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# Journal of Law and the Biosciences

## Navigating the new era of assisted suicide and execution drugs

Sean Riley 

*Journal of Law and the Biosciences*, Volume 4, Issue 2, August 2017, Pages 424–434,

<https://doi.org/10.1093/jlb/lxx028>

**Published:** 28 September 2017

**Issue Section:** [Notes & Developments](#)

## I. INTRODUCTION

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Lethal medication provisions are in a precarious state. Over the past decade, pharmaceutical companies have attempted to stamp out the use of their drugs in executions, creating several economic and regulatory hurdles for access to these

medications. As a result, patients seeking physician-assisted suicide (PAS) as well as death penalty states aiming to execute their capital offenders have been forced to turn to unregulated and dangerous alternatives for these drugs. This note attempts to unpack the quality, safety, and access issues emerging from these recent changes and to explore the implications for the future of these practices.

In order to fully grasp the exact mechanisms at work, this note will first offer a brief pharmacological description of the lethal medications and detail many technical aspects of their use. The next section provides a historical account of the past decade, illustrating the emergent quality, safety, and access issues. This note then evaluates the competing notions of 'botched' executions and 'complications' in PAS while analysing the standards set forward to measure safety and efficacy for each. Finally, this note closes by exploring the future of each practice in light of our discussion.

## II. LETHAL MEDICATIONS

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Though poisons have long been used for lethal practices, be it punishment or suicide, the modern era of lethal medication provisions began with the development of lethal injection as a means of execution by Oklahoma in the late 1970s. Conceived by the state's medical examiner, Jay Chapman, the original protocol consisted of three drugs: the first, sodium thiopental, serves as an anesthetic, administered before any other drugs to ensure the patient is unconscious; the second drug, pancuronium bromide, works as a paralytic agent that disables a patient's ability to control the lungs, often suffocating them; and the third drug, potassium chloride causes rapid cardiac arrest.<sup>1</sup> This method was first implemented in 1982 by the Texas Department of Criminal Justice, and its exact protocol has been replicated in all 929 executions via lethal injections in the country until 2007.<sup>2</sup>

Most lethal injection protocols have followed this three-drug order and layout. The first drug guarantees that the condemned do not suffer any pain as a result of the preceding drugs. Potassium chloride is known to be excruciating as it travels

through the veins on its way to stopping the heart. Pancuronium bromide, while not explicitly painful itself, has the potential to instill a sense of suffocation via paralysis. Critics claim that the condemned potentially may be awake, but would have no way to communicate that they were, or that they were in pain.

States have responded to this and other challenges with a variety of changes in policy. Some mandate physician participation, specifically requiring them to check for consciousness in between the first and second drugs. Given near-unanimous opposition from the medical community, this has neutered many states attempts to execute; California has been unable to find willing physician's to participate for over a decade. Additionally, several states have switched to one-drug protocols, where only the first drug is administered, but in significantly higher doses.<sup>3</sup> There is, again, much criticism as to the physiological response to such doses, as little is known about the effects. Others have tried new drugs: as of September 2017, over 18 different drugs have been proposed or authorized, and of these, at least 10 have been used.<sup>4</sup> Many of these are detailed in Table 1.

Meanwhile, the standard PAS protocol in the USA involves the prescription of a lethal dose of a barbiturate, typically pentobarbital or secobarbital, to be consumed by the patient in liquid form. Often, the dose is mixed with juice, in what is often called a 'potion', to combat the bitter taste of the drugs. The patient is legally required to drink the potion by themselves, to ensure the decision remains autonomous. Physicians are free to prescribe, off-label, any drug they deem fit for these lethal purposes, under protection from prosecution. Only three lethal medications (secobarbital, pentobarbital, and phenobarbital) have been used, according to state statistics, aside from anti-nausea and anti-anxiety medications to combat side effects.<sup>5</sup> In the Netherlands and Belgium, physicians typically rely on sodium thiopental and pancuronium bromide when euthanizing patients at their behest.<sup>13</sup>

Most of the controversy circles around barbiturates, the primary lethal medications used. Neurologically, barbiturates essentially put patients to sleep by slowing down the brain's electrical activity, by stimulating the gamma-amino-butyric-acid

(GABA) receptors. This activates an inhibitory response, which reduces the firing of neurons. If enough of this occurs, breathing slows down and can eventually cease, leading to death. Each barbiturate varies in how fast acting and how long lasting they are, creating major differences a patient's consciousness or pain during death.<sup>14</sup>

As recently as 2013, due to access issues, midazolam, a benzodiazepine, has supplanted barbiturates as the typical first drug. While benzodiazepines have many overlapping uses with barbiturates, they are typically prescribed as sedatives rather than as anesthetics. Midazolam facilitates the binding of the brain chemical GABA to its receptors, just like barbiturates, but to a lesser degree.<sup>15</sup> Though midazolam is considered to be one of the stronger benzodiazepines, there is broad medical opposition to its role as a lethal medication.<sup>16</sup>

**Table 1.**

Lethal medications used in PAS and executions.

<b>Drug name (trade name)</b>	<b>Therapeutic class</b>	<b>Medical uses</b>	<b>Lethal protocols</b>	<b>Unique pharmacological characteristics</b>
<b>Sodium thiopental (Pentothal)</b> <sup>6</sup>	Barbiturate	Anesthetic; used in surgery in poorer countries; primary execution drug till 2010	PAS drug in Europe; used in three-drug and one-drug executions (first drug)	Ultra-rapid onset; short lasting
<b>Pentobarbital (Nembutal)</b> <sup>7</sup>	Barbiturate	Sedative; pre-anesthetic; treats insomnia	PAS drug; used in one-drug, two-drug, and three-drug executions (first drug)	Slow onset; long lasting
<b>Secobarbital (Seconal)</b> <sup>8</sup>	Barbiturate	Sedative; treats insomnia	PAS drug; proposed for executions, but	Rapid onset; short lasting

never used

<b>Phenobarbital (Luminal)</b>	Barbiturate	Sedative; treats seizures	PAS drug; proposed for executions, but never used	Ultra-slow onset; long lasting
<b>Midazolam (Versed)<sup>9</sup></b>	Benzodiazepine	Sedative; treats anxiety and amnesia	Used in one-drug, two-drug, and three-drug protocols (first drug)	Rapid onset; intermediate-lasting; effects capped at 'lower level of sedation'
<b>Etomidate<sup>10</sup></b>	General anesthetic	Anesthetic; used for quick procedures, like intubation	Used in 3-drug protocol (first drug)	Rapid onset; ultra-short-lasting
<b>Pancuronium bromide<sup>11</sup></b>	Neuromuscular relaxant	Paralytic agent	Used in three-drug protocol (second drug)	Paralyses patient's lungs; no effect on consciousness
<b>Potassium chloride<sup>12</sup></b>	Potassium supplement	Treats potassium deficiency	Used in three-drug protocol (third drug)	Common drug; induces cardiac arrest in high dose

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The pervasive belief that these, or any, noxious drugs are guaranteed to provide for a peaceful and painless death must be dispelled; modern medicine cannot yet achieve this. Certainly some, if not most, executions and suicides have been complication-free, but this notion has allowed much of the general public to write them off as humane, and turn a blind eye to any potential problems. Executions or PAS have never been as clean as they appear, even with the US's medicalization efforts during the 1980s.

### III. RECENT HISTORY

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#### A. Legal Landscape

In America, PAS did not gain much notability until Jack Kevorkian's escapades in the 1990s brought legalization into public consideration. Despite the Supreme Court's upholding of state bans on assisted suicide in *Washington v Glucksberg*, Oregon became the first jurisdiction to legalize and implement PAS, in 1997.<sup>17</sup> Shortly after, the Bush administration attempted to ban the practice by deeming PAS to be an 'illegitimate medical practice', a violation of the Controlled Substances Act.<sup>18</sup> In 2006, the Supreme Court overruled this effort in *Gonzalez v Oregon*, reaffirming that states have the right to legislate over the practice of PAS. Since then, six other jurisdictions (Washington, Montana, Vermont, California, Colorado, and D.C.) have legalized.

The death penalty has had a rockier history. In 2007, after a series of questionable executions, the Supreme Court imposed a nationwide moratorium on executions as it granted cert to *Baze v Rees*, an Eighth Amendment challenge to Kentucky's three-drug lethal injection protocol. The court upheld the original three-drug protocol, and created several influential standard. First, the first drug must render an inmate fully unconscious. Second, in order for a protocol to be constitutional, it must not pose 'a substantial risk of serious harm'. This risk must be 'very likely to cause serious illness and needless suffering'.<sup>19</sup> Third, any challenge to an existing protocol must present an alternative method which poses less risk. Challenges moving forward have built from the legal foundation laid out here.

#### B. Pharmaceutical Distribution Controls

The primary catalyst for the disruption came between 2009 and 2011, when Hospira, the sole FDA-approved manufacturer of sodium thiopental, announced a shortage of the drug and eventually ceased production. While initially pressured to abandon production by European governments where the drugs were manufactured, anti-

death penalty activists seized the opportunity to amplify pressure at home. Pharmaceutical companies caved and withdrew support of the use of their drugs in executions. As states switched to new drugs, manufacturers took steps to limit access to these drugs through distribution controls.

Lundbeck, the Danish manufacturer of pentobarbital, constructed a specialty pharmacy drop ship program to prevent distributions to prisons. This program sells directly to customers rather than through a wholesaler, allowing them to personally supervise and monitor who purchases its products. Any buyers are forced to sign documentation promising to refuse sale to prisons.<sup>20</sup> Over 30 companies have mimicked these distribution controls—creating a tangled supply network.<sup>21</sup> The boycott has been remarkably successful, leading to a marked decline in the death penalty over the past 5 years. But death penalty advocates would not go out without a fight.

### **C. International Supplier Ban**

Some death penalty states, before turning to new drugs, turned instead to new suppliers, including those abroad, who had no ethical qualms about providing sodium thiopental. Several found a supplier in London, a mail-order one-man wholesaler ran by Medhi Alavi, aptly named Dream Pharma. Alavi specifically located sodium thiopental through a German company in Austria.<sup>22</sup> Five states acquired the drug from Alavi, though only two used it in executions. Another one-man operation, this time out of India, would also step in the supply chain by acquiring drugs from Indian pharmaceutical companies by lying that they would be used in developing countries, as is common.<sup>23</sup> Importations like these were eventually challenged in court.

Although the FDA initially refused to investigate or intervene on the matter, exercising its enforcement discretion established in a previous death penalty case in the 1980s, *Heckler v Chaney*, it eventually seized imports as stakeholder pressure mounted. After backlash from death penalty states, the FDA relented and released the drugs. Less than 1 month later, three death row inmates, from different states,

sued the agency in what would become *Cook v FDA*. The plaintiffs charged that the agency had been in violation of the Food, Drug, and Cosmetic Act (FDCA) by allowing the imports of unapproved and misbranded drugs, undermining the purpose of the FDCA to prevent harmful substances from misuse by the public. The drugs failed to include necessary warnings and other information on the label. The D.C. District Court found:

The FDA appears to be simply wrapping itself in the flag of law enforcement discretion to justify its authority and masquerade an otherwise seemingly callous indifference to the health consequences of those imminently facing the executioner's needle. How utterly disappointing!<sup>24</sup>

Upon appeal, the D.C. Circuit Court affirmed this decision. The defense argued that enforcement action is not judicially reviewable. The court disagreed, holding that the FDA is obliged to enforce FDCA sanctions on unregistered and unapproved drugs.<sup>25</sup> International imports of sodium thiopental or any other death penalty drug were illegal. Despite evidence that Nebraska has continued to seek imports from India, most states have ceased importation.<sup>26</sup>

## D. Price Gouging

Due to the stringent distribution controls, many patients seeking secobarbital or pentobarbital for PAS now have trouble finding or affording the drugs.<sup>27</sup> Before 2012, patients would pay about \$500 for a sufficient lethal dose of the drug, but by 2016, prices had inflated to figures upwards of \$25,000.<sup>28</sup> Commercial manufacturers have not taken the necessary steps to ensure access, despite the supposed design of distribution controls to provide the drug for legitimate medical purposes. Compassion & Choices, a right-to-die advocacy group, has lobbied Akorn, who acquired pentobarbital from Lundbeck, to reconsider distribution for PAS, but to no avail.<sup>29</sup>



Price gouging has been made simpler by the controversy surrounding these drugs—  
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with pentobarbital harder to access, Valeant Pharmaceuticals, the manufacturer of secobarbital, has cornered the market and inflated prices. This is not a new practice for the Canadian company; they are currently under Congressional investigation for price gouging and other forms of fraud.<sup>30</sup> Costs for secobarbital have increased from

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Secobarbital now typically costs 10 times as much as pentobarbital. In March 2016, Valeant released a statement indicating that its drug, Seconal, is to be used in for purposes other than aid in dying.<sup>31</sup> A huge part of the problem stems from lack of coverage of the practice by most forms of health insurance.<sup>32</sup> California is the only state to take efforts to assure access, but this is only for those unable to afford the drugs.<sup>33</sup> Patients have been forced to turn to compounding pharmacies for the medications (where drugs can be acquired for around \$500) as well as piecing together various untested methods recommended by physicians and the internet.<sup>34,35</sup>

## E. Compounding Pharmacies

More recently, death penalty states and patients seeking lethal medications have turned to compounding pharmacies for their drugs. Compounders are independent pharmacists who create drugs from scratch to cater to unique needs, such as allergies to mass manufactured medications or inability to digest a medication in its mass-distributed form. While filling an undeniable need in health care, these pharmacists operate in a dubious regulatory environment. Due to the immediate needs of patients who seek compounded drugs, federal regulation of these drugs is nearly impossible. Instead, the FDA leaves regulation to the states, meaning states actively seeking to enforce the death penalty are now the arbiters of these regulations. Some states have implemented secrecy laws that protect the identity of participating physicians, pharmacists, and drug suppliers, a further decrease in the level of transparency over these compounders. As the past 3 or so years have seen a dramatic increase in the use of compounded drugs, there has been a corresponding rise in 'botched' executions, though the secrecy laws have neutered most attempts to link failed executions to compounded drugs. Even years later and under oath,

state officials have still refused to submit the source of their drugs.

Without the rigors of regulation to mandate strict sterility or testing, compounded medications encounter some notable risks, namely subpotency, superpotency, and contamination.<sup>36</sup> Subpotency and superpotency concern whether a drug is significantly more or less active than is expected. Put into the context of lethal injection, if any of the drugs in the cocktail were superpotent, the condemned experience extreme pain. If the first drug were subpotent, the condemned might not be rendered unconscious. Contamination also poses the risk of a painful death through bacterial infection or other unforeseen side effects. There are several examples that demonstrate how these problems can stem from compounded drugs, most notably, the 2012 New England Compounding Center meningitis outbreak.

## F. New Drugs

Throughout the melodrama that has been the lethal injection drug supply controversy, both executions and PAS have needed to switch to new, and often untested, drugs. The first shift within executions was the removal of the second and third drugs from the protocol, as judges in California and Ohio ruled that without proper anesthetic, they might induce unnecessary suffering.<sup>37</sup> Eventually, the barricade of sodium thiopental forced executioners to switch to pentobarbital, a drug originally proposed for lethal injections in its origin, but rejected because of its use in animal euthanasia. As Lundbeck's distribution controls squeezed pentobarbital supplies, states began to depart from the use of barbiturates by introducing midazolam.

A number of botched executions, including the now infamous cases of Clayton Lockett in Oklahoma and Joseph Wood in Arizona, brought severe criticism of the drug's role in executions.<sup>38</sup> The Supreme Court, in the case *Glossip v Gross*, ruled that the use of midazolam in executions is constitutional.<sup>39</sup> Since that ruling in 2015, states have primarily used pentobarbital or midazolam, depending on what was available. Certain states have formally proposed the use of secobarbital, amobarbital, propofol, methohexital, phenobarbital, and etomidate.

PAS has also seen a shift in drugs prescribed. In 2013, Oregon PAS patient used pentobarbital in 90% of cases, though before that it was split with secobarbital.<sup>40</sup> The effects of the drought quickly took hold, with secobarbital use jumping up to 60% of cases, and by 2015, it accounted for 86% of PAS ingestions.<sup>41</sup> Pentobarbital has only been prescribed twice since 2015.<sup>42</sup> By 2016, the price gouge of secobarbital led to the rise of a new method promoted in the Netherlands and Belgium (where euthanasia and PAS are legal): phenobarbital (a barbiturate once proposed for executions but never used by Arkansas) along with morphine sulfate and chloral hydrate. There have been reports of this drug mixture being too harsh, forcing terminally ill patients to turn to other new and untested cocktails.<sup>43</sup>

The right-to-die advocacy organization, Exit International, publishes a handbook, *The Peaceful Pill Handbook*, every few months to provide information on various lethal medications and combinations, including many of those already mentioned, as well as cyanide, morphine, propoxyphene, amitriptyline, chloroquine, insulin, and chloral hydrate. Sale of the book is restricted to those over 50, so as to prevent abuse. There are obvious scientific and medical concerns over these recommendations, given the moral, legal, and practical limitations to investigating death and suicide.

### **III. MEASURING BOTCHED EXECUTIONS AND PAS COMPLICATIONS**

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What exactly is a ‘botched’ execution or assisted suicide? Many objective and subjective measures exist, such as consciousness monitoring, time until death, visual and auditory cues of pain, and incidence of vomiting, seizing, or nausea. While loose legal and medical standards exist to some degree, there is still room for ethical discussion about what these measures and standards should be. Given the technical and moral differences between the two practices, measurements for the two must be fully separated, as clinical errors or adverse drug reactions may be forgiven within one, but not in the other.

As far as the death penalty goes, a huge wake exists between what advocates and opponents would view as a ‘botched’ execution—many believe that the condemned should suffer a painful and torturous death as punishment for their crimes, while others argue that the mere imposition of death by the states is itself immoral and unconstitutional. Austin Sarat, author of *Gruesome Spectacles: Botched Executions and America's Death Penalty*, created an extensive review of all ‘botched’ executions in the past 120 or so years. Within it, he found lethal injection to be by far the most problematic of all methods implemented, at a staggering 7.12% botched rate, compared to 3.12% for hanging and 1.92% for electrocution.<sup>44</sup> Abolitionists have used these statistics in an attempt to rip off the veil over the supposed humanity of execution via lethal injection—but a closer look into each individual execution shows that Sarat employed an exceedingly low threshold for an execution to qualify as a botching. At least 23 out of 75 of the supposed lethal injection botched executions seem to qualify as ‘botched’ for only one reason: the process took longer than 10 minutes—there remains no evidence of any pain or clinical complication or struggle.<sup>45</sup> Other suspect qualifications include inmates who struggled to be strapped into the gurney or technician inability to find an appropriate vein after a few tries.

PAS has more rigid definitions, as few would argue that any level of pain is acceptable. But there remains the difficult task of qualifying what counts as a complication when the final expected result is death, and when the alternative is typically a patient's predictably painful death otherwise. In one of the first and most prolific attempts to do so, researchers from the Netherlands published findings on clinical problems in PAS and euthanasia throughout a short period in the 1990s, a few years before formal legalization. The article establishes three classifications of error: technical problems, complications, and problems with completion. Technical problems include difficulty finding veins or with administering the drugs. Complications involve adverse physiological reactions, such as vomiting, discoloration, difficulty breathing, and seizures. Problems with completion include extensive time between medication administration and death as well as regaining of consciousness (and hence failure of the procedure).<sup>46</sup> The results showed a higher proportion of each complication than data from US states with legalized PAS,

though translating the results can be difficult given differing standards.

According to data published by Oregon, 5% of patients experienced difficulties, such as regurgitation or seizures, after ingestion of the medication, since the inception of the law in 1997.<sup>47</sup> These reports must be taken with some caveats: only 51% of cases have been reported back, and of those, any after the year 2010, required the physician to fill out or sign off on the follow up report, despite only being present in approximately 30% of reported cases. There are six reported instances where patients ingested the lethal medications, went unconscious, and awoke sometimes days later. Many argue that these numbers are too low to matter or to extrapolate any significant meaning, but they still demonstrate a need for investigation. Reporting and monitoring practices need fundamental improvements, and research must be ramped up.<sup>48</sup>

Many feel that no one, except the patients themselves, should be able to determine what levels of risk are acceptable. This point should strike a chord with advocates who argue for legalization of PAS on the basis of autonomy. Physicians, as of now, are limited in the clinical data they can consult when approached by patients seeking to end their life; advice and caution are at best anecdotal. Considering that this is their death, PAS is one of the most impactful medical decisions these patients will ever make. Complications, whether a little bit of nausea or an extended onset till death, can be torturous for a patient or for loved ones. Patients have individual conceptions of pain, discomfort, privacy, and risk; establishing standards must always consider these subjective. The need for standards, whether clinical, legal, or ethical, extends to the condemned as well.

## **IV. THE FUTURE OF LETHAL MEDICATION PROVISIONS**

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The use of these drugs is difficult to predict. The legalization of PAS, despite the roadblock it hit in dozens of state legislatures this year alone, is likely to continue, but which medications are employed is subject to many legal, economic, and medical factors. Though public opinion already backs the practice, norms around

the end-of-life are likely to continue shifting as the population ages. The death penalty, despite many thinking its end is near, is likely to plug along in one way or another. In the face of all these challenges, courts have allowed the practice to continue. Opposition from the scientific and medical communities has only slowed the death penalty down, but states have adapted. Some have even replaced lethal injection with alternative methods, such as bringing back the electric chair or firing squads, or instituting new methods, such as nitrogen gas hypoxia.<sup>49</sup>

The dearth in relevant clinical data on these drugs for lethal purposes remains a peripheral issue. Due to the ethical infeasibility of running clinical trials (considering that the control would be death), physicians and executioners can only rely on lethal dose indicators for mice and anecdotes of past instances of their use. In the end, little is known about dying. The processes of death will always, to some extent, be a mystery. For now, whether a death is peaceful and painless can only be assumed. Maybe one day science will tell us more.

There is room for policy innovation. To better regulate drug supply, the government could create 'a central mechanism to confirm the authenticity and eligibility of patients' requests, dispense medication, and monitor demand and use'.<sup>50</sup> Mandates on physician presence could ensure efficacy and manage complications as well as provide for better reporting and monitoring, which itself can improve decision making. In PAS, this might be seen as a breach in autonomy or of family space, but it is worth consideration. Although physician mandates have been tried by some states in executions, the typical result is a halt in executions, since physicians seize the opportunity to boycott. This is potentially for the better, maybe executions should only be carried out with active physician participation, so as to guarantee safety, efficacy, and monitoring. States could redesign their data collection efforts by fixing reporting procedures, sometimes as simple as rewording a form or as complex as mandating follow-up forms be turned in or else loved ones incur a penalty. Transparency is critical to knowledge exchange, and knowledge exchange critical to autonomy. Proponents and opponents of each practice alike need to encourage, not fight against, the call for more research into these practices and their implementation.

\* Sean Riley is an aspiring end-of-life researcher, currently studying at Erasmus Medical Center in Rotterdam, the Netherlands. Prior to that, he received his M.A. in Bioethics & Science Policy from Duke University, where his principal research on lethal injection and assisted suicide contributed to much of this manuscript. After finishing his research in the Netherlands, he hopes to bring Dutch insight and methodology on these issues and apply them to the evolving field of end-of-life care in the United States. He intends to pursue this through a PhD in Health Policy.

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