IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

RICKY JOVAN GRAY, Plaintiff, v. TERENCE RICHARD MCAULIFFE, Governor, Commonwealth of Virginia, HAROLD W. CLARKE, Director, Virginia Department of Corrections, EDDIE PEARSON, Warden, Greensville Correctional Center, DAVID ZOOK, Warden, Sussex I State Prison, OTHER UNKNOWN EXECUTIONERS, EMPLOYEES, AND AGENTS, Virginia Department of Corrections, Defendants.	No. 16-cv-982-HEH IMMINENT EXECUTION **SCHEDULED FOR** **JANUARY 18, 2017**

COMPLAINT FOR DECLARATORY JUDGMENT

1. There is a constitutionally intolerable risk that, on January 18, 2017, the Virginia Department of Corrections ("VDOC") will chemically torture Plaintiff Ricky Gray to death. The VDOC will do so behind a veil of secrecy that frustrates Mr. Gray's efforts to learn any meaningful details about the chemicals that will be used to cause his death. The risk of chemical torture is a violation of Mr. Gray's Eighth Amendment right to be free from cruel punishment. The veil of secrecy that the VDOC has pulled across the details surrounding how Mr. Gray is to be executed is a violation of Mr. Gray's Fifth and Fourteenth Amendment right to Procedural Due Process.

2. Mr. Gray is a death row inmate in the custody of the VDOC, which is scheduled to execute Mr. Gray on January 18, 2017, by lethal injection. The VDOC employs a three-drug protocol to execute death row inmates: A first drug intended to anesthetize the inmate; a second drug to paralyze the inmate; and a third drug to kill the inmate by inducing cardiac arrest. The three-drug protocol is intended to kill an inmate only after the first drug's anesthetizing effects prevent the inmate from feeling the agonizing effects of the second and third drugs.

3. But in reality, three-drug protocols similar to the one the VDOC intends to use to execute Mr. Gray have on numerous occasions not operated as intended. Instead, the first drug has sometimes failed to adequately sedate the inmate, who subsequently has endured the torturous effects of the second and third drugs while aware of what was happening. And recently, disturbing details have emerged about the specific drugs that the VDOC intends to use to kill Mr. Gray, which as explained herein increase the risk that he will be executed by a constitutionally intolerable method.

4. Specifically, Mr. Gray recently learned that the VDOC intends to employ a novel, radical, and never-tested application of a three-drug lethal injection protocol. The VDOC intends to use compounded midazolam hydrochloride ("compounded midazolam") as the first drug in its protocol—which is supposed to anesthetize Mr. Gray in order to render him insensate to the otherwise-excruciating effects of the other two drugs—and compounded potassium chloride as the third drug in the protocol, which will kill Mr. Gray by causing his heart to stop beating. This is the first time an execution has *ever* been carried out in the United States using compounded midazolam or compounded potassium chloride. It is also the first time that an execution has ever been carried out in the United States using a combination of more than one compounded drug.

5. This new and untested method of execution risks subjecting Mr. Gray to extraordinary and needless pain and suffering. Midazolam, the first drug in the protocol, is incapable of reliably if ever rendering inmates insensate to the excruciating level of pain inflicted by the second and third drugs in the protocol. Indeed, midazolam lacks the chemical properties of an anesthetic and is thus not designed for anesthesia. Worse, both the midazolam and the potassium chloride the VDOC plans to use have been made by a compounding pharmacy. These pharmacies typically follow an informal recipe attempting to approximate the patented process used in manufacturing drugs approved by the U.S. Food and Drug Administration ("FDA"). The finished product is designed to replicate a variation of—but is not the same as—any FDA-approved manufactured drug that goes by the same name. This method for creating drugs unnecessarily adds enormous risk that the drugs will be ineffective, sub-potent, expired or contaminated, or that they will contain unintended additives or a substantial level of particulates. Any one of these problems increases the risk that the compounded midazolam would not work as it is required to in order to make the planned protocol compliant with constitutional guarantees, because it would fail to render Mr. Gray insensate to the known pain produced by the administration of the subsequent drugs.

6. Recent botched executions have shown the horrific results of using FDA-approved, manufactured midazolam. Less than a week ago, Alabama botched its execution of inmate Ronald Bert Smith using FDA-approved midazolam. For about 13 minutes after Mr. Smith had been injected with midazolam, he struggled for breath "and heaved and coughed and clenched his left fist." Kent Faulk, *Alabama Death Row inmate Ronald Bert Smith heaved, coughed for 13 minutes during execution*, AL.com, Dec. 8, 2016, *available at* http://www.al.com/news/birmingham/index.ssf/2016/12/alabama_death_row_inmate_is_se.html.

It was only the most recent in a long line of botched executions involving midazolam. Separately, other executions in recent years have gone disastrously due to problems associated with the compounding of a different drug, pentobarbital. Yet, in an unprecedented move, the VDOC plans to execute Mr. Gray using *compounded* midazolam, combining the extraordinary dangers already posed by manufactured midazolam with the inherent danger attached to using a compounded—and by definition, unapproved—drug.

7. The VDOC's planned use of compounded midazolam creates an objectively intolerable risk that Mr. Gray will not be properly anesthetized before he is injected with chemicals that unquestionably cause pain and suffering in an inadequately anesthetized person. In addition, the VDOC's novel plan to use a compounded drug as the third drug in the protocol—compounded potassium chloride, which is designed to stop Mr. Gray's heart and complete the execution—is extraordinarily dangerous. The use of potassium chloride in itself threatens to inflict profound pain and suffering on Mr. Gray, who would suffer silently, trapped in the paralysis caused by the second drug in the protocol. Moreover, the use of compounded potassium chloride adds the threat that the chemical will not work, leaving Mr. Gray alive, paralyzed, and in extreme pain.

8. Despite these hazards, a Virginia statutory provision never applied to any previous execution prevents Mr. Gray from learning any meaningful information about the drugs that the VDOC proposes to use to kill him. The so-called "secrecy statute," as amended July 1, 2016, states that

> [t]he identities of any pharmacy or outsourcing facility that enters into a contract with the Department for the compounding of drugs necessary to carry out an execution by lethal injection, any officer or employee of such pharmacy or outsourcing facility, and any person or entity used by such pharmacy or outsourcing facility to obtain equipment or substances to facilitate the compounding of

> such drugs and any information reasonably calculated to lead to the identities of such persons or entities . . . shall be confidential, shall be exempt from the Freedom of Information Act . . . , and shall not be subject to discovery or introduction as evidence in any civil proceeding unless good cause is shown.

Va. Code § 53.1-234. This statute, combined with the fact that the VDOC has pled ignorance in response to a host of basic questions about the preparation and maintenance of the drugs that will be used to execute Mr. Gray, violates Mr. Gray's constitutional right to procedural due process.

9. Mr. Gray brings this complaint seeking declaratory relief pursuant to 42 U.S.C. § 1983 for violations and threatened violations of his right to be free from cruel and unusual punishment under the Eighth and Fourteenth Amendments to the U.S. Constitution, and his right to procedural due process under the Fifth and Fourteenth Amendments of the U.S. Constitution. Mr. Gray seeks temporary, preliminary, and permanent injunctive relief to prevent Defendants from executing him under the VDOC's unsafe and untested lethal-injection protocol.

PARTIES

10. Plaintiff Ricky Gray is a person within the jurisdiction of the Commonwealth of Virginia. He is currently an inmate under the supervision of the VDOC, Prisoner No. 1100057. Mr. Gray is under a sentence of death and is confined at the Sussex I State Prison, Building 3, Sussex County, Virginia. His execution is scheduled for January 18, 2017. He exhausted the appeals of his sentence of death only 37 days ago (November 7, 2016), when the U.S. Supreme Court denied Mr. Gray's request for a rehearing on his petition for a writ of certiorari.

