



COMMONWEALTH of VIRGINIA

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The Honorable Jackson H. Miller
Member, House of Delegates
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The Honorable Marcus B. Simon
Member, House of Delegates
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The Honorable Scott A. Surovell
Member, Senate of Virginia
Post Office Box 289
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Gentlemen:

I am responding to your requests for an official advisory opinion in accordance with § 2.2-505 of the *Code of Virginia*. Considering the time-sensitive nature of the requests submitted, I have consolidated my response into a single opinion.

Issues Presented

You have presented questions concerning the constitutionality and applicability of the Governor's Amendment in the Nature of a Substitute ("Substitute") to House Bill 815 (H.B. 815), currently pending before the General Assembly. Questions related to the process by which the Commonwealth carries out a court-imposed sentence of death are of extraordinary importance, as this is among the most solemn and consequential powers exercised by the state.

Specifically, Delegate Miller has asked the following:

1. Whether state or federal law prohibits the Commonwealth from obtaining lethal-injection drugs from a compounding pharmacy;
2. Whether state or federal law prohibits a compounding pharmacy from selling lethal-injection drugs to the Commonwealth of Virginia; and
3. Whether state or federal law prohibits the Commonwealth from using compounded drugs in the lethal-injection process.

Senator Surovell and Delegate Simon, in a combined request, have asked the following questions:

1. Whether the proposed limitation on the discoverability of the identities of compounding pharmacies and their employees violates a habeas petitioner's right to gather evidence;
2. Whether any Virginia law prohibits the Department of Corrections from studying alternative lethal-injection protocols;
3. Whether any Virginia law prohibits the Department of Corrections from adopting a one-drug or other alternate protocol;
4. Whether any Virginia law prohibits the Department of Corrections from delaying executions until the 2017 General Assembly session;
5. Whether the Commonwealth of Virginia, or any of its employees, faces potential liability for using lethal-injection drugs "in violation of manufacturers' instructions"; and
6. Whether a compounding pharmacy would violate federal law if it provided drugs for a lethal injection in accordance with the Substitute, and whether Virginia government officials might be subject to federal prosecution if they possessed drugs compounded for use in the lethal-injection process.

The sixth question posed by Senator Surovell and Delegate Simon is nearly identical in substance to the questions posed by Delegate Miller. For that reason, I will subsume my response to this sixth question in my response to Delegate Miller's requests.

Background

At the threshold, it is necessary to acknowledge the framework in which these questions arise. The United States Supreme Court recently reaffirmed that "capital punishment is constitutional."¹ That being so, "there must be a [constitutional] means of carrying it out."² Thus, the United States Supreme Court has confirmed the constitutional validity of execution by lethal injection.³

Within that framework, Virginia's basic lethal injection protocol also has been upheld against constitutional challenges.⁴ Similarly, the use of compounded drugs in the lethal injection process has been upheld as constitutional.⁵ It is now well-recognized, however, that the Commonwealth of Virginia has faced increased difficulty in obtaining the drugs needed for use in an execution by lethal injection.⁶

¹ *Glossip v. Gross*, 135 S. Ct. 2726, 2732-33, (2015). *See also* *Baze v. Rees*, 553 U.S. 35, 47 (2008).

² *Glossip*, 135 S. Ct. at 2728.

³ *Id.* at 2736-37; *Baze*, 553 U.S. at 50. In fact, the Supreme Court "has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment." *Glossip*, 135 S. Ct. at 2732.

⁴ *See* *Emmett v. Johnson*, 532 F.3d 291 (4th Cir. 2008); *see also* *Walker v. Johnson*, 328 F. App'x 237 (4th Cir. 2009).

⁵ *See, e.g.,* *Zink v. Lombardi*, 783 F.3d 1089, 1101 (8th Cir.), *cert. denied*, 135 S. Ct. 2941 (2015); *Ladd v. Livingston*, 777 F.3d 286, 289 (5th Cir.), *cert. denied*, 125 S. Ct. 1197 (2015); *Wellons v. Comm'r, Ga. Dep't of Corr.*, 754 F.3d 1260, 1265 (11th Cir. 2014); *Whitaker v. Livingston*, 732 F.3d 465, 468 (5th Cir. 2013); *Prieto v. Clarke*, No. 3:15cv587, 2015 U.S. Dist. LEXIS 134622 (E.D. Va. Oct. 1, 2015).

⁶ *See, e.g.,* *Prieto v. Clarke*, No. 3:15cv587, 2015 U.S. Dist. LEXIS 134622, at *3-4 (E.D. Va. Oct. 1, 2015).

The 2016 General Assembly passed legislation that would have made electrocution a permissible default method of execution if lethal injection drugs were unavailable. Specifically, as enrolled, H.B. 815 would have added the following language to § 53.1-234 of the *Code of Virginia*:

If the Director certifies that the method of execution chosen by the prisoner or set forth in this section is not available for any reason, the remaining method of execution shall be employed, provided that the Director shall not certify that execution by lethal injection is not available unless the Director has made reasonable efforts to procure such lethal substances.

