

THE STATE OF SOUTH CAROLINA
IN THE SUPREME COURT

RECEIVED

Jan 30 2024

APPEAL FROM RICHLAND COUNTY
Court of Common Pleas

S.C. SUPREME COURT

Jocelyn Newman, Circuit Court Judge

Appellate Case No. 2022-001280

Case No. 2021-CP-40-02306

FREDDIE EUGENE OWENS, BRAD KEITH SIGMON, GARY DUBOSE
TERRY, and RICHARD BERNARD MOORE,*Respondents-Appellants,*

v.

BRYAN P. STIRLING, in his official capacity as the Director of the South
Carolina Department of Corrections, SOUTH CAROLINA DEPARTMENT OF
CORRECTIONS; and HENRY MCMASTER, in his official capacity as
Governor of the State of South Carolina,*Appellants-Respondents.*

**BRIEF OF *AMICI CURIAE* CONCERNED PUBLIC HEALTH PROFESSIONALS,
SCIENTISTS, FORMER REGULATORS, AND EDUCATORS
IN SUPPORT OF RESPONDENTS-APPELLANTS**

Anthony F. Shelley
Kathleen T. Wach
Rachel Mendelson
Miller & Chevalier Chartered
900 Sixteenth St. NW
Black Lives Matter Plaza
Washington, DC 20006
Tel. (202) 626-5800
Email: ashelley@milchev.com
kwach@milchev.com
rmendelson@milchev.com

John L. Warren III (S.C. Bar #101414)
Counsel of Record
Law Office of Bill Nettles
2008 Lincoln St.
Columbia, SC 29201
Tel. (803) 814-2826
Email: JW@billnettleslaw.com

(Admitted in the District of Columbia)

January 30, 2024

TABLE OF CONTENTS

	<u>Page</u>
STATEMENT OF INTEREST.....	1
ARGUMENT	3
<i>SOUTH CAROLINA’S SECRECY LAW IS PREEMPTED BY FEDERAL DRUG STATUTES AND REGULATIONS.....</i>	<i>3</i>
A. Under the U.S. Constitution’s Supremacy Clause, Federal Law Preempts Conflicting State Law	4
B. There Is an Extensive and Intricate Framework of Federal Drug Laws and Regulations, and It Applies to Drugs Used for Lethal Injection	5
C. South Carolina’s Secrecy Law Conflicts with the Federal Drug Regulatory Regime	8
D. Federal Oversight over Lethal Injection Drugs Is Critically Necessary, and Compromising It Through State Secrecy Laws Threatens the Public’s and Incarcerated Individuals’ Health and Safety	11
CONCLUSION.....	14

TABLE OF AUTHORITIES

Page(s)

Cases

Beaty v. FDA,
853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd in relevant part*, *Cook v. FDA*, 733
F.3d 1 (D.C. Cir. 2013).....7, 12

Ex parte Brown,
393 S.C. 214, 711 S.E.2d 899 (2011)3

Chaney v. Heckler,
718 F.2d 1174 (D.C. Cir. 1983), *rev'd on other grounds*, *Heckler v. Chaney*,
470 U.S. 821 (1985).....7

Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992).....4

Cook v. FDA,
733 F.3d 1 (D.C. Cir. 2013)7

Doe v. State,
421 S.C. 490, 808 S.E.2d 807 (2017)10

FDA v. Brown & Williamson Tobacco Corp.,
529 U.S. 120 (2000).....7, 8

Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta,
458 U.S. 141 (1982).....5

Geier v. Am. Honda Motor Co.,
529 U.S. 861 (2000).....4, 8

Gibbons v. Ogden,
22 U.S. (9 Wheat.) 1 (1824).....4

Hines v. Davidowitz,
312 U.S. 52 (1941).....4, 8

Jones v. Rath Packing Co.,
430 U.S. 519 (1977).....4

McCulloch v. Maryland,
17 U.S. (4 Wheat.) 316 (1819).....4

Priester v. Cromer,
401 S.C. 38, 736 S.E.2d 249 (2012)4, 5, 10

<i>Roane v. Bar (In re Fed. Bureau of Prisons’ Execution Protocol Cases)</i> , 980 F.3d 123 (D.C. Cir. 2020)	7, 8
<i>State v. Langford</i> , 400 S.C. 421, 735 S.E.2d 471 (2012)	3
<i>Thayer v. S.C. Tax Comm’n</i> , 307 S.C. 6, 413 S.E.2d 810 (1992)	10

