics.”20

A month later, a group of inmates sued the FDA in U.S. District Court in the District of Columbia.21 The only parties were the inmates and the FDA. The states that have a vital interest in obtaining drugs for lethal injection were not named as parties or given notice that the suit had been filed.

The District Court found, “It is undisputed that thiopental is both ‘misbranded’ and an unapproved ‘new drug’ under the FDCA.”22 Whether drugs for lethal injection are “under the FDCA” at all is a question the Supreme Court deemed “thorny” and declined to answer in Heckler.23 The District Court in this case was untroubled by that question, as well as by the fact that the parties with the greatest interest in challenging FDA jurisdiction were not present, and applied the FDCA on the debatable but unchallenged assumption that it applied.

A closer look at the “misbranded” and “new drug” requirements illustrates why the requirements do not make sense as applied to lethal injection and why they ought not apply. Thiopental is deemed a “new drug,” despite its decades of use in this country, because it had never been submitted to the FDA for approval. The FDA, as noted in the statement quoted above, does not consider approval or disapproval of drugs for lethal injection to be within its mission. Nor should it, as a policy matter. The approval criterion of “safe and effective” makes no sense for lethal injection, given that “effective” use in this context results in the death of the inmate, the polar opposite of safety.

The District Court noted, “It is unlawful to introduce a ‘new drug’ ... into interstate commerce.”24 But the importing states were not importing the drugs to introduce them into interstate commerce. There were importing for their own use. The District Court did not discuss this issue.

The “misbranded” provision of the FDCA25 contains a host of requirements regarding labeling of drugs and registration of their sources, but again, as a policy matter, these provisions
make little sense as applied to a drug that will be acquired by a state prison department for a specific, very limited, nonmedical purpose. Labeling and registration requirements are to protect the public in the sale and marketing of widely sold drugs, where prescribing physicians, pharmacists, and consumers are likely to be relying on the label information and the integrity of the supplier. States do not need such information. They can and routinely do have the drugs tested to insure their composition and concentration. The requirement that a drug be labeled “Rx only” has no rational application in this context, as prescriptions are not required, available, or obtained for an execution by lethal injection.

The District Court brushed past these considerations in an opinion more remarkable for its use of exclamation points than for its appreciation of the purpose of the statute. The District Court placed great weight on the use of the word “shall” in § 381 that an imported article “shall be refused admission” if it is misbranded or in violation of the “new drug” requirement despite the Supreme Court’s rejection of a very similar argument in closely related circumstances in Heckler. The District Court did not make any independent examination of whether the drugs really were “misbranded” or whether the “new drug” rule really applied. The question of whether the FDA has jurisdiction over execution drugs at all, an issue called “unclear” by the FDA and “thorny” by the Supreme Court, was completely ignored. The reason for ignoring the “thorny” question was the fact that no party disputed it, while the entities with incentive to dispute it – the States – were not parties to the suit. The court enjoined the FDA from admitting any further thiopental and ordered it to tell the States they had to return their existing stocks.

The FDA appealed, but the Court of Appeals decision was not much better. That court also ignored the jurisdictional question despite its own division in the prior case and the Supreme Court’s characterization of it.

The Court of Appeals noted that Congress has expressly directed the FDA “to ‘evaluate the risks associated with the impact’ of a drug shortage before taking an enforcement action that ‘could reasonably cause or exacerbate a shortage.’” This is an acknowledgment by Congress that the FDA does have such flexibility. Yet the court brushed this off by merely saying that there was no indication that Congress had this particular statute in mind. That is not an answer. Congress may indeed have been thinking in broader terms, but there is no reason to believe that it intended to exclude this particular statute from those the FDA has flexibility in enforcing.

An amicus brief, written by the author of this paper, objected that the interests of the states could not be impaired in the manner the judgment in this case did without joining them as parties under Federal Rule of Civil Procedure 19. The Court of Appeals accepted that argument, but only in part. The court reversed the portion of the judgment directing recovery of the states’ existing stocks. The court gave no reason why the impairment of the States’ ability to import in the future with giving them an opportunity to be heard was not equally improper.
Midazolam and *Glossip*

With the supply of imports cut off, states turned to pentobarbital, which was made in the United States by a Danish company, Lundbeck. That company also came under pressure from European governments and restricted its distribution to prevent its use for executions. “Corporate public relations drove what pharmaceutical companies said, but it was European governments that changed what they actually did.”

While some states were able to get pentobarbital from compounding pharmacies, others were not, and so they turned to another drug, midazolam. This drug is from a different class of drugs than the barbiturates. Some states used it as part of a two-drug protocol along with hydromorphone. In the 2014 executions of Dennis McGuire in Ohio and Joseph Wood in Arizona, the inmates took a long time to die and made gasping sounds during that time. These executions were certainly uncomfortable for the witnesses to watch, but there is no reason to believe that the inmates, having received massive doses of sedatives, were not unconscious or were in pain. Nonetheless, opponents of the death penalty repeatedly referred to these executions as “botched,” and eventually that characterization became predominant in media reports.

In Florida and Oklahoma, midazolam was substituted for thiopental in the three-drug protocol previously used throughout the country. This method avoids the long-execution problem that occurred in the McGuire and Wood cases because the midazolam is not the agent causing death. Instead, its purpose is to sedate the inmate while the second and third drugs cause death. As with the original three-drug protocol that went to the Supreme Court in the 2008 case of *Baze v. Rees*, it is undisputed that the third drug, potassium chloride, would be extremely painful if the inmate were not effectively sedated by the first drug. Under the original protocol reviewed in *Baze*, it was also undisputed that the massive dose of barbiturate in the first step would be sufficient to preclude any pain if properly administered.

With midazolam, that last point is disputed, and the dispute reached the Supreme Court this year in the case of *Glossip v. Gross*. The barbiturates previously used, if properly administered, would “induce[] a deep, comalike unconsciousness” while the second and third drugs were administered. While that would be sufficient to prevent an Eighth Amendment violation, it is not necessary. What is necessary is to prevent such extreme pain as to make the punishment torturous. The experts for the inmates testified that midazolam is not capable of reliably keeping a person unconscious and insensate to pain under the circumstances involved here, but curiously they did not testify squarely that the inmate would be in extreme pain or that there was a substantial risk of that happening. The state’s expert testified to the contrary. The inmates had the burden of proof, and the District Court’s decision that they had not carried it was not clearly erroneous, which is the standard when an appellate court reviews a trial court’s decision on a question of fact.

The Supreme Court also affirmed for a second, independent reason. Previous challenges to methods of execution in the modern era have claimed that the method created a risk of pain
that was unnecessary because they caused pain or created a risk of pain that was unnecessary given the available, superior alternatives. In 1992, accepting the inmate’s argument, Justice Stevens said, “In light of our contemporary understanding of the methods of execution and in light of less cruel alternatives presently available, I believe that execution by cyanide gas is ‘incompatible with “the evolving standards of decency that mark the progress of a maturing society.”’”42 Similarly, in Baze v. Rees, Justice Ginsburg’s acceptance of the inmates’ argument was based on the fact that what they were challenging was a “failure to include readily available safeguards.”43 The plurality opinion in that case held that in challenges of this kind the inmate “must show that the risk [of severe pain] is substantial when compared to the known and available alternatives.”44

Based solidly on Baze, the Supreme Court in Glossip held an inmate challenging the method of execution must show “that any risk of harm was substantial when compared to a known and available alternative method of execution.”45 Notwithstanding the dissent’s claim that this is a “wholly novel requirement”46 it comes straight from Baze, at least for methods that are challenged as creating a risk of pain rather than a purpose or a certainty of being extremely painful.

Confidentiality

There is a long tradition of confidentiality for the identities of the persons who carry out capital punishment. The punishment of murder is one of the most important functions of state government, and that function should not be interfered with by harassment of the people who carry it out.

In recent years, many states have found it necessary to extend that traditional confidentiality to the suppliers of lethal injections drugs. Relative to the volumes normally involved in drug sales, the quantities used in lethal injection are small, and the profit that a company makes for selling them is small. Any substantial amount of difficulty caused by people who simply disagree with the death penalty in picketing a supplier’s offices or flooding its phone lines with calls could easily dissuade the company from supplying the drugs. Allowing this would provide a “heckler’s veto” by which a minority could subvert the will of the majority.

To the extent that federal agencies obtain knowledge of confidential sources, they should be required to maintain that confidentiality.

The Unsuitable Status Quo

The combination of the European pressure, the Cook ruling on imports, and the Glossip decision has left the status of lethal injection where no one should want it. Congress could fix the problem very simply, and should.

No one disputes that the barbiturates are preferable to midazolam. The states presently using midazolam would use thiopental or pentobarbital if they could get it. Asian companies are
willing to supply it. The State of Nebraska attempted to import it from a willing seller, but the FDA, in obedience to the *Cook* injunction, said it would block the shipment.

The Supreme Court’s ruling that the District Court’s decision on the risk of pain issue was supported by evidence does not settle the matter in the sense of preventing another trial court hearing different testimony from coming to another conclusion. The Florida Supreme Court sent a case to a trial court for a hearing on this issue after the *Glossip* decision. Yet regardless of the evidence produced, such challenges are very unlikely to be successful given the *Baze/Glossip* “available alternative” requirement, the distribution restriction by the only domestic source of pentobarbital, and the *Cook* injunction against imports.

If the challenges to midazolam are correct, this situation results in executions going forward despite a risk of severe pain. Whether they are correct or not, this situation results in expensive, fruitless litigation. There is no reason for this. It is all unnecessary and pointless.

As a matter of good policy, the FDA was right in the beginning to say that regulation of lethal injection is outside its purview. The purpose of the drug portion of the Food, Drug, and Cosmetic Act is to ensure that medical patients have safe and effective drugs for treatment. The purpose of the act simply has nothing to do with execution of death sentences, and the Supreme Court was right in *Heckler* to give the FDA discretion not to apply it, as even the most stridently anti-death-penalty Justices recognized.

Congress can and should simply codify that original FDA policy. With a single stroke, drugs obtained, possessed, and used by states or the federal government for lethal injection should be exempted from the drug limitations of Title 21 of the United States Code. Given the intense judicial scrutiny of executions, an overlay of administrative regulation is completely unnecessary. A suggested bill is attached to this paper.
§ 357. Drugs Used for Execution of Capital Sentences.

(a) Notwithstanding any other provision of this title, the authorities of United States or any State with the responsibility of executing judgments of death in criminal cases may acquire, import, possess, manufacture, or transfer to the like authorities of other jurisdictions drugs to be used for the purpose of executing such judgments. No license or other authorization shall be required.

(b) The Food and Drug Administration and the Drug Enforcement Administration shall, upon request of an authority referred to in subdivision (a), provide assistance as needed to facilitate the acquisition of drugs as provided in subdivision (a) and to test the drugs as needed to ensure their purity and potency.

(c) Any supplier of drugs, including but not limited to an outsourcing facility or a compounding pharmacy, may supply drugs for the purpose of executing sentences of death to a government authority referred to in subdivision (a), whether in the same State or another State, without a prescription and without affecting its classification under other provisions of law.

(d) Notwithstanding any other law, the authorities referred to in subdivision (a) may keep the identity of suppliers of drugs confidential. If a confidential supplier is disclosed to the Food and Drug Administration or the Drug Enforcement Administration, that agency shall maintain the confidentiality of the information.

(e) The purpose of this section is to facilitate the acquisition of the drugs needed to execute capital sentences in a manner that avoids unnecessary pain to the condemned inmate and to render unnecessary a resort to other drugs or methods that may be less effective for that purpose. This section shall be liberally construed to carry out its purpose.
References:

1. Michael Graczyk of the Associated Press has covered executions in Texas throughout this period. His reported observations have been compiled by the Texas Attorney General’s office and are available on request.

2. See, e.g., Act of April 30, 1790, Ch. IX § 33, 1 Stat. 119.


6. See id., at 654-659


9. 718 F.2d 1174 (CA DC 1983).

10. Id., at 1182.

11. Id., at 1188.

12. Id., at 1192.

13. Id., at 1199 (emphasis added).


19. Id., at 1240.

21. Among the counsel for the inmates was the Office of the Federal Public Defender for the District of Arizona. There is no legal authority for that office to represent inmates in a civil suit detached from any criminal case. See 18 U.S.C. §§3006A, 3599.


27. See id., at 37-39.


29. See id., at 43.

30. Cook v. FDA, 733 F. 3d 1 (CA DC 2013).

31. Id., at 10 (quoting 21 U.S.C. §356c-1(a)(5)).

32. See id., at 5-6.

33. See id., at 11-12.

34. Gibson & Lain, 103 Geo. L. J., at 1244.


38. 135 S. Ct., at 2732.

39. See id., at 2782-2784 (Sotomayor, J., dissenting).

40. Id., at 2740-2741 (opinion of the Court).
41. See id., at 2739, 2741.


43. 553 U.S., at 123 (dissenting opinion) (emphasis added).

44. Id., at 61.

45. 135 S. Ct., at 2738.

46. Id., at 2781.