The Governor, upon review of the bill, removed this language and returned the Substitute to the General Assembly, inserting the following language:

The Director may make and enter into contracts with a pharmacy, as defined in § 54.1-3300, or outsourcing facility, as defined in § 54.1-3401, for the compounding of drugs necessary to carry out an execution by lethal injection. Any such drugs provided to the Department pursuant to the terms of such a contract shall be used only for the purpose of carrying out an execution by lethal injection. The compounding of such drugs pursuant to the terms of such a contract (i) shall not constitute the practice of pharmacy as defined in § 54.1-3300; (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 Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 and the Drug Control Act (§ 54.1-3400 et seq.). The pharmacy or outsourcing facility providing such drugs to the Department pursuant to the terms of such a contract shall label each such drug with the drug name, its quantity, a projected expiration date for the drug, and a statement that the drug shall be used only by the Department for the purpose of carrying out an execution by lethal injection.

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, including their names, residential and office addresses, residential and office telephone numbers, social security numbers, and tax identification numbers, shall be confidential, shall be exempt from the Freedom of Information Act (§ 2.2-3700 et seq.), and shall not be subject to discovery or introduction as evidence in any civil proceeding unless good cause is shown.

The General Assembly is scheduled to convene on April 20, 2016, to discuss and take possible action on the Substitute.

Applicable Law and Discussion

1. Whether the manufacture, sale, and use of compounded drugs for an execution by lethal injection would violate state or federal law.

The language of the Substitute removes the lethal injection process, as well as the lethal injection drug procurement procedure, from regulation by the Virginia Board of Pharmacy, the Virginia Board of Medicine, the Virginia Department of Health Professions, and from the provisions of the Virginia Drug

Control Act. Thus, the Substitute exempts an individual, acting in accordance with its language, from regulation under the identified statutes.

If federal statutory law applies at all to the production, purchase, and use of compounded drugs for use in lethal injections, the two relevant statutes are the Food, Drug, and Cosmetic Act (“FDCA”),⁷ and the Controlled Substances Act.⁸ Although the discussion below includes a detailed analysis of both statutes, note that the Food and Drug Administration (“FDA”), the agency charged with implementing both statutes, has concluded that it lacks clear regulatory authority over the use of drugs for purposes of conducting executions, and courts will likely be constrained to defer to the FDA’s reasonable construction. Even if the FDA were to change that position, however, it is my opinion that the conduct authorized by the Substitute would not violate these federal laws for the reasons set forth below.

a. The Food, Drug, and Cosmetic Act

The core mission of the FDA is to “promote the public health by promptly and efficiently reviewing clinical research” and to “protect the public health by ensuring that . . . [human] drugs are safe and effective.”⁹ The primary enabling legislation for the FDA is the FDCA, which requires that drugs distributed in interstate commerce be approved by the FDA for specific uses.¹⁰ To obtain FDA approval, drug manufacturers are required to demonstrate, through clinical trials, the safety and efficacy of a new drug for each intended use.¹¹

In accordance with the FDA’s public-safety mission, the FDCA makes it unlawful to introduce into interstate commerce a “misbranded” drug¹² or an unapproved “new drug.”¹³ An “unapproved new drug” is one that is neither “generally recognized, among experts . . . as safe and effective” for its labeled use,¹⁴ nor approved by the FDA as safe and effective for its proposed use.¹⁵ Also, § 353(b)(1) of the FDCA prohibits the dispensation of certain Schedule II, III, IV, or V controlled drugs without a prescription.¹⁶

Actions brought for violations of the FDCA are, with certain limited exceptions, exclusively within the purview of the federal government.¹⁷ For this reason, the “FDCA leaves no doubt that it is the

⁷ 21 U.S.C. §§ 301 to 399f.

⁸ 21 U.S.C. §§ 801 to 971.

⁹ 21 U.S.C. § 393(b).

¹⁰ 21 U.S.C. § 355(a).

¹¹ 21 U.S.C. § 355(d); *see also* *Weinberger v. Hynson*, 412 U.S. 609, 612-14 (1973).

¹² 21 U.S.C. § 331(a).

¹³ 21 U.S.C. §§ 355(a) & 331(d).

¹⁴ 21 U.S.C. § 321(p)(1).

¹⁵ 21 U.S.C. § 355(d).

¹⁶ 21 U.S.C. § 353(b)(1); *see also* 21 C.F.R. § 290.1 (“Any drug that is a controlled substance listed in schedule II, III, IV, or V . . . must be dispensed by prescription only as required by section 503(b)(1) of the Federal Food, Drug and Cosmetic Act . . .”). The regulations also set forth a procedure through which a prescription exemption may be obtained. *See* 21 C.F.R. § 310.200(b).

¹⁷ 21 U.S.C. § 337.

Federal Government rather than private litigants who are authorized to file suit for noncompliance.”¹⁸ Private litigants therefore lack standing to assert a claim under the Act.¹⁹

As pertinent here, the questions posed by the Substitute are: (1) whether the preparation, sale, or use of a lethal-injection drug by a compounding pharmacy would implicate or violate the “new drug” restrictions of the FDCA, and (2) whether dispensing a lethal-injection substance without a prescription violates § 353(b)(1) of the Act.

“Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient.”²⁰ Compounding “is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools.”²¹ Most states specifically regulate compounding practices “as part of their regulation of pharmacies.”²² Thus, “[f]or approximately the first 50 years after the enactment of the FDCA, the FDA generally left regulation of compounding to the States,” and “[p]harmacists continued to provide patients with compounded drugs without applying for FDA approval of those drugs.”²³

“The FDA eventually became concerned, however, that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby avoiding the FDCA’s new drug requirements.”²⁴ The FDA grappled with the question of whether, “[w]hen a pharmacist creates a compounded medication to suit an individual patient,” that “resulting creation constitutes a ‘new drug’ requiring FDA approval.”²⁵ Although the definition of “new drug” seemingly encompassed a compounded substance, “[i]f each individualized drug product produced through compounding required FDA approval, few would undergo the costly and arduous approval process,” and that lack of approval “would in turn make nearly all compounding unlawful under the FDCA.”²⁶

In 1997, Congress reacted to this concern by enacting the Food and Drug Administration Modernization Act,²⁷ and, subsequently, the Drug Quality and Security Act of 2013.²⁸ This legislation established exemptions from new drug approval requirements for certain compounding pharmacies and “outsourcing facilities,” the latter of which, if they meet certain statutory requirements, are permitted to compound substances for general distribution and not necessarily pursuant to a prescription for an “identified individual patient[.]”²⁹

¹⁸ *Buckman Co. v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 349 (2001).

¹⁹ *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (holding that an FDA administrative decision regarding enforcement of the FDCA was not judicially reviewable because the Act’s enforcement provisions “commit complete discretion to the Secretary to decide how and when they should be exercised”).

²⁰ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002).

²¹ *Id.* at 361.

²² *Id.*

²³ *Id.* at 362.

²⁴ *Id.*

²⁵ *Med. Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 389 (5th Cir. 2008).

²⁶ *Id.*

²⁷ 111 Stat. 2328 (codified at 21 U.S.C. § 353a).

²⁸ 127 Stat. 587 (codified at 21 U.S.C. § 353b).

²⁹ 21 U.S.C. § 353b(d)(4)(C).

Following these statutory amendments, the generally accepted view is that, “[t]hough compounded drugs are ‘new drugs,’ they are neither *uniformly* exempt from the new drug approval requirements nor *uniformly* subject to them.”³⁰ “Properly construed, the statutory scheme . . . creates a limited exemption from the new drug approval requirements for compounded drugs that comply with conditions explicitly delineated in [the Act].”³¹

The compounding exemption established by § 353a of the FDCA applies if: (1) the compounded substance is prepared by a licensed individual in response to a valid prescription, or, if prepared before receipt of a prescription, is made only in “limited quantities” and based upon a preexisting relationship between the parties; (2) the compounded substance is made from approved ingredients that meet manufacturing and safety standards, and the substance does not appear on an FDA list of drug products found to be unsafe or ineffective; (3) the individual compounding the drug does not “compound regularly or in inordinate amounts . . . any drug products that are essentially copies of a commercially available drug product”; (4) the compounded substance is not identified by the FDA as a drug product that presents demonstrable difficulties for compounding in terms of safety or effectiveness; and (5) for States that have not entered into a memorandum of understanding with the FDA, the compounding entity or individual does not distribute compounded drugs out of state in quantities exceeding five percent of the total prescription orders.³²

The only prerequisite not satisfied by the facial provisions of the Substitute is the first—whether preparation and purchase of a compounded substance, absent a prescription, would remove that preparation from the compounding exemption in § 353a, thereby triggering the “new drug” restrictions codified elsewhere in the Act. The resolution of the two questions presented by the FDCA therefore result in a single inquiry: does the preparation, purchase, and use of a compounded substance, prepared for purposes of lethal injection, violate the FDCA if obtained in the absence of a valid prescription?

In my opinion, courts would likely answer this question in the negative. First, no court has ever invalidated a state’s lethal injection protocol or drug procurement on the grounds that the substances to be used were obtained without a prescription.³³ Second, it is settled law that use of drugs in the lethal injection context does not constitute the practice of medicine,³⁴ rendering a prescription both unnecessary

³⁰ *Med. Ctr. Pharm.*, 536 F.3d at 394 (emphasis in original).

³¹ *Id.*; see also *id.* at 406 (“If and only if the compounded drugs satisfy § 353a’s conditions, those drugs are exempt from the requirements of §§ 351(a)(2)(B), 352(f)(1), and 355.”).

³² 21 U.S.C. § 353a; see also *Med. Ctr. Pharm.*, 536 F.3d at 402-03 (discussing *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 364-65 (2002)).

³³ However, one court has held that the FDCA prohibits state departments of corrections from importing lethal injection substances from a foreign country, where the company selling the substance was not registered with the FDA and, therefore, the imports were “misbranded.” See *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). This case dealt with the restrictions on importing foreign drugs, rather than the compounding or domestic procurement of lethal injection substances from a duly-registered entity.

³⁴ See VA. CODE ANN. § 54.1-3300 (2013) (defining “practice of pharmacy” as “the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease”); VA. CODE ANN. § 54.1-2900 (Supp. 2015) (defining “practice of medicine” as “the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities”); *Shapiro v. Dep’t of Corr.*, No. CL12-1894-03 (Richmond Cir. Ct. Sept. 21, 2012) (“[T]he Court rules that execution by lethal injection by the Commonwealth of Virginia is not the regulated practice of medicine, pharmacy, or anesthesiology.”), *appeal refused*, Record No. 122176 (Va. Apr. 23, 2013); see also *Emmett v.*

and unavailable.³⁵ Third, concluding that the procurement process for lethal-injection drugs violates the FDCA because those drugs were obtained without a prescription would, functionally, invalidate the lethal injection process itself, a method-of-execution employed by approximately thirty-three states and the federal government.³⁶ There is no indication that Congress intended the FDCA to be applied to constructively abolish the process of execution by lethal injection, particularly given that the federal government has, itself, adopted lethal injection as the accepted method of execution.³⁷

Fourth, applying the FDCA as a bar to the preparation, purchase, and use of lethal-injection substances would not further the purposes of that Act. “[W]ith an emphasis on trade regulation, the FDCA’s main purpose is to ‘prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices and cosmetics’” in the interest of public health and safety.³⁸ To effectuate this purpose, “the Act generally requires the FDA to prevent the marketing of any drug or device where the ‘potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.’”³⁹ The public health and safety purposes underlying the FDCA are by their very nature inapposite to the purchase and use of drugs for capital punishment.⁴⁰ For this reason, a court would likely hold that the compounding of lethal injection drugs falls outside the scope of subject matter that the FDA has authority to regulate under the FDCA.⁴¹

Johnson, 511 F. Supp. 2d 634, 642 (E.D. Va. 2007) (“[S]urgery and execution have the polar opposite medical objectives.”); Walker v. Johnson, 448 F. Supp. 2d 719, 723 (E.D. Va. 2006) (“An execution by lethal injection is not a medical procedure and does not require the same standard of care as one.”); Abdur’Rahman v. Bredesen, 181 S.W.3d 292, 313 (Tenn. 2005) (holding that, because the lethal injection process did not involve the practice of medicine, “the lethal injection protocol falls outside of licensing statutes applicable to physicians and healthcare providers”).

³⁵ See 21 C.F.R. § 1306.04(a) (“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”).

³⁶ See 28 C.F.R. § 26.3(a)(4); see also *Implementation of Death Sentences in Federal Cases*, 58 Fed. Reg. 4898 (Jan. 19, 1993).

³⁷ See *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) (“[I]nterpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available.”).

³⁸ *State v. Deputy*, A.2d 411, 419 (Del. Super. Ct. 1994) (quoting *U.S. v. 1851 Cartons*, 146 F.2d 760, 761 (10th Cir. 1945)), *aff’d*, 1994 Del. LEXIS 203 (June 21, 1994).

³⁹ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quoting *United States v. Rutherford*, 442 U.S. 544, 556 (1979)).

⁴⁰ See, e.g., *Deputy*, A.2d at 419 (“The Court is unaware of any judicial authority construing either the DAPCA or FDCA’s purpose to include the prevention of lawful executions of inmates.”); see also *Chaney v. Heckler*, 718 F.2d 1174, 1200 (D.C. Cir. 1983) (Scalia, J., dissenting) (opining that the FDA’s refusal to regulate lethal injection drugs likely stemmed from the agency’s “proper[] refus[al] to permit its powers and the laws it is charged with enforcing from being wrongfully enlisted in a cause that has less to do with assuring safe and effective drugs than with preventing the states’ constitutionally permissible imposition of capital punishment”), *rev’d*, 470 U.S. 821 (1985).

⁴¹ See, e.g., *Brown & Williamson*, 529 U.S. at 140-43 (concluding that the FDA lacked authority to regulate cigarettes under the FDCA because, in order for an item to fall within the purview of the agency, “the FDA must determine that there is a reasonable assurance that the product’s therapeutic benefits outweigh the risk of harm to the consumer,” and, “if tobacco products were within the FDA’s jurisdiction, the Act would require the FDA to remove them from the market entirely,” an action that would contradict other provisions of federal law); see also *Abdur’Rahman v. Bredesen*, 181 S.W.3d 292, 313 (Tenn. 2005) (“[T]he Drug Control Act and the Pharmacy Practice Act were designed to prevent the illegal sale or distribution of controlled substances and to provide a

Fifth, the FDA has, itself, disclaimed any intent to regulate or approve substances for use in lethal injection. In *Heckler v. Chaney*,⁴² a group of death row inmates unsuccessfully challenged the FDA's refusal to enforce the FDCA against states obtaining lethal injection drugs for use in executions. The Court held that the FDA's decision not to take enforcement action was not subject to judicial review under the Administrative Procedure Act.⁴³ Although the Court focused on the unreviewable nature of the agency's decision not to act, it also acknowledged the FDA Commissioner's statement that, even if the FDA had jurisdiction in the area of regulating lethal injection drugs, the agency would decline to exercise that authority. Specifically, the Commissioner stated that enforcement proceedings "are initiated only when there is a serious danger to the public health or a blatant scheme to defraud," and "those dangers are [not] present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions"⁴⁴

Because *Heckler* was decided on other grounds, the Court did not need to decide what it called "the thorny question of the FDA's jurisdiction."⁴⁵ Notably, however, the FDA took the position in *Heckler* that "FDA jurisdiction in the area was generally unclear but in any event *should not be exercised to interfere with this particular aspect of state criminal justice systems.*"⁴⁶ The *Heckler* suit was filed in 1980 and decided in 1985. For the past 36 years, the FDA has consistently declined to regulate or act in this area. Considering the long-standing interpretation of its agency mission, it is unlikely that the FDA could—or would—assert regulatory authority over the compounding of drugs for use in lethal injections. Indeed, courts generally defer to an agency's reasonable interpretation of the scope of its authority.⁴⁷

Finally, the Act does not appear to provide any enforcement mechanism against a state government or agency. That is, the civil and criminal penalties established in the FDCA are directed against any "person" who violates the terms of the Act.⁴⁸ The term "person" is statutorily defined as "an individual, partnership, corporation, and association,"⁴⁹ and does not, by its language, encompass any branch of state government. Considering this absence of remedies, the general directives of the FDCA may not apply to state—as opposed to private—action.⁵⁰

system for drug abuse control. These purposes would not be served or advanced by a strained interpretation making them applicable to the lethal injection statutes or to the lethal injection protocol.").

⁴² 470 U.S. 821 (1985).

⁴³ *Id.* at 837-38.

⁴⁴ *Id.* at 824-25; *see also* *Ringo v. Lombardi*, No. 2:09cv04095, 2011 U.S. Dist. LEXIS 90679, at *16 (W.D. Mo. Aug. 15, 2011) ("The FDA has expressed the position that it does not regulate or approve chemicals for use in executions by lethal injections."), *vacated as moot*, 677 F.3d 793 (8th Cir. 2012).

⁴⁵ *Heckler*, 470 U.S. at 828.

⁴⁶ *Id.* at 824 (emphasis added).

⁴⁷ *See generally* *City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013).

⁴⁸ 21 U.S.C. § 333(a).

⁴⁹ 21 U.S.C. § 321(e).

⁵⁰ *See, e.g.,* *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208-09 (1998) ("Absent an unmistakably clear expression of intent to alter the usual constitutional balance between the States and the Federal Government, we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers."); *Dellmuth v. Muth*, 491 U.S. 223, 227-28 (1989) ("To temper Congress' acknowledged powers of abrogation with due concern for the Eleventh Amendment's rule as an essential component of our constitutional structure, we have applied a simple but stringent test: Congress may abrogate the States' constitutionally secured immunity from suit in federal court only by making its intention unmistakably clear in the language of the statute." (internal quotations omitted)).

Weighing these considerations, it is my opinion that a compounding pharmacy would not violate the FDCA by dispensing a compounded drug to the Virginia Department of Corrections without a prescription—but in accordance with state law—for use in the lethal injection process. It is also my opinion that the Virginia Department of Corrections would not violate the FDCA by purchasing a compounded drug for use in a lethal injection, as this is a matter that falls outside the scope and purpose of the federal act.

b. The Controlled Substances Act

The second federal statute potentially implicated by the Substitute is the Controlled Substances Act (“CSA”).⁵¹ “The stated purpose of the CSA is to provide increased research into, and prevention of, drug abuse and drug dependence . . . and to strengthen existing law enforcement authority in the field of drug abuse.”⁵² To facilitate this aim, “the CSA creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act’s five schedules.”⁵³

Under the CSA, “it is unlawful to prescribe or dispense controlled substances without a federal registration.”⁵⁴ Upon registration, the individual or entity is “authorized to possess, manufacture, distribute, or dispense [controlled] substances or chemicals . . . to the extent authorized by their registration.”⁵⁵

The Virginia Department of Corrections possesses a Controlled Substance Registration Certificate from the Drug Enforcement Agency. For this reason, the Department’s possession or dispensation of controlled substances, obtained from a compounding pharmacy for lethal injection purposes, would not violate the registration requirement of the CSA.

As with the FDCA, the CSA also prohibits the dispensation of Schedule II, III, IV, and V controlled substances without the written prescription of a practitioner.⁵⁶ Accordingly, the remaining inquiry is whether the procurement of a lethal injection drug from a compounding pharmacy, absent a prescription, would violate the CSA.

For the same reasons discussed above, it is my opinion that the dispensing of lethal injection drugs, without a prescription, would not violate the CSA. “The CSA expressly limits federal authority under the Act to the ‘field of drug abuse.’”⁵⁷ For this reason, “[v]iewed in context, the prescription requirement is better understood as a provision that ensures patients use controlled substances under the

⁵¹ 21 U.S.C. §§ 801 to 971.

⁵² *Oregon v. Ashcroft*, 368 F.3d 1118, 1121 (9th Cir. 2004) (internal quotations omitted), *aff’d sub nom* *Gonzales v. Oregon*, 546 U.S. 243 (2006); *see also* 21 U.S.C. § 801.

⁵³ *Gonzales*, 546 U.S. at 250.

⁵⁴ *Ashcroft*, 368 F.3d at 1121; *see also* 21 U.S.C. § 841(a)(1), § 823(f), § 822(a)(2).

⁵⁵ 21 U.S.C. § 822(b).

⁵⁶ 21 U.S.C. § 829; *see also* 21 C.F.R. § 1306.11.

⁵⁷ *Ashcroft*, 368 F.3d at 1125-26 (striking down a directive declaring that a physician who wrote a prescription for lethal substances for the purposes of physician-assisted suicide was in violation of the CSA, reasoning that “physician assisted suicide is not a form of drug ‘abuse’ that Congress intended the CSA to cover,” but is, instead, “an unrelated, general medical practice to be regulated by state lawmakers in the first instance”).

supervision of a doctor so as to prevent addiction and recreational abuse,” and, “[a]s a corollary, . . . also bars doctors from peddling to patients who crave the drugs for those prohibited purposes.”⁵⁸

Applying the CSA’s prescription provision to bar a state agency from obtaining lethal injection drugs would advance none of these statutory objectives.⁵⁹ As with the FDCA, it would also produce the incongruous result of eliminating the federal government’s ability to procure lethal injection substances for its own use. Moreover, “[t]he CSA explicitly contemplates a role for the States in regulating controlled substances.”⁶⁰ Here, state law would expressly permit the procurement of a controlled substance, by a state agency, for use in a lethal injection.⁶¹

Because there is no indication in the language or purpose of the CSA that Congress intended for this Act to apply to state agencies in the process of obtaining lethal injection drugs, it is my opinion that the prescription-requirement provisions of the CSA do not apply in this context. Accordingly, persons or entities acting in accordance with the Substitute would not violate the CSA.

2. Whether the restrictions on discovery implicate a habeas petitioner’s “right” to gather evidence.

In a separate request, Senator Surovell and Delegate Simon have asked whether the Substitute’s provisions protecting the identity of the compounding pharmacy or outsourcing facility, its officers and employees, and the supply sources it employs would violate a habeas petitioner’s right to gather evidence. It is my opinion that the language of the Substitute does not violate any constitutional protection or other federal law and it is, therefore, for the General Assembly to decide whether such limitations on disclosure are in the public interest.

The language of the Substitute permits a would-be litigant to discover, and make use of, the names of the drugs that would be used in an execution by lethal injection, as well as the protocol under which those drugs would be administered.

To clarify, however, a suit challenging the manner in which an individual is to be executed does not challenge the validity of the underlying conviction or sentence. As such, a method-of-execution suit is not a habeas corpus proceeding.⁶² As the U.S. Supreme Court recently confirmed, “a method-of-execution claim must be brought under § 1983 because such a claim does not attack the validity of the prisoner’s conviction or death sentence.”⁶³ Accordingly, a prospective method-of-execution suit would

⁵⁸ *Gonzales*, 546 U.S. at 274.

⁵⁹ See *Zink v. Lombardi*, No. 2:12cv4209, 2013 U.S. Dist. LEXIS 175467, at *17 (W.D. Mo. Dec. 11, 2013) (“[The inmate] has failed to establish a likelihood that the ‘medically legitimate purpose’ requirement of the FDAC and CSA was intended to control a state’s interest in carrying out executions by the administration of lethal drugs.”).

⁶⁰ *Gonzales*, 546 U.S. at 251.

⁶¹ See generally *id.* at 270 (“Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate [state practice] generally. The silence is understandable given the structure and limitations of federalism . . .”).

⁶² Even if some aspect of a method-of-execution challenge might be cognizable in a habeas proceeding, “habeas corpus is a civil and not a criminal proceeding.” *Smyth v. Godwin*, 188 Va. 753, 760 (1949).

⁶³ *Glossip v. Gross*, 135 S. Ct. 2726, 2738 (2015); see also *Hill v. McDonough*, 547 U.S. 573 (2006); *Nelson v. Campbell*, 541 U.S. 637 (2004); *Emmett v. Johnson*, 532 F.3d 291, 297 (4th Cir. 2008) (“Challenges to execution

be appropriately filed as a civil rights action under 42 U.S.C. § 1983.⁶⁴ With respect to your particular question regarding habeas corpus proceedings, the Substitute's "good cause" requirement is congruent with the federal rules governing federal habeas corpus proceedings, which already require a showing of "good cause" before any discovery is permitted.⁶⁵

Upon a showing of good cause, a judge presiding over either civil proceeding has the authority and discretion to fashion appropriate safeguards to allow for access to relevant information by party litigants.⁶⁶ It is, therefore, my opinion that enactment of the Substitute would not impermissibly obstruct a civil litigant's ability to discover evidence for purposes of challenging the legality of the manner of a prospective execution.⁶⁷

3. Whether the Virginia Department of Corrections is prohibited from studying or adopting alternate lethal-injection protocols.

Senator Surovell and Delegate Simon, have also asked two separate, but related questions: (1) whether there are "any provisions of Virginia law prohibiting the Department of Corrections from studying alternative drug[] protocols pending further executions," and (2) whether "there are any provision[s] of Virginia law prohibiting a one-drug protocol or adopting an alternate protocol to the one presently utilized." The answer to both questions is no.

Under Code § 53.1-234, "[e]xecution by lethal injection shall be permitted in accordance with procedures developed by the Department [of Corrections]."⁶⁸ There are no further statutory or administrative code provisions that govern the consideration or adoption of alternative lethal-injection drugs or alternative lethal-injection protocols. Because development of the lethal-injection protocol is committed to the discretion of the Director of the Virginia Department of Corrections, there is no statutory bar to the consideration or adoption of alternative lethal-injection drugs or protocols.⁶⁹

procedures are properly raised by condemned inmates under § 1983."); *Reid v. Johnson*, 333 F. Supp. 2d 543, 545 (E.D. Va. 2004).

⁶⁴ See, e.g., *Prieto v. Clarke*, No. 3:15cv587, 2015 U.S. Dist. LEXIS 134622 (E.D. Va. Oct. 1, 2015) (lethal injection challenge filed under 42 U.S.C. § 1983); *Walker v. Johnson*, 448 F. Supp. 2d 719 (E.D. Va. 2006) (same); *Lenz v. Johnson*, 443 F. Supp. 2d 785 (E.D. Va. 2006) (same).

⁶⁵ See Rule 9, RULES GOVERNING SECTION 2254 CASES IN THE U.S. DIST. COURTS.

⁶⁶ FED. R. CIV. PRO. 26c.

⁶⁷ See *West v. Schofield*, 460 S.W.3d 113, 125 (Tenn. 2015) (plaintiff seeking relief under 42 U.S.C. § 1983) ("[T]here is neither a statutory nor a constitutional barrier to the adoption of a common-law privilege that would prohibit the disclosure in civil litigation of the identities of those persons involved in the execution of condemned inmates."); see also *Owens v. Hill*, 758 S.E.2d 794 (Ga. 2014) (holding that a state statute shielding the identities of persons and entities involved in executions, including the drug manufacturers, did not violate any provision of the state or federal constitution), *cert. denied*, 135 S. Ct. 449 (2014); 2015 Op. S.C. Att'y Gen. LEXIS 62 (July 27, 2015) (discussing the state's interest in the anonymity of members of execution teams, including suppliers of lethal injection compounds).

⁶⁸ VA. CODE ANN. § 53.1-234; see also *Emmett*, 532 F.3d at 293 ("[T]he statutory scheme leaves the development and implementation of the specific procedures for lethal injection to the discretion of the Director and those he appoints to assist him."); 1994 Op. Va. Att'y Gen. 81 (discussing, generally, the 1994 amendments to Code § 53.1-234, and concluding that the alterations did not violate the *ex post facto* clauses of the Virginia and federal constitutions).

⁶⁹ This opinion does not address whether there are any policies or procedures adopted by the Department of Corrections that might govern whether and when alterations to the lethal-injection protocol should be considered or implemented.

Furthermore, the Department of Corrections does study alternative drug protocols. In fact, the Department of Corrections has changed its protocol twice, once in 2011 and again in 2014, to permit the use of a different first chemical as the chemicals have become unavailable. The Department of Corrections actively monitors the other states and the federal government with regard to how each implements the death penalty.

4. Whether the Department of Corrections may postpone executions until the 2017 General Assembly Session.

Senator Surovell and Delegate Simon have also asked whether “there is any provision of Virginia law which would prohibit the Department of Corrections from delaying executions until the General Assembly has time to meet next year to gather more information and further study this issue.” Because the Department of Corrections has no authority to schedule or postpone executions, it is my opinion that Virginia law prohibits the Department of Corrections from unilaterally delaying executions for any reason, or for any period of time.

Under Code § 53.1-232, the sentencing court is vested with the sole authority to “fix a day when the execution shall occur.”⁷⁰ The sentencing court sets the execution date “when it is notified in writing by the Attorney General or the attorney for the Commonwealth” that at least one of four procedural requirements has been met.⁷¹ Within ten days following receipt of the written notification, “[t]he trial court shall conduct a proceeding to set the [execution] date,” which “shall be no later than sixty days after the date of the proceeding.”⁷² And, “[o]nce an execution date is scheduled, a stay of execution may be granted by the trial court or the Supreme Court of Virginia only upon a showing of substantial grounds for habeas corpus relief.”⁷³

Because the Department of Corrections cannot exercise authority it does not have, the Department cannot “delay[] executions until the General Assembly has time to meet next year.”

5. Would the Commonwealth of Virginia be liable for using lethal-injection drugs in a manner other than that recommended by the manufacturer?

Next, Senator Surovell and Delegate Simon have asked whether “the Commonwealth of Virginia including any of its agents or employees face any potential civil liability or consequences if [they] continue[] to use [lethal injection] drugs in violation of manufacturers’ instructions”

The question is asked after stating that “multiple drug manufacturers have threatened Virginia.” However, the nature of the threat is not stated but implies that it would entail civil liability. Without more facts, or knowing what the nature of the threatened litigation might be, it is impossible to opine on the merits of such a threat. However, I note generally that, absent any express contractual provision to the contrary, a vendor cannot unilaterally impose obligations upon a purchaser following consummation of a sale. In particular with drugs regulated by the FDA, “off-label drug usage is not unlawful,” and the FDA “generally contemplates that approved drugs will be used in off-label ways.”⁷⁴ For these reasons, and in the absence of additional facts to inform this response, it does not currently appear that Virginia would

⁷⁰ VA. CODE ANN. § 53.1-232(A).

⁷¹ VA. CODE ANN. § 53.1-232.1.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ United States v. Caronia, 703 F.3d 149, 166 (2d Cir. 2012).

face any potential civil liability for use of a lethal-injection drug contrary to the wishes of its manufacturer.

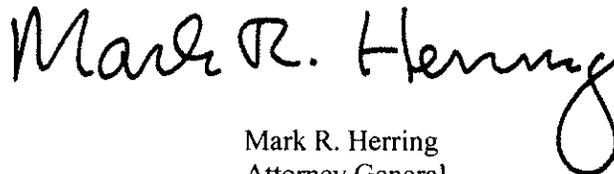
Conclusion

For the reasons set forth above it is my opinion that the FDCA and the CSA do not prohibit the procurement of compounded drugs for use in the lethal injection process, and entities and individuals acting in accordance with the Substitute would not violate federal law. Also, it is my opinion that, whether the case is a habeas corpus proceeding or manner-of-execution challenge under 42 U.S.C. § 1983, the Substitute's limitation on disclosure of the identities of compounding pharmacies and their employees would not violate the constitutional rights of a civil litigant, nor any federal law. Also, although the Virginia Department of Corrections may consider or adopt alternative lethal-injection drugs or protocols without further statutory authorization, the Department has no authority to suspend or stay executions. Finally, the facts you recite do not appear to support the imposition of any potential civil liability for using a lethal-injection drug against the wishes of its manufacturer.

Decisions related to the process by which the Commonwealth carries out a court-imposed sentence of death deserve the greatest deliberation and consideration, as this is among the most solemn and consequential powers exercised by the state. In an effort to help inform your deliberations on the Substitute, I am providing this opinion as an explanation of the current state of the law related to procurement of drugs for use in carrying out a court-imposed sentence of death by lethal injection. I trust this information will be of use as you and your colleagues in the General Assembly carefully weigh the wisdom and merits of any policy in this area.

With kindest regards, I am

Very truly yours,

A handwritten signature in black ink that reads "Mark R. Herring". The signature is written in a cursive, flowing style with a large loop at the end of the last name.

Mark R. Herring
Attorney General