Constitution and Statutes

U.S. Const. art. VI, cl. 2	3, 4
21 U.S.C. § 353b	6
21 U.S.C. § 360eee	5
21 U.S.C. § 360eee-3	5
21 U.S.C. § 372	10
21 U.S.C. § 828	9
21 U.S.C. § 878	6
21 U.S.C. § 880	6
Ariz. Rev. Stat. § 13-757	1
Ark. Code Ann. § 5-4-617	1
Controlled Substances Act, 21 U.S.C. §§ 801 <i>et seq.</i>	5, 6
Drug Supply Chain Security Act, Pub. L. No. 113-54, tit. II, 127 Stat. 587, 599 (2013)	5, 6
Federal Food, Drug, and Cosmetics Act, 21 U.S.C §§ 301 <i>et seq.</i>	5, 6, 7
Fla. Stat. § 945.10	1
Ga. Code Ann. § 42-5-36	1
Idaho Code Ann. § 19-2716A	1
Ind. Code Ann. § 35-38-6-1	1
Miss. Code Ann. § 99-19-51	1

Mo. Rev. Stat. § 546.720	1
N.C. Gen. Stat. § 132-1.2.....	1
Neb. Rev. Stat. § 83-967.....	1
Okla. Stat. tit. 22, § 1015	1
S.C. Code Ann. § 24-3-580 (2023).....	1, 8, 9, 10, 11
S.D. Codified Laws § 23A-27A-31.2	1
Tenn. Code Ann. § 10-7-504	1
Tex. Code Crim. Proc. art. 43.14.....	1
Wyo. Stat. Ann. § 7-13-916.....	1
 Other Authorities	
21 C.F.R. § 1301.71	6
SCACR 213	3
Chris McDaniel, <i>Inmates Said the Drug Burned as They Died. This Is How Texas Gets Its Execution Drugs.</i> , BuzzFeed News (Nov. 28, 2018, 5:09 PM), https://www.buzzfeed.com/chrismcdaniel/inmates-said-the-drug-burned-as-they-diedthis-is-how-texas?bfsource=relatedmanual	12, 13
Eric Berger, <i>Lethal Injection Secrecy and Eighth Amendment Due Process</i> , 55 B.C. L. Rev. 1367, 1385 (2014), https://digitalcommons.unl.edu/cgi/viewcontent?article=1210&xt=lawfacpub	13
FDA, <i>Drug Compounding and Drug Shortages</i> (Mar. 24, 2023), https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages	6
FDA, <i>Drug Supply Chain Integrity</i> (June 13, 2017), https://www.fda.gov/drugs/drug-safety-and-availability/drug-supply-chain-integrity	6
FDA, <i>Information for Outsourcing Facilities</i> (Mar. 29, 2022), https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities	7
Jim Edwards, <i>Drug Company? Driving School? It's All the Same in the Lethal Injection Business</i> , CBS News: MoneyWatch (Jan. 6, 2011, 6:09 PM), https://www.cbsnews.com/news/drug-company-driving-school-its-all-the-same-in-the-lethal-injection-business/	12

John Schwartz, Seeking Execution Drug, States Cut Legal Corners, N.Y. Times
(Apr. 13, 2011), <https://www.nytimes.com/2011/04/14/us/14lethal.html> 11

Lethal Injection Information Center, *Oklahoma Abandons Lethal Injection* (Mar.
1, 2018), <https://lethalinjectioninfo.org/oklahoma-abandons-lethal-injection/> 13

Lethal Injection Information Center, *Oklahoma Abandons Lethal Injection* (Mar.
1, 2018), <https://lethalinjectioninfo.org/oklahoma-abandons-lethal-injection/> 3

Lethal Injection Information Center, *Virginia Repeals Execution Secrecy Law*
(Apr. 27, 2020), <https://lethalinjectioninfo.org/virginia-repeals-execution-secrecy-law/> 13

Letter from William K. Hubbard, Assoc. Comm’r for Policy & Planning, FDA, to
Gregory Gonot, Deputy Attorney Gen., State of California (Aug. 25, 2003),
<https://web.archive.org/web/20170603210131/http://fda.gov/drugs/drugsafety/ucm179893.htm> 6

Office of Legal Counsel, U.S. Dep’t of Justice, *Whether the Food and Drug
Administration Has Jurisdiction over Articles Intended for Use in Lawful
Executions*, 2019 WL 2235666 (O.L.C. May 3, 2019)..... 7

Prashant Yadav et al., *When Government Agencies Turn to Unregulated Drug
Sources: Implications for the Drug Supply Chain & Public Health Are Grave*,
58 J. of Am. Pharmacies Ass’n 477, 478 (2018),
[https://www.japha.org/article/S1544-3191\(18\)30336-4/pdf](https://www.japha.org/article/S1544-3191(18)30336-4/pdf)..... 12

Press Release, Office of Gov. Katie Hobbs, *Governor Katie Hobbs Unveils
Executive Action Improving Oversight and Transparency with Arizona’s
Death Penalty Process* (Jan. 20, 2023), <https://azgovernor.gov/office-arizona-governor/news/2023/01/hobbs-unveils-executive-action-improving> 13

Scott Gottlieb, M.D., *Remarks on Enhanced Drug Distribution Security* (Feb. 28,
2018), <https://www.fda.gov/news-events/speeches-fda-officials/remarks-enhancing-drug-distribution-security-02282018> 5

STATEMENT OF INTEREST

The *amici curiae* are ten public health professionals, scientists, former regulators, and educators. A list of the *amici* is included in the Appendix to this brief. These individuals have spent decades working in their respective fields seeking to protect the public health and to ensure the safety and efficacy of drugs in the United States.¹

One of the issues presented in this appeal is whether South Carolina properly can avoid discovery that would allow Respondents-Appellants (“Respondents”), who are incarcerated individuals facing execution in the state, sufficient information about lethal injection drugs to reasonably ensure protection of their constitutional rights. The state bases its defense to discovery on the state’s so-called “secrecy” (or “shield”) law as recently amended, *see* S.C. Code Ann. § 24-3-580 (2023), which, according to the state, prohibits the disclosure of the persons, procedures, supply chain, drugs, and other details associated with lethal injection. At least fifteen other states have secrecy laws, though South Carolina’s ranks as perhaps the most extreme and limiting of any of the states’ measures. *See infra* p. 10; *see, e.g.*, Ariz. Rev. Stat. § 13-757; Ark. Code Ann. § 5-4-617(i)(2); Fla. Stat. § 945.10(1)(g), (j)(1); Ga. Code Ann. § 42-5-36; Idaho Code Ann. § 19-2716A(4); Ind. Code Ann. § 35-38-6-1(f); Miss. Code Ann. § 99-19-51(3)(c), (4); Mo. Rev. Stat. § 546.720(2); Neb. Rev. Stat. § 83-967(2); N.C. Gen. Stat. § 132-1.2(7); Okla. Stat. tit. 22, § 1015(B); S.D. Codified Laws § 23A-27A-31.2; Tenn. Code Ann. § 10-7-504(h)(1); Tex. Code Crim. Proc. art. 43.14(b); Wyo. Stat. Ann. § 7-13-916.

The *amici* are deeply concerned about the significant public health risks South Carolina has created by enacting a law that ensures the evasion of federal statutes and regulations regarding

¹ The *amici* confirm that no counsel for a party authored this brief in whole or in part and that no party or its counsel made a monetary contribution intended to fund the preparation or submission of the brief.

pharmaceuticals and related supply chains. Specifically, secrecy laws prevent federal drug enforcement officials and the public from understanding the sources of execution drugs and how they are acquired, safeguarded, and used. They overtly sanction a lack of transparency and oversight of the acquisition and transportation of dangerous drugs used in lethal injection, stymieing the proper enforcement of the federal drug regulation regime that the *amici* have worked to create and implement or have extensively studied. The ensuing compromised federal enforcement necessarily injures the public health by, for example, allowing the continuation and perpetuation of illicit drug supply chains that greatly increase the chances and instances of lethal, dangerous drugs reaching the general public.

Lethal injection is currently the only legal method of execution in South Carolina. However, South Carolina cannot violate or obstruct federal laws in its efforts to conduct lethal injections. The *amici* believe profoundly that the South Carolina secrecy law undermines federal law and that an opinion by this Court sanctioning this state's (and necessarily other states') willful noncompliance with, and secret avoidance of, governing federal drug-enforcement statutes and regulations will exacerbate risks to patients, incarcerated persons, and the broader public. The *amici* seek to participate in order to help inform the Court of the legal infirmity and dangers posed by secrecy laws in general, and South Carolina's in particular.