11. Defendant Terence Richard McAuliffe is the Governor of the Commonwealth of Virginia. He is the final executive authority in the Commonwealth, statutorily and constitutionally responsible for carrying out all death sentences in Virginia, including the manner in which those sentences are executed. He has direct authority over the VDOC and its Director.

12. Defendant Harold W. Clarke is the Director of the VDOC, 6900 Atmore Drive, Richmond, VA 23225, which oversees the correctional facilities where Mr. Gray is currently incarcerated and where Mr. Gray will be killed.

13. Defendant Eddie Pearson is the Warden at Greensville Correctional Center, 901 Corrections Way, Jarratt, VA 23870-9614. He is an employee of the VDOC and under the authority of the Director. Greensville Correctional Center is the facility at which Defendants plan to carry out Mr. Gray's execution.

14. Defendant David Zook is the Warden at Sussex I State Prison, 24414 Musselwhite Drive, Waverly, Virginia, 23891-1111. He is an employee of the VDOC and under the authority of the Director. Sussex I State Prison is the facility where Mr. Gray is being held on Death Row prior to being moved to Greensville Correctional Center for his execution.

15. Upon information and belief, Unknown Employees and Agents of the VDOC are involved in the development and carrying out of executions by lethal injection. Mr. Gray does not know the identities of these persons.

16. Defendants are all state officials acting under color of state law. They are all sued in their official capacities.

JURISDICTION AND VENUE

17. This action arises under the Fifth, Eighth, and Fourteenth Amendments to the United States Constitution and under 42 U.S.C. § 1983. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 (federal question), 1343 (civil rights violations), 2201(a) (declaratory relief), and 2202 (further relief).

18. This Court has personal jurisdiction over Defendants as they are residents of the Commonwealth of Virginia, and are presently located in the Commonwealth of Virginia, or are

elected or appointed officials of the Commonwealth of Virginia or otherwise acting on behalf of the Commonwealth of Virginia.

19. Venue in this Court is proper under 28 U.S.C. § 1391 because the events giving rise to the claims—including executions and the procurement and maintenance of drugs used in the executions—are set to occur in the Eastern District of Virginia. Venue in the Richmond Division is proper under Local Rule 3(C) because all defendants reside within this Division, and because a substantial part of the events or omissions giving rise to this claim occurred in this Division.

EXHAUSTION OF ADMINISTRATIVE REMEDIES

20. Exhaustion of administrative remedies is unnecessary under the Prison Litigation Reform Act ("PLRA"), 42 U.S.C. § 1997(e), because this suit does not challenge prison conditions and because there are no available administrative remedies that could address the challenged constitutional violations.

21. Nonetheless, and out of an abundance of caution, Mr. Gray submitted multiple requests to the VDOC asking the VDOC not to use the three-drug protocol that the VDOC has proposed, and for further information regarding the protocol. In all instances, the VDOC has declined to provide answers or relief, instead stating that it has no authority to grant Mr. Gray's requests.

22. Immediately after learning of the new protocol the VDOC intends to use in his execution, Mr. Gray filed an Informal Complaint to begin the process of exhausting his administrative remedies. His complaint asked that the VDOC "stop using lethal injection and electrocution processes that knowingly or unreasonably create a serious risk of cruel and unusual punishment because there are not reasonable safeguards." He also asked that the VDOC provide

him with information about the substances and process relied upon for carrying out an execution by lethal injection so that he could "make an informed choice about [his] method of execution." Mr. Gray received a response denying his complaint because the Commonwealth carries out executions at Greensville Correctional Center and Mr. Gray was being held at Sussex I State Prison at the time. Mr. Gray submitted a grievance on November 1, 2016, for which the internal appeals process was completed on November 14, 2016. The VDOC ruled that his request was not accepted for intake because it was "beyond the control of the Department of Corrections." Inexplicably—and illustrative of the VDOC's arbitrary and insufficient administrative review process—although Mr. Gray filed no additional grievances or complaints, he received four additional first-level responses from the VDOC to the November 1, 2016, grievance on November 21–22, 2016, with new findings. In these new responses, the VDOC takes the position that Mr. Gray's request for information and complaints about the objectionable procedures developed for execution by lethal injection are "governed by the Code of Virginia."

FACTUAL ALLEGATIONS

23. The legislature of the Commonwealth has authorized the VDOC to carry out death sentences by *either* (i) "electrocut[ion]" (*i.e.*, the "electric chair"), or (ii) "inject[ion of] a lethal substance" (*i.e.*, "lethal injection"). Va. Code § 53.1-234. The inmate is required to choose whether he wishes to be killed by "electrocution," or by "injection with a lethal substance." *Id.* In the event he does not make the choice, the statute prescribes that lethal injection will be the VDOC's chosen method of execution. *Id.* Mr. Gray has not made any election, meaning that the VDOC will execute him using its chosen method of lethal injection.

24. As described below:

a. the VDOC's proposed lethal injection "protocol" creates a demonstrated risk of severe pain (*see infra* Points I.A-B, I.D);

b. the Commonwealth has erected a "secrecy statute" that is specifically intended to frustrate inmates' attempts to learn about the drugs to be used in their executions (*see infra* Point I.C);

c. the electrocution "option" is not a "known and available alternative" as defined under law because electrocution, itself, is unconstitutional (*see infra* Point II.A); and

d. there is, at present, at least one known alternative available to the VDOC: execution by firing squad (*see infra* Point II.B).

I. The VDOC's Unconstitutional Lethal Injection Protocol and the Unconstitutional "Secrecy Statute" that Shields It from Review and Scrutiny

25. Section 53.1-234 does not prescribe a specific drug protocol to be used in an execution by lethal injection. Rather, the statute provides simply that death is to be caused by "inject[ion of] a lethal substance," leaving it to the VDOC to prescribe the protocol. Va. Code § 53.1-234. The VDOC, in turn, has refused to publish or otherwise release its protocol. The majority of the information that Mr. Gray has been able to learn about the protocol has been gleaned through several informal communications with the Virginia Attorney General's Office about the drugs it has procured. Through these informal communications, Mr. Gray has learned that the VDOC has chosen to use compounded midazolam as the first drug and compounded potassium chloride as the third drug in its three-drug protocol.

26. This is unprecedented. Counsel for Mr. Gray are not aware of any other instance in which a state or any established authority or jurisdiction has used compounded midazolam to

effectuate an execution. The use of FDA-approved midazolam, in itself, poses a host of serious risks. But the use of a compounded preparation significantly magnifies the risks already posed by FDA-approved midazolam. Aggregated, these risks are substantial and create an unacceptable threat of severe pain.

27. As described below, midazolam is, by design, ineffective at serving the intended purpose of placing Mr. Gray under anesthesia for the duration of the execution (*see infra* subsection A), and the use of a compounded drug greatly exacerbates the risk that the midazolam will not desensitize Mr. Gray from intolerable pain and suffering (*see infra* subsection B). The risks associated with the use of compounded drugs may be even *further* exacerbated by improper preparation, storage, and transport. However, the Commonwealth's "secrecy statute" is designed to prohibit death row inmates like Mr. Gray from obtaining discovery of this relevant information (*see infra* Subsection C). Further underscoring the exceedingly cruel nature of the VDOC's proposed method of execution, Mr. Gray has a severe diagnosed health condition that all but guarantees that he will experience psychological terror when subjected to lethal injection (*see infra* Subsection D).

A. FDA-Approved Midazolam Poses Several Risks of Excruciating and Needless Pain and Suffering.

28. FDA-approved midazolam is a poor choice for the first drug in a three-drug protocol that includes a paralytic drug as the second drug and potassium chloride as the third. Unlike the second and third drugs in the protocol, the first drug must fulfill a medicinal role as an anesthetic/sedative. FDA-approved midazolam poses several risks of pain and suffering when used in a three-drug protocol in comparison to anesthetic drugs like sodium thiopental or pentobarbital. Because of its chemical properties, even if the midazolam in the Commonwealth's possession were FDA-approved, there would still be a high likelihood that it

would fail to render Mr. Gray insensate or would wear off before the paralytic drug and potassium chloride are completely administered. This is so for at least three reasons.

29. *First*, FDA-approved midazolam is a member of the benzodiazepine class of drugs, which is used to relieve anxiety. It is *not* used to initiate or maintain anesthesia. Instead, it is often used as a sedative to reduce anxiety prior to induction and maintenance of anesthesia with a different drug. Based on known, uncontroverted scientific information regarding midazolam, there is a substantial risk that it would fail to keep Mr. Gray in a state in which he would be shielded from experiencing extreme pain and suffering. Importantly, FDA-approved midazolam has no pain-relieving effects, and it is not used as a sole agent to maintain unconsciousness in painful procedures. Accordingly, there is a high likelihood that midazolam will fail to render Mr. Gray insensate to pain sufficient to ensure that he will not feel the intense pain and suffering associated with the paralytic drug and compounded potassium chloride.

30. *Second*, due to the way in which FDA-approved midazolam functions, it begins to lose effectiveness rapidly—much more quickly than anesthetics like pentobarbital and sodium thiopental. Indeed, as recent executions in other states involving midazolam have demonstrated, while midazolam can render inmates initially unconscious,[1] it is not as effective as anesthesia. Inmates to whom midazolam have been administered have regained consciousness and have suffered tremendously when the paralytic drug and potassium chloride were administered.

[1] The VDOC has, in the past, claimed to employ a so-called "pinch test" to test the effectiveness of the first drug in the protocol, pursuant to which—after the drug is administered—an official participating in the execution will pinch the inmate's toe to see if the inmate reacts. If the inmate does not react, then the VDOC deems the inmate to be properly anesthetized. This, however, is highly likely to result in a "false positive" because—as indicated above—the fact that there is no reaction (i) may just as easily be attributable to the fact that the inmate is relaxed, but not anesthetized, and/or (ii) may just be evidence that the inmate is sedated *at this moment*, only to regain consciousness before he is killed. It is for this reason that the VDOC's so-called "pinch test" is utterly ineffective.

31. *Third*, FDA-approved midazolam has what is known as a "ceiling effect." A ceiling effect refers to the limits of the effect a drug can exert on the body, even when administered in large doses. Benzodiazepines like midazolam have *no* effect on the brain in amounts above their ceiling effect because the receptors on which they act become saturated. Thus, the VDOC cannot attempt to achieve an anesthetic effect by simply increasing the dosage of midazolam that is administered to Mr. Gray. It will do nothing to reduce the likelihood he will feel tremendous pain and will do nothing to protect him from the grisly effects of the paralytic drug and potassium chloride. To the contrary, whatever the dosage, it is substantially likely that Mr. Gray will be awake and sensate to the noxious stimuli he will experience as the result of air hunger, suffocation, the horror of being paralyzed from the paralytic drug or the sensation of being burned alive from the inside from potassium chloride, and then cardiac arrest. In short, because of the ceiling effect, it is not possible to overcome the inadequacy of midazolam's anesthetic properties by using a large dose. It is therefore not possible to prevent Mr. Gray from experiencing unfathomable suffering following the administration of midazolam.

32. The ghastly consequences of using FDA-approved midazolam in an execution have been documented. For one, the use of midazolam in the protocol creates a substantial risk of air hunger and suffocation. Air hunger is the inability to satisfy the physiologic and psychological urge to breathe, similar to suffocation. It is the inability to draw a breath to satisfy the body's involuntary need to breathe. Air hunger and suffocation are terrifying and painful experiences. An intravenous injection of midazolam will not prevent Mr. Gray from feeling or being aware of the agony of air hunger or suffocation.

33. A large dose of midazolam, such as 500 mg or 1000 mg, also carries a substantial risk of producing what are known as "tonic-clonic seizures," which are generalized seizures that affect the entire brain, and convulsions. Such seizures often result in severe pain and suffering.

34. Defendants have no scientific basis to include midazolam as the first of a three-drug protocol. There is no basis to conclude that using midazolam to carry out a lethal injection execution is more humane, safer, or more effective than using a proper anesthetic.

35. The substantial risk of harm posed by midazolam is not just academic—the drug has been implicated in numerous botched executions. For example, Ohio used midazolam mixed with the opioid hydromorphine to execute inmate Dennis McGuire in January 2014. For 26 minutes, Mr. McGuire was left gasping for air on the execution gurney before he was killed. Three months later, Oklahoma used midazolam in the gruesome execution of Clayton Lockett. Mr. Lockett, who initially lost consciousness following the administration of midazolam, regained consciousness and, struggling to speak while violently convulsing, bucking, twitching, and writhing, said, "something's wrong." The executioners tried but failed to administer more drugs, and the execution was called off, but Mr. Lockett died ten minutes later. The execution took 43 minutes, during which Mr. Lockett exhibited extraordinary pain and suffering. Even though there were failures in the administration of the midazolam, the official autopsy revealed that the concentration of midazolam in Mr. Lockett's blood was greater than the therapeutic level necessary to render a person unconscious. Mr. Lockett's execution, which drew intense public interest and a media firestorm, vividly demonstrates what Mr. Gray will experience behind a veil of paralysis.

36. Three months after Mr. Lockett's agonizing execution, Arizona used midazolam to execute Joseph Wood. It took almost two hours—the longest lethal injection in United States

history. During those two hours, Mr. Wood gasped for air at least 640 times while visibly struggling and making sounds of pain and agony that sounded "similar to when a swimming-pool filter starts taking in the air." *See* Michael Kiefer, *Reporter describes Arizona execution: 2 hours, 640 gasps*, Arizona Republic, July 26, 2014. Arizona later stated that it would never again use midazolam as part of its execution protocol. Following Mr. Wood's execution, Kentucky's Attorney General removed midazolam from the state's protocol.

37. Therefore, as science instructs and real-world experience confirms, FDA-approved midazolam cannot be relied upon to effectuate a humane, constitutional execution. The drug is simply not suited for the task.

B. Unapproved Compounded Drugs Obtained From Unknown Compounding Pharmacies Pose an Inherent Risk of Harm.

38. "Compounding" refers to the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug. 21 U.S.C. § 353b(d)(1)). This practice is usually performed by licensed pharmacists, pursuant to a licensed physician's prescription order for an individual patient who cannot have his or her needs met by an existing product approved by the FDA. For example, a physician may order a licensed pharmacist to compound a drug if the patient has an allergy to an inactive ingredient contained in the approved product or if the approved product is in a solid oral dosage form but the patient needs a liquid dosage form. Historically, the practice of pharmacy, including pharmacy compounding, has been overseen and regulated by state boards of pharmacy. Compounded drugs are by definition not FDA-approved and carry increased risks of contamination, sub-potency, and rapid degradation.

39. In 2012, a multistate outbreak of fungal meningitis linked to contaminated steroid injections compounded at the New England Compounding Center in Framingham,

Massachusetts resulted in nearly 800 cases of illness and 64 deaths. In response to this public health crisis, Congress enacted the Drug Quality and Security Act ("DQSA"). Title I of the DQSA, commonly referred to as the Compounding Quality Act ("CQA"), clarified the FDA's enforcement authority with respect to compounding pharmacies under 21 U.S.C. § 353A. The act enhanced the FDA's oversight over compounding pharmacies by increasing the number of inspections of compounding pharmacies the agency can conduct.

40. In 2014, the FDA conducted more than 90 inspections of compounding facilities, which led to numerous facilities engaged in poor sterile practices being forced to cease production of sterile drugs and recall drugs manufactured under substandard conditions. The FDA has stated that "[n]ew problems continue to be identified at compounding pharmacies across the country." FDA, *Implementation of the Compounding Quality Act*, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm (last visited Dec. 1, 2016). Although the FDA has increased its oversight of compounding pharmacies, compounded drugs are still not subject to the FDA's drug approval process, and compounding pharmacies are not subject to the FDA's current good manufacturing practice (cGMP) regulations.

41. Compounding involves the use of raw ingredients, including Active Pharmaceutical Ingredients (APIs), which are the active ingredients in the compounded drug. There are significant questions about the quality of APIs used in compounding. Compounding pharmacies have been identified as "a primary route of entry for counterfeit bulk drugs." Prepared Statement of Honorable Fred Upton before the Subcommittee on Oversight and Investigations - Counterfeit Bulk Drugs, June 8, 2000, *available at* http://www.gpo.gov/fdsys/pkg/CHRG-106hhrg65846/html/CHRG-106hhrg65846.htm. It is

difficult to trace the raw chemicals back to the original manufacturer for information about their quality and integrity. Accordingly, a chemical labeled as a particular active ingredient may actually be a different ingredient, and there is no way to have confidence that the APIs are not contaminated. If poor ingredients are used, "[t]he compounded drug may be contaminated, super-potent or sub-potent, non-sterile, or at risk of an unusually short shelf life." *Id*.

42. Because compounding pharmacies do not typically have the type of sophisticated equipment used by large-scale drug manufacturers—equipment that is necessary to produce both high quality and large quantities of pharmaceuticals—compounding pharmacies keep batch sizes small. Compounded drugs often degrade and lose efficacy more quickly than non-compounded drugs. For this reason, compounding pharmacies usually set relatively short "beyond use dates" ("BUDs") for compounded drugs. A BUD is the compounded drug equivalent of an expiration date. Moreover, unlike manufactured drugs, compounded drugs are not subject to release testing, which means that compounded drugs are not required to meet the stringent requirements regarding contamination, dilution, and degradation that manufactured drugs are required to meet.

43. According to United States Pharmacopeia ("USP") chapter 797, *Pharmaceutical Compounding—Sterile Preparations*, storage periods for high-risk compounded sterile preparations (CSPs) cannot exceed the following time periods before administration (in the absence of passing a sterility test): 24 hours, if stored at room temperature; 72 hours, if kept refrigerated; or 45 days if kept in a solid, frozen state. To set a BUD beyond these periods, extensive and documented sterility testing is necessary. Even then, dates are usually set within 90 days. Estimated BUDs depend on the nature and quality of raw ingredients used, the quality of the process applied by the compounding pharmacy, and the precision and professionalism of the testers of the drug in question. Whether the pharmacy employs the more stringent conditions

to increase the BUD beyond three days can be determined by inspecting documentation relevant to the pharmacy and the testing.

44. Because any BUD can be dramatically affected by subsequent storage conditions, CSPs must be kept in carefully prescribed conditions related to the stability and properties of the specific medicine in question. Stability "depends on the purity and concentration of specific ingredients, packaging and environmental exposure and storage (humidity, illumination and temperature), especially for solutions. Small changes in any one of those variables can cause rapid loss of drug strength or much shorter than expected shelf-life." David Newton & Bernard Dunn, *A Primer on USP Chapter 797 "Pharmaceutical Compounding-Sterile Preparations," and USP Process for Drug and Practice Standards*, *available at* http://www.nhia.org/members/documents/usp_797_primer.pdf. For example, difference by one pH unit in some solutions can decrease stability to less than 50% of the BUD time assigned. "[T]here can be danger in either assuming correct compounding or expecting a seemingly small formulation change to produce an insignificantly small stability change." *Id*. Thus, it is imperative to test both stability and sterility multiple times over a drug's shelf life, not just shortly after it is compounded.

45. The risks posed by poor storage conditions of compounded execution drugs have been amply demonstrated. In March 2015, a syringe of compounded pentobarbital sodium in the Georgia Department of Corrections' possession was discovered to have precipitated, appearing "cloudy" just hours prior to the scheduled execution of Kelly Gissendaner. The Department of Corrections sent the drug to a lab for analysis, and concluded that the likely cause of the precipitation was the temperature of the drugs, which were kept in poor storage conditions.

Mark Berman, *After execution hiatus, Georgia says its lethal injection drugs were kept too cold*, Wash. Post (Apr. 16, 2015).

46. The risks posed by using drugs from compounding pharmacies have also been demonstrated. When Oklahoma executed inmate Michael Lee Wilson in January 2014, it used compounded pentobarbital as the first of three drugs. Upon administration of the purported pentobarbital, Mr. Wilson cried out, "I feel my whole body burning!" Charlotte Alter, *Oklahoma Convict Who Felt "Body Burning" Executed with Controversial Drug*, Time Magazine (Jan. 10, 2014). Mr. Wilson's reaction is consistent with exposure to contaminants introduced by the unsafe compounding of pentobarbital, as shown by a report analyzing the execution that found "the injection used in Mr. Wilson's execution likely contained cross-contaminates that he was allergic to, [and] bacteria and endotoxins could have had an altered pH due to contaminates or inadequate procedures used in the preparation of the drug." Inmate Jose Luis Villegas similarly complained of a burning sensation when Texas executed him with compounded pentobarbital in April 2014. *See* Vivian Kuo & Ralph Ellis, *U.S. Supreme Court grants stay of 'excruciating execution*,' CNN (May 21, 2014). Likewise, when inmate Eric Robert was executed with compounded pentobarbital in South Dakota in October 2012, he gasped heavily, his skin turned a blue-purplish hue, his eyes remained open throughout the execution, and his heart continued to beat ten minutes after he stopped breathing. He took more than twenty minutes to die. *See* Dave Kolpacl & Kristi Eaton, *Eric Robert Execution*, Associated Press, *available at* http://www.huffingtonpost.com/2012/10/16/erlc-robert-execution_n_196940.html. These events were consistent with the administration of a compounded drug that was contaminated or sub-potent.

47. Risks attendant to the use of a sub-standard compounded drug include that the compounded drug will be sub-potent, expired, contaminated, contain unintended additives, or will contain a substantial level of particulates. Further, deficiencies in storing and handling the drugs in compliance with very specific guidelines create the risk that the compounded drugs will expire before they are used. Any one of these issues increases the risk that the compounded midazolam would not work as it is required to render Mr. Gray insensate.

48. The VDOC supplied Mr. Gray's counsel with photographs of the bottles containing the purported compounded midazolam and purported compounded potassium chloride the VDOC plans to use for Mr. Gray's execution. The labels on these bottles indicate that the BUDs for the CSPs are in early 2017. The VDOC has not provided any evidence to support these BUDs, and, for the reasons noted above, significant risk exists that these compounded drugs will destabilize by Mr. Gray's scheduled execution.

49. What is more, the Commonwealth has increased exponentially the risks associated with the use of compounded drugs in lethal injections by *removing itself entirely* from its standard oversight and regulatory function with regard to compounding pharmacies. Generally, compounding is considered the "practice of pharmacy." Va. Code § 54.1-330; 54.1-3401. This designation brings the pharmacy under a robust set of regulations and laws regarding the preparation and dispensation of compounded drugs. The Virginia Board of Pharmacy has the right to inspect compounding pharmacies' facilities and records and, if standards are not followed, the Board may suspend or revoke licensure and registration. Pursuant to the above-described "secrecy statute," however, "[t]he compounding of" drugs to be used for lethal injection "(i) shall not constitute the practice of pharmacy . . . (ii) is not subject to the jurisdiction of the Board of Pharmacy, the Board of Medicine, or the Department of Health Professions; and

(iii) is exempt from the provisions of . . . the Drug Control Act." Va. Code § 53.1-234. By statute, the Commonwealth has relieved itself of responsibility—mandated in all other pharmaceutical contexts—to regulate the preparation, maintenance, and sourcing of compounded drugs in executions.

50. Because of the inherent risks and lack of safeguards in using compounded drugs, and because midazolam is an inherently inadequate anesthetic, there is a high likelihood that the supply of compounded drugs the VDOC plans to use in its lethal-injection protocol will not properly anesthetize Mr. Gray for the duration of the execution process. Without adequate anesthesia that lasts the duration of the execution, Mr. Gray will experience excruciating pain as a result of the conscious asphyxiation caused by the paralytic agent and the painful internal burning and cardiac event caused by the potentially defective compounded potassium chloride overdose.

C. The VDOC Claims Ignorance Regarding the Drugs It Will Use to Kill Mr. Gray, and Virginia's Legislature Has Enacted an Unconstitutional Statute Designed to Frustrate Mr. Gray's Ability to Take Discovery on These Drugs.

51. The foregoing description constitutes what Mr. Gray knows about the protocol that the VDOC intends to use, which he learned from two informal e-mails from the Attorney General's Office (one on October 6, 2016, and another on November 4, 2016). Use of the three-drug protocol that relies on midazolam to anesthetize Mr. Gray against noxious stimuli, coupled with the use of compounded drugs that introduce risks of pain and suffering and drug failure, poses substantial risks that Mr. Gray will experience overwhelming pain and suffering during his execution, precisely the kind of cruel and unusual punishment forbidden by the Eighth Amendment.

52. But there is much that Mr. Gray *doesn't* know, due to a combination of (i) admitted ignorance on the part of the VDOC about the drugs it intends to administer to Mr. Gray, and (ii) a secrecy statute that purports to prohibit Mr. Gray from learning the provenance of the execution drugs or anything directly from the compounding pharmacy itself.

53. The Virginia Attorney General's office has not provided any information about:

a. the identity or capacity of the compounding pharmacy that made the compounded midazolam and potassium chloride;

b. the credentials of the compounding pharmacy that made the midazolam and potassium chloride or any persons or agents involved in mixing, testing, storing or transferring the chemical mixtures of compounded midazolam and potassium chloride;

c. the exact date that the midazolam and potassium chloride were compounded;

d. the manufacturers of the ingredients used in the compounded midazolam and potassium chloride;

e. the ingredients used to make the preparations, the circumstances under which the preparations were made, or whether these ingredients were manufactured by an FDA-approved registered facility and comply with standards of the United Sates Pharmacopeia;

f. the manner in which the preparations have been stored, handled, and transported since they were compounded;

g. how the Beyond Use Dates were set;

h. a description of the facility at which the drugs were compounded;

i. any inspections or other regulatory enforcement efforts undertaken in connection with the compounding pharmacies; or

j. what information the VDOC obtained about the appropriateness of using compounded midazolam in the execution of inmates sentenced to death in Virginia.

54. In response to a question about how much midazolam will be administered to Mr. Gray, the Attorney General's office confusingly stated that "[the] VDOC does not anticipate changing the dosage of [this] substance[] from the amount used in prior executions by lethal injection." However, the Commonwealth has never before used midazolam in an execution, and no state has *ever* used compounded midazolam as the first drug in a three-drug lethal injection protocol. If the VDOC were to administer a dosage of midazolam that is equal to the dosage of the anesthetic drug used in prior executions, the midazolam—a much weaker drug than pentobarbital or sodium thiopental—would not come close to anesthetizing Mr. Gray. The VDOC's belief that "not . . . changing the dosage . . . from the amount used in prior executions by lethal injection" would be adequate to prevent Mr. Gray from suffering excruciating pain as a result of the second and third drugs in the lethal injection protocol is wholly unsupported.

55. Further, Mr. Gray has no way of learning this critical information, due to the so-called "secrecy statute" enacted by the legislature in 2016. This statute purports to prohibit the VDOC from disclosing:

> The identities of any pharmacy or outsourcing facility that enters into a contract with the Department for the compounding of drugs necessary to carry out an execution by lethal injection, any officer or employee of such pharmacy or outsourcing facility, and any person or entity used by such pharmacy or outsourcing facility to obtain equipment or substances to facilitate the compounding of such drugs and any information reasonably calculated to lead to the identities of such persons or entities.

Va. Code § 53.1-234. This information "shall be confidential, shall be exempt from the Freedom of Information Act . . . , and shall not be subject to discovery or introduction as evidence in any civil proceeding unless good cause is shown." *Id.* In short, absent litigation and court-ordered discovery, Mr. Gray is cut off from obtaining and reviewing information necessary to learn about the effectiveness of these dangerous compounded drugs.

56. The secrecy statute incentivizes the VDOC to turn to compounding pharmacies for its lethal injection supplies even if the VDOC could obtain manufactured, FDA-approved versions of the drugs (and, at present, Mr. Gray has no idea if the VDOC has even attempted to do so).[2] If applicable, the secrecy statute would shield the VDOC from discovery or disclosure requests regarding the quality or legitimacy of the compounding pharmacies at the expense of inmates' constitutional rights to procedural due process. The VDOC is so desperate to avoid disclosing its suppliers and the source of the APIs that it was willing to pay tens of thousands of dollars for compounded drugs that, in reality, should cost in the tens or hundreds of dollars, at most. In this case, the VDOC has paid the exorbitant sum of **$66,000** for the two compounded drugs that will be used to execute Mr. Gray. By enacting the secrecy statute, the Commonwealth has developed a dangerous "gray" (if not black) market of secret lethal injection suppliers, exempt from scrutiny by industry regulators, law enforcement, potential litigants, or Virginia residents.

57. The VDOC is actively attempting to prevent Mr. Gray from vindicating his Eighth Amendment right to be free from cruel punishment. The VDOC is dangerously ignorant about the dubious drugs that it intends to administer to Mr. Gray to cause his death. The VDOC

[2] It is known that some states are able to get some version of anesthetic drugs like pentobarbital. It is not known whether these drugs are coming from reputable manufacturers.

has also enacted a barrier to Mr. Gray learning anything about the compounding process or the quality of the drugs to be used by forbidding the disclosure of any information that might enable Mr. Gray to assess the proposed method of execution without litigation. Without reasonable inquiry, these circumstances create an unnecessary and intolerably high risk that the drugs that will be administered to Mr. Gray will violate his Eighth Amendment rights.

D. Ricky Gray Has a Diagnosed Psychological Condition that Creates a Substantial Risk He Will Suffer True Psychological Terror as a Result of the Lethal Injection Drugs.

58. As described above, the second drug in the three-drug protocol (in this case, manufactured roncuronium bromide) is a paralytic drug. It serves no purpose in anesthetizing Mr. Gray or in killing him. It will be administered to Mr. Gray purely to for cosmetic reasons, so that viewers do not see him writhing and showing outward signs of distress while the lethal third drug is administered. It is this drug that makes a horrifyingly painful execution appear to observers as though the inmate has peacefully gone to sleep. In the event that Mr. Gray is conscious while paralyzed—which, for reasons described above, is highly likely—he will experience a new level of personal terror, due to a diagnosed medical condition resulting from terrifying childhood trauma and abuse.

59. Throughout Mr. Gray's childhood, he was frequently raped by his older step-brother. Among other horrific abuses, his step-brother would hold him down so that he couldn't move, and then penetrate him anally. This severe and protracted sexual abuse has left Mr. Gray with lifelong scars, both physical and psychological. Mr. Gray also suffered from brutal physical abuse at the hands of his father during his childhood. Because of these traumas, Mr. Gray suffers from Posttraumatic Stress Disorder, the hallmark of which is a terrifying nightmare in which Mr. Gray continues to experience himself as a child being raped. In these nightmares, Mr. Gray

desperately tries to move away from his attacker, to move his arms or his legs, but they will not move. He is paralyzed, utterly helpless.

60. This recurring nightmare is a classic description of the physiological state known as "tonic immobility." Tonic immobility is a physiological response to extreme terror and helplessness. The body, via signals sent down the vagal nerve, shuts down. Heart rate, respiration rate, and blood pressure all plummet, and the muscles cease functioning. According to a trauma expert who evaluated Mr. Gray, it is extremely likely that Mr. Gray experienced tonic immobility many times during the rapes he endured as a child, and now re-experiences the terrifying state in his nightmares. To this day, Mr. Gray suffers this nightmare on such a frequent and disabling basis that he needs to have some light in his cell at night, so that if he wakes up in terror, believing that he is still a child and still being raped, he will more quickly be able to ground himself in the present.

61. The VDOC's protocol will mimic this state of paralysis and tonic immobility. This will cause Mr. Gray extreme terror, and play upon one of Mr. Gray's most significant and longstanding fears. Mr. Gray will therefore experience the psychological torture from his nightmare of being harmed while immobilized, a personalized torment that counsels in favor of an alternative method of execution.

II. The VDOC Has at Least One Known and Available Alternative that Significantly Reduces the Substantial Risk of Severe Pain Imposed by Midazolam and the Compounded Three-Drug Protocol: the Firing Squad[3]

A. Execution by Electrocution Is Not a "Known and Available Alternative," Because It Also Carries a Recognized Risk that the Inmate Will Suffer Severe Pain and Is, In Itself, Unconstitutional.

62. As noted above, the Virginia legislature has authorized the VDOC to carry out death sentences by electrocution if the inmate requests it. Va. Code § 53.1-234. This "option," however, is not an option at all: death in the "electric chair" carries with it a recognized risk of severe pain that renders death by electrocution a violation of the Eighth Amendment's prohibition against cruel punishment. The Commonwealth admits as much. As recently stated by Defendant Governor McAuliffe:

> [When Virginia executes people via the electric chair,] we take human beings, we strap them into a chair, and then we flood their bodies with 1,800 volts of electricity, subjecting them to unspeakable pain until they die. . . . Virginia citizens do not want their commonwealth to revert back to a past when excessively inhumane punishments were committed in their name.

L. Vozzella and M. Berman, *In a move that could jeopardize executions, McAuliffe wants to shield the identity of makers of lethal-injection drugs*, Wash. Post, Apr. 11, 2016.

63. Electrocution can inflict gruesome pain and suffering. According to a 1985 description by Justice Brennan, electrocutions remained virtually identical to those conducted more than a century earlier:

[3] Plaintiff focuses here on the available alternative of the firing squad. But it of course is the case that other available alternatives may exist, such as a single-dose lethal injection protocol using barbiturates such as pentobarbital or sodium thiopental, as other states are increasingly adopting. Permitting Mr. Gray the opportunity to seek discovery concerning the method by which the Commonwealth intends to execute him could enable him to determine whether such a "one-drug" protocol could be an option.

> Witnesses routinely report that, when the switch is thrown, the condemned prisoner "cringes," "leaps," and "fights the straps with amazing strength." "The hands turn red, then white, and the cords of the neck stand out like steel bands." The prisoner's limbs, fingers, toes, and face are severely contorted. The force of the electrical current is so powerful that the prisoner's eyeballs sometimes pop out and "rest on [his] cheeks." The prisoner often defecates, urinates, and vomits blood and drool. "The body turns bright red as its temperature rises," and the prisoner's "flesh swells and his skin stretches to the point of breaking." Sometimes the prisoner catches on fire, particularly "if [he] perspires excessively." Witnesses hear a loud and sustained sound "like bacon frying," and "the sickly sweet smell of burning flesh" permeates the chamber. This "smell of frying human flesh in the immediate neighbourhood of the chair is sometimes bad enough to nauseate even the Press representatives who are present." In the meantime, the prisoner almost literally boils: "the temperature in the brain itself approaches the boiling point of water," and when the postelectrocution autopsy is performed "the liver is so hot that doctors have said that it cannot be touched by the human hand." The body frequently is badly burned and disfigured.

Glass v. Louisiana, 471 U.S. 1080, 1086–88 (1985) (Brennan and Marshall, JJ., dissenting from denial of certiorari).

64. Virginia has had at least four botched electrocutions—electrocutions where pain, agony, or grotesque treatment were visible to witnesses—since 1976:

> On August 10, 1982, Frank J. Coppola's head and legs burst into flames. On October 17, 1990, blood poured from Wilbert Lee Evans's eyes and nose and witnesses noted audible moaning and a sizzling sound like a pressure cooker before its top has been taken off. On August 22, 1991, Derick Lynn Peterson moaned audibly as electric current was applied to him, and after two minutes of current and a four minute wait, a prison doctor determined he was still alive; after another four-minute wait, the doctor again announced that he was still alive; finally a second surge of electricity was applied bringing the total length of time for the electrocution over thirteen minutes. A witness to Roger Keith Coleman's May 20, 1992, electrocution reported smoke coming from Coleman's leg. Coleman required two 1,700-volt jolts to die.

M. Shapiro, "State of Electrocution," Va. Lawyer Magazine 32 n.25 (Dec. 2012), *available at* http://www.vsb.org/docs/valawyermagazine/vl1212-electrocution.pdf.

65. Medical evidence shows that electrocution does not render a person instantly unconscious because the amount of electricity that reaches the skull is insufficient to cause complete incapacitation. As electrical currents run through the body, they can cause severe muscle contractions, burned and charred skin, and heart stoppages similar to a heart attack, all of which an inmate will feel as he dies.

66. This execution method is plainly inconsistent with "the evolving standards of decency that mark the progress of a maturing society." *Roper v. Simmons*, 543 U.S. 551, 561 (2005) (quoting *Trop v. Dulles*, 356 U.S. 86, 100–01 (1958) (plurality opinion)). Indeed, as the Supreme Courts of Georgia and Nebraska have held, the pain and suffering caused by electrocutions is a form of cruel and unusual punishment inconsistent with basic notions of human dignity. *State v. Mata*, 745 N.W.2d 229 (Neb. 2008); *Dawson v. State*, 554 S.E.2d 137 (Ga. 2001). No state currently uses electrocution as its primary or only execution method. *See Mata*, 745 N.W.2d at 263.

B. Although the Commonwealth Has Refused to Provide, by Statute, a "Known and Available Alternative" that Passes Constitutional Muster, At Least One Exists: The Firing Squad.

67. The firing squad has been a generally recognized form of punishment in the United States since before the nation's founding. The first recorded firing squad execution took place in 1608, when the colony of Virginia executed George Kendall for conspiring with Spain. Deborah W. Denno, *The Firing Squad as a "Known and Available Method of Execution" Post-Glossip*, 49 U. Mich. J. L. Reform 749, 778 (2016). After the Supreme Court reinstated the death penalty in 1976 following a nine-year hiatus, *see Gregg v. Georgia*, 428 U.S. 153 (1976)

(joint opinion of Stewart, Powell, and Stevens, JJ.), the first executed inmate died at the hands of a five-man firing squad just one year later. Kirk Johnson, *In Utah, Execution Evokes Eras Past*, N.Y. Times, June 16, 2010, *available at* goo.gl/p9D9k3. In all, firing squads have executed 144 American inmates. Denno, *supra* at 778.

68. Two states, Oklahoma and Utah, currently allow for the firing squad. Okla. Stat. tit. 22 § 1014; Utah Code § 77-18-5.5(1)–(4). Under both state statutes, the firing squad can be used only when other execution methods—lethal injection, for example—are held unconstitutional or are otherwise unavailable. *Id*. In 2010, a firing squad executed Utah inmate Ronnie Lee Gardner. *See* Kirk Johnson, *Double Murderer Executed by Firing Squad in Utah*, N.Y. Times, June 18, 2016, *available at* goo.gl/t7BaAu. At least three of Utah's eight death-row inmates are set to die by the firing squad in coming years, having elected death by firing squad under an earlier version of the Utah statute that has since been repealed. Michael Muskal, *Three of Utah's 8 Death Row Inmates Have Chosen Firing Squads*, L.A. Times, Mar. 24, 2015, *available at* goo.gl/Tc65mp.

69. The firing squad is used around the world as a method of execution. Approximately 28 countries conduct firing-squad executions. *See* "Methods of Execution," Cornell Center on the Death Penalty Worldwide (June 22, 2012), *available at* goo.gl/uauqVF. Of the 58 countries that still retain capital punishment, five times as many use firing squads as use lethal injection. *See id.*; *see also* "Death Sentences and Executions: 2015," Amnesty Int'l Global Report, *available at* goo.gl/phBwa0.

70. For more than 400 years, the firing squad has been an available execution method in the United States. Thus, the firing squad is clearly a known execution method.

71. The firing squad is also an available alternative to the VDOC. Upon information and belief, there are numerous people employed by the VDOC who have the training necessary to successfully perform an execution by firing squad. According to the U.S. Department of Justice, Virginia employed 22,848 state and local law-enforcement officers in 2008—roughly 293 officers per 100,000 residents. Bureau of Justice Statistics, "Census of State and Local Law Enforcement Agencies, 2008," U.S. Department of Justice 15 (2011), *available at* goo.gl/Qas08i. It is feasible for the VDOC to find a group of these trained officers to conduct a firing-squad execution. In Utah, for instance, the state invites law-enforcement officers to volunteer for a position on the firing squad. Denno, *supra* at 783 n. 244. "[T]hose from the area where the crime happened" have priority. Brady McCombs, *Firing Squad Gets Final OK. So How Does It Work?*, The Associated Press, Mar. 24, 2015, *available at* goo.gl/fKE5wx. The state then selects five individuals from the volunteer pool. *Id*. Upon information and belief, Utah has never experienced a volunteer shortage. *Id*. The shooters remain anonymous, and one of their rifles "is loaded with a blank round so nobody knows which officer killed the inmate." *Id*.

72. Virginia's large law-enforcement population means, upon information and belief, that the Commonwealth also has the guns and ammunition for a firing-squad execution. Police departments nationwide spend an average of $43,894 each year on guns and $248,940 on ammunition. Police Research Executive Forum, "Police Department Service Weapon Survey" 4 (2013), *available at* goo.gl/bu8a14. The guns and ammunition to arm a five-man firing squad would be but a small fraction of the state's total weapon supplies. The types of firearms needed are neither hard to find nor difficult to use. Utah firing squads, for example, rely on .30 caliber Winchester rifles. McCombs, *supra*. The average police department in the United States owns

212 rifles, and 93 percent of police departments equip some of their officers with a rifle or other assault weapon. Police Research Executive Forum, *supra*, at 2.

73. While Virginia may not yet have permitted the firing squad by state law, nothing in *Glossip v. Gross* requires that the alternative method of execution be expressly permitted by the state's existing execution protocol. 135 S. Ct. 2726, 2796 (2015). Furthermore, requiring that an alternative method be expressly permitted by statute would have the practical effect of allowing the Commonwealth to protect an unconstitutional method of execution from review by revising its execution protocol to prohibit any other alternative, which the Court in *Glossip* did not intend to do.

74. Although the VDOC may not have developed a protocol for carrying out a firing-squad execution, on information and belief, model procedures are available and readily implementable. Utah's firing-squad protocol is instructive. The state follows a simple procedure: First, "[t]he prisoner is seated in a chair that is set up in front of a wood panel and in between stacked sandbags that keep the bullets from ricocheting around the room." McCombs, *supra*. "About twenty or twenty-five feet across from the inmate is the opposite wall with two slit-like openings. The anonymous firing squad members stand behind this wall and put their high-powered guns through the openings." Denno, *supra* at 783–84. Second, "[a] doctor then places a round white target on the inmate's chest." *Id*. at 784. Third, each squad member aims and fires. *Id*. Because "firearms have no purpose *other* than destroying their targets . . . [e]ight or ten large-caliber rifle bullets fired at close range can inflict massive damage, causing instant death every time." *Wood v. Ryan*, 759 F.3d 1076, 1103 (9th Cir. 2014) (reversed on other grounds).

75. The firing squad significantly reduces a substantial risk of severe pain when compared with the midazolam three-drug protocol lethal injection. A study of executions from 1900 to 2010, for example, concluded that while 7.12 percent of the 1,054 lethal-injection executions were "botched," none of the 34 firing-squad executions went awry. *Glossip v. Gross*, 135 S. Ct. 2726, 2796 (2015) (Sotomayor, J., dissenting) (citing A. Sarat, Gruesome Spectacles: Botched Executions and America's Death Penalty 177 (2014)); *see also Wood*, 759 F.3d at 1103 (the firing squad is "foolproof"; lethal injection is "inherently flawed and ultimately doomed to failure."); Denno, *supra* at 781 (A "study of executions from 1976 to 2001 failed to detect any botched firing squad executions, even though other methods, including lethal injection, were consistently problematic." (citing Arif Khan & Robyn M. Leventhal, Medical Aspects of Capital Punishment Executions, 47 J. Forensic Sci. 847, 849–50 (2002))). "Just as important, there is some reason to think that [death by firing squad] is relatively quick and painless." *Glossip*, 135 S. Ct. at 2796 (Sotomayor, J., dissenting). That contrasts sharply with death by lethal injection, which, as shown throughout this Complaint, has caused a number of prolonged and extraordinarily painful executions in recent years.

FIRST CAUSE OF ACTION

Declaratory Judgment re:
Violation of Ricky Gray's Right to be Free from Cruel and Unusual Punishment Under the Eighth and Fourteenth Amendments to the U.S. Constitution

76. Mr. Gray incorporates by reference each and every statement and allegation set forth in this Complaint as if fully stated here.

77. The Eighth Amendment guarantees every person the right to be free from cruel and unusual punishment. Cruel and unusual punishment is inflicted where a method of

execution creates a "substantial risk of serious harm, an objectively intolerable risk of harm . . . ." *Baze v. Rees*, 553 U.S. 35, 50 (2008) (citation and internal quotation marks omitted).

78. Further, the Eighth Amendment requires that state conduct surrounding capital punishment not be arbitrary and capricious, *Furman v. Georgia*, 408 U.S. 238, 255 (1972), and that such conduct comport with "evolving standards of decency that mark the progress of a maturing society," *Roper v. Simmons*, 543 U.S. 551, 561 (2005); *Atkins v. Virginia*, 536 U.S. 304, 312 (2002).

79. The Eighth Amendment is applicable to the states through the Due Process Clause of the Fourteenth Amendment. *Baze*, 553 U.S. at 47.

80. The use of a three-drug lethal injection protocol with compounded midazolam violates the Eighth Amendment's prohibition against cruel and unusual punishment because it does not comport with prevailing standards of decency, and thus its use as a method of execution must be categorically barred.

81. A state may not impose a death sentence upon any inmate using an unconstitutional method of execution. Accordingly, there should be no requirement to plead an alternative method of execution when making a claim, such as this, that a method of punishment is categorically unconstitutional. "Irrespective of the existence of alternatives, there are some risks 'so grave that it violates contemporary standards of decency to expose anyone unwillingly to' them." *Glossip*, 135 S. Ct. at 2793 (Sotomayor, J., dissenting, joined by Ginsburg, J., Breyer, J., and Kagan, J.) (quoting *Helling v. McKinney*, 509 U.S. 25, 36 (1993)).

82. For purposes of this claim, Mr. Gray does not concede there is a way to constitutionally carry out a lethal injection execution that uses a three-drug compounded

midazolam method. Mr. Gray asserts that such an execution is per se unconstitutional. This distinguishes Mr. Gray from the inmate in *Baze*.

83. Therefore, Mr. Gray should not be required to plead or prove any alternative method of execution in order to prevail on this claim. Should the Court nevertheless find that pleading an alternative method is required, however, Mr. Gray incorporates by reference, as if fully set forth here, the alternative methods and procedures proposed in this Complaint.

84. Defendants, acting in their official capacities under color of Virginia law, intend to execute Mr. Gray by injecting him with compounded midazolam as the first drug. This creates a substantial risk of serious harm because, among other reasons, there is a high likelihood that it will fail to render Mr. Gray insensate to the excruciatingly painful and agonizing effects of the second and third drugs in Defendants' three-drug protocol.

85. Moreover, Defendants intend to execute Mr. Gray by injecting drugs made by a compounding pharmacy lacking adequate promises of safety, and the many risks attendant to using a sub-standard compounded drug include that the drug will be sub-potent, expired, or contaminated, or that will contain unintended additives or a substantial level of particulates. Likewise, deficiencies in storing and handling the drugs in compliance with very specific guidelines create the risk that the compounded drugs will expire before they are used.

86. Therefore, the three-drug lethal injection protocol employed by the VDOC does not comport with "evolving standards of decency that mark the progress of a maturing society," as demonstrated by the fact that at least 13 states across the country have adopted or announced that they will adopt a protocol that does not pose the substantial risks of serious harm that are present in the VDOC's three-drug protocol. *See* "State by State Lethal Injection," Death Penalty Information Center, *available at* http://www.deathpenaltyinfo.org/state-lethal-injection.

SECOND CAUSE OF ACTION

Declaratory Judgment re:
Violation of Mr. Gray's Right to Procedural Due Process
Under the Fifth and Fourteenth Amendments to the United States Constitution

87. Mr. Gray incorporates by reference each and every statement and allegation set forth in this Complaint as if fully stated here.

88. The Fifth and Fourteenth Amendments guarantee that "[n]o person…shall be deprived of life, liberty, or property without due process of law." U.S. Const. amend. V (1791); U.S. Const. amend XIV (1868) ("nor shall any State deprive any person of life, liberty, or property, without due process of law"); *see also Adams v. United States ex rel. McCann*, 317 U.S. 269, 276 (1942) ("procedural devices rooted in experience were written into the Bill of Rights not as abstract rubrics in an elegant code but in order to assure fairness and justice before any person could be deprived of 'life, liberty, or property.'").

89. Due process entitles a person whose constitutional rights might be affected by state actions to, at minimum, both notice of those actions and an opportunity to be heard "at a meaningful time and in a meaningful manner." *Fuentes v. Shevin*, 407 U.S. 67, 80 (1972) ("Parties whose rights are to be affected are entitled to be heard; and in order that they may enjoy that right they must first be notified.").

90. Executing Mr. Gray without giving him notice of the procedures to be used to kill him violates his rights under the Fifth and Fourteenth Amendments.

91. The Virginia Attorney General's office has not provided Mr. Gray any information about:

a. the identity or capacity of the compounding pharmacy that made the compounded midazolam and potassium chloride;

b. the credentials of the compounding pharmacy that made the midazolam and potassium chloride or any persons or agents involved in mixing, testing, storing or transferring the chemical mixtures of compounded midazolam and potassium chloride;

c. the exact date that the midazolam and potassium chloride were compounded;

d. the manufacturers of the ingredients used in the compounded midazolam and potassium chloride;

e. the ingredients used to make the preparations, the circumstances under which the preparations were made, or whether these ingredients were manufactured by an FDA-approved registered facility and comply with standards of the United Sates Pharmacopeia;

f. the manner in which the preparations have been stored, handled, and transported since they were compounded;

g. how the Beyond Use Dates were set;

h. a description of the facility at which the drugs were compounded;

i. any inspections or other regulatory enforcement efforts undertaken in connection with the compounding pharmacies; or

j. what information the VDOC obtained about the appropriateness of using compounded midazolam in the execution of inmates sentenced to death in Virginia.

92. By failing to disclose essential information about the lethal injection protocol and effectively preventing Mr. Gray from learning such information directly from the compounding

pharmacy, Defendants have denied Mr. Gray the ability to effectively protect his Eighth Amendment rights and have thwarted his right to judicial review.

93. Through its secrecy statute and its lack of disclosure, the Commonwealth has deliberately prevented Mr. Gray from learning crucial information about his impending execution, thus denying him the ability to review and challenge the protocol pursuant to his due process rights under the Fifth and Fourteenth Amendments.

REQUEST FOR RELIEF

WHEREFORE Mr. Gray respectfully requests that this Court grant the following relief:

(a) Temporary, preliminary, and permanent injunctive relief by enjoining the Defendants from executing Mr. Gray with inadequate anesthesia in the form of compounded midazolam and using unsafe compounding methods in their execution procedures that violate his right to be free from cruel and unusual punishment under the Eighth Amendment, as applied to the states via the Fourteenth Amendment;

(b) Temporary, preliminary, and permanent injunctive relief by enjoining the Defendants from enforcing Virginia's statutory prohibition on producing discovery in this civil proceeding concerning the source of the compounded drugs to be used in an execution, Va. Code § 53.1-234;

(c) Issuance of an Order declaring unconstitutional the Defendants' lethal-injection protocols and procedures, as a violation of Mr. Gray's right to be free from cruel and unusual punishment under the Eighth Amendment, as applied to the states via the Fourteenth Amendment, and the right to equal protection under the Fourteenth Amendment;

(d) Issuance of an Order declaring unconstitutional under the Fifth and Fourteenth Amendments of the United States Constitution, Virginia's statutory prohibition on producing

discovery in this civil proceeding concerning the source of the compounded drugs to be used in an execution, Va. Code § 53.1-234;

(e) An award of costs, including reasonable attorney's fees, pursuant to 42 U.S.C. § 1988; and

(f) Such other and further relief as this Court may deem just and appropriate.

Dated: December 14, 2016

Respectfully submitted,

HOGAN LOVELLS US LLP

By: /s/ Haley K. Costello Essig

Haley K. Costello Essig (Bar # 85541)
Park Place II, Ninth Floor
7930 Jones Branch Drive
McLean, Virginia 22102
Tel: (703) 610-6100
Fax: (703) 610-6200
E-mail: haley.essig@hoganlovells.com

Lisa J. Fried
Nathaniel S. Boyer
875 Third Avenue
New York, New York 10022
Tel: (212) 918-3000
Fax: (212) 918-3100
E-mail: lisa.fried@hoganlovells.com
E-mail: nathaniel.boyer@hoganlovells.com
Pro Hac Vice Applications Forthcoming

Counsel for Plaintiff Ricky Jovan Gray