The parties have presented on appeal the issue of the applicability and legality of South Carolina's secrecy law and whether the secrecy law properly can limit the discovery Respondents seek regarding potential claims of the unconstitutionality of death by lethal injection in the state; further, Respondents have asserted that, if the state's reading of the secrecy law is adopted, the secrecy law itself is unconstitutional. *See* Am. Final Br. of Respondents-Appellants at 50-53 (Dec. 27, 2023). Like Respondents, the *amici* too contend that the secrecy law is unconstitutional, but

the *amici* recognize that the grounds for unconstitutionality they assert – namely, pursuant to the U.S. Constitution’s Supremacy Clause – differ from the precise bases pressed by Respondents. Nonetheless, while an *amicus* brief generally should “be limited to argument of the issues on appeal as presented by the parties” (Rule 213, SCACR), this Court will “consider[] arguments raised only by an *amicus* when they concern a ‘matter of significant public interest.’” *State v. Langford*, 400 S.C. 421, 432, 735 S.E.2d 471, 477 (2012) (quoting *Ex parte Brown*, 393 S.C. 214, 216, 711 S.E.2d 899, 900 (2011)).

The legality of a state law that authorizes keeping secret the circumstances under which the state puts prisoners to death and that, concomitantly, has serious consequences for the general public health is a matter of significant public interest. As the Former Director of the Oklahoma Department of Corrections stated, when he announced in 2018 that his state would abandon executions by lethal injection because of the lack of transparency surrounding prior botched executions: “I can’t think of anything that should inhibit total transparency on something as serious as an execution of a human being” Lethal Injection Information Center, *Oklahoma Abandons Lethal Injection* at 00:47 (Mar. 1, 2018), <https://lethalinjectioninfo.org/oklahoma-abandons-lethal-injection/>. Respectfully, before potentially endorsing a state law with such grave consequences for individuals on death row and that puts at risk the public health generally, the Court should consider all material constitutional issues.

ARGUMENT

SOUTH CAROLINA’S SECRECY LAW IS PREEMPTED BY FEDERAL DRUG STATUTES AND REGULATIONS

Federal law invalidates South Carolina’s secrecy law because, under the Supremacy Clause of the U.S. Constitution, the extensive federal drug regulatory regime preempts the secrecy law.

Given that the South Carolina secrecy law is invalid, it cannot constrain Respondents' discovery regarding the details of the state's use of lethal injection.

A. Under the U.S. Constitution's Supremacy Clause, Federal Law Preempts Conflicting State Law

"The preemption doctrine is rooted in the Supremacy Clause of the United States Constitution and provides that any state law that conflicts with federal law is 'without effect.'" *Priester v. Cromer*, 401 S.C. 38, 43, 736 S.E.2d 249, 252 (2012) (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992)). The Supremacy Clause itself states: "[The] Constitution, and the Laws of the United States . . . and all Treaties made . . . under the Authority of the United States, shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

From the early days of the nation, the preemption test has been stated in broad terms: in *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824), the U.S. Supreme Court, via Chief Justice Marshall, established that state laws, "though enacted in the exercise of powers not controverted, must yield" if they "interfere with, or are contrary to the laws of Congress, made in pursuance of the constitution." *See also McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 405-06 (1819). In modern times, this Court, as well as the U.S. Supreme Court, has reiterated that preemption occurs "where compliance with both federal and state regulations is physically impossible or where the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Priester*, 401 S.C. at 44, 736 S.E.2d at 252 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); *see id.* at 43, 736 S.E.2d at 252 ("Preemption 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.") (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)); *accord Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000).

Moreover, “[f]ederal regulations have no less pre-emptive effect than federal statutes.” *Priester*, 401 S.C. at 43-44, 736 S.E.2d at 252 (quoting *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982)). And this Court, of course, is no less vigilant than the federal courts in protecting federal law and declaring that federal statutes and regulations preempt conflicting South Carolina measures. *E.g.*, *Priester*, 401 S.C. at 59, 736 S.E.2d at 260 (finding state common-law products liability claim concerning automobile windshield requirements preempted because “Appellant’s state tort suit requiring laminated glass would stand as an obstacle to significant federal safety objectives”).

B. There Is an Extensive and Intricate Framework of Federal Drug Laws and Regulations, and It Applies to Drugs Used for Lethal Injection

Federal law extensively regulates drugs. The Food and Drug Administration (“FDA”), under authority granted by the Federal Food, Drug, and Cosmetics Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and the Controlled Substances Act (“CSA”), 21 U.S.C. §§ 801 *et seq.*, has established a comprehensive regime of both regulation and enforcement to ensure that drugs distributed in the U.S. are safe and effective. Congress, recognizing the increasingly global and complex drug supply chain, amended the FDCA and enacted the Drug Supply Chain Security Act (“DSCSA”), Pub. L. No. 113-54, tit. II, 127 Stat. 587, 599 (2013), to regulate more tightly the supply chain and address unsafe, ineffective, and counterfeit drugs. The DSCSA establishes a federal system for tracing prescription drug products through the pharmaceutical supply chain and requires various participants – including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers – to provide, receive, and maintain certain product and distribution information. *See* 21 U.S.C. §§ 360eee, 360eee-3(b). The DSCSA requires full supply chain traceability, from the drug manufacturer all the way through to the entity that dispenses the drug to a patient, creating a “closed system.” *See* Scott Gottlieb, M.D., *Remarks on Enhanced*

Drug Distribution Security (Feb. 28, 2018), <https://www.fda.gov/news-events/speeches-fda-officials/remarks-enhancing-drug-distribution-security-02282018>. The DSCSA aims to strengthen the integrity of the U.S. drug supply chain and reduce the likelihood of counterfeit or unapproved drugs being distributed in the U.S. See FDA, *Drug Supply Chain Integrity* (June 13, 2017), <https://www.fda.gov/drugs/drug-safety-and-availability/drug-supply-chain-integrity>.

In furtherance of that same goal, the CSA requires that anyone who handles controlled substances, such as pentobarbital (the drug South Carolina has obtained for the executions in this instance), register with the U.S. Drug Enforcement Administration (“DEA”). 21 U.S.C. §§ 878(a), 880. Registrants are required, among other things, to “provide effective controls and procedures to guard against theft and diversion of controlled substances.” 21 C.F.R. § 1301.71(a). The registration requirement strengthens the “closed system” and allows the FDA and DEA to protect the public from unsafe or ineffective drugs obtained from unverified sources and specifically from drugs that can be abused. See Letter from William K. Hubbard, Assoc. Comm’r for Policy & Planning, FDA, to Gregory Gonot, Deputy Attorney Gen., State of California (Aug. 25, 2003), <https://web.archive.org/web/20170603210131/http://fda.gov/drugs/drugsafety/ucm179893.htm>.

Even outside of the importation, manufacture, and sale of drugs through the traditional pharmaceutical system, the FDA also regulates drugs obtained through “compounding pharmacies.” 21 U.S.C. § 353b. The FDCA allows compounding pharmacies to make drugs based on existing formulations rather than acquiring them from distributors – for instance, to serve a patient with an allergy to an ingredient in a widely distributed medication. FDA, *Drug Compounding and Drug Shortages* (Mar. 24, 2023), <https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages> (“Compounded drugs are not FDA-approved. In some cases, they can serve an important role for patients whose medical needs cannot

be met by an FDA-approved drug product. For example, a patient may be unable to swallow a pill or may have an allergy to an inactive ingredient in an FDA-approved drug.”). As part of the regulatory regime, compounding pharmacies are subject to regular FDA inspection, to ensure their compliance with distribution requirements. FDA, *Information for Outsourcing Facilities* (Mar. 29, 2022), <https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities>.

Furthermore, this regime of federal drug laws and regulations applies in the death-penalty context. The D.C. Circuit, most often tasked with applying federal administrative law, has ruled on this issue more than once, and each time has declared unequivocally that lethal injection drugs are subject to FDA regulation and oversight. *See Roane v. Bar (In re Fed. Bureau of Prisons’ Execution Protocol Cases)*, 980 F.3d 123, 137 (D.C. Cir. 2020) (“the FDCA applies when already-covered drugs like pentobarbital are used for lethal injections”); *see also Cook v. FDA*, 733 F.3d 1, 12 (D.C. Cir. 2013) (“The FDCA imposes mandatory duties upon the agency charged with its enforcement. The FDA acted in derogation of those duties by permitting the importation of thiopental [for use in executions.]”); *Chaney v. Heckler*, 718 F.2d 1174, 1178 (D.C. Cir. 1983) (rejecting FDA’s claim that the “FDA’s jurisdiction did not extend to the regulation of state-sanctioned use of lethal injections”), *rev’d on other grounds, Heckler v. Chaney*, 470 U.S. 821 (1985); *Beaty v. FDA*, 853 F. Supp. 2d 30, 42 (D.D.C. 2012) (holding that refusal by the FDA to regulate lethal injection drugs “undermin[ed] the purpose of the FDCA”), *aff’d in relevant part, Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013).²

² The Office of Legal Counsel within the U.S. Department of Justice, in a 2019 memorandum, opined that the FDA lacked jurisdiction over drugs used in executions, based on its reading of *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). *See* Office of Legal Counsel, U.S. Dep’t of Justice, *Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions*, 2019 WL 2235666 (O.L.C. May 3, 2019). The

C. South Carolina’s Secrecy Law Conflicts with the Federal Drug Regulatory Regime

The South Carolina secrecy law conflicts with governing federal drug statutes and regulations and otherwise creates “an obstacle to the accomplishment and execution of” the important . . . federal objectives” of the federal drug regulatory scheme. *Geier*, 529 U.S. at 881 (quoting *Hines*, 312 U.S. at 67). The secrecy law’s chief provision provides that “[n]otwithstanding *any* other provision of law” – not just any other provision of *state* law – “any identifying information of a person or entity that participates in the planning or administration of the execution of a death sentence shall be confidential.” S.C. Code Ann. § 24-3-580(B) (2023) (emphasis added). Consistent with that general rule, “[a] person shall not knowingly disclose the identifying information of a current or former member of an execution team” and, if the person does, he or she “*must* be imprisoned not more than three years.” *Id.* § 24-3-580(C) (emphasis added). “Identifying information” of current or former “[e]xecution team” members includes any “record or information” revealing the identity of a person or entity that “prescribes, compounds, tests, uses, manufactures, imports, transports, distributes, supplies, prepares, or administers” lethal injection drugs. *Id.* § 24-3-580(A)(1)-(2). In addition, the secrecy law flatly prohibits local government officials from disclosing the identity of the execution team or “any details regarding the procurement” of lethal injection drugs. *Id.* § 24-3-580(G).

The upshot is that these provisions create a likely insurmountable obstacle to complying with federal law. As an initial example, if a compounding pharmacy were making execution drugs, it would be *prohibited* from providing any information to the FDA about to whom it is providing the drugs, which is a requirement of federal law. Put differently, the compounding pharmacy

memorandum is not binding, and the D.C. Circuit has since rejected the position adopted in the memorandum, including its reading of *Brown & Williamson*. See *Roane*, 980 F.3d at 136.

“must” go to jail in South Carolina for “not more than three years” if it makes the disclosure required under federal law. And the lack of proper federal reporting would then prevent the inspection and enforcement concerning the pharmacy as required under federal law.

Similarly, the South Carolina secrecy law provides that “no prescription from any physician shall be required for any pharmacy or pharmacist to supply, manufacture, or compound any drug intended for use in the administration of the death penalty.” S.C. Code Ann. § 24-3-580(F) (2023). Yet, under federal law, the pentobarbital the state intends to use for the executions at issue here is classified as a Schedule II drug and, as such, requires a prescription for its use. *See* 21 U.S.C. § 828(a). Again, South Carolina invites – indeed, demands – the opposite of what federal law requires. Overall, it is unclear where or how South Carolina procured pentobarbital; but it has admitted it took more than 1,300 contacts before the state was able to obtain the drug. *See* Aff. of Bryan P. Stirling ¶¶ 6-7 (Sept. 19, 2023). The wide-ranging efforts the state has made to obtain or import the drug into the state cannot help but touch on multiple aspects of the federal drug regulation regime, not just the federal prescription mandate. The state can, of course, exempt drugs from state regulation as it wishes. It cannot, however, unilaterally shield those drugs from *federal* regulation. The secrecy law nevertheless does precisely that.

More generally, the overarching bent of the South Carolina law is directly at odds with the purposes of the federal drug regulatory regime. The secrecy law aims to keep confidential the supply-chain process for drugs used in executions, so much so that it even instructs state officials to “work . . . to ensure that the state’s accounting and financial records related to any transaction for the purchase, delivery, invoicing, etc. of or for supplies, compounds, drugs, medical supplies, or medical equipment utilized in the execution of a death sentence are kept in *deidentified* condition.” S.C. Code Ann. § 24-3-580 (2023) (emphasis added). As a result, the secrecy law

thwarts the “closed system” that federal regulations create – *i.e.*, a system in which drugs can be traced from manufacturer to end user. Given the secrecy that the South Carolina law mandates, there may be no way for federal regulators or the public to trace the drugs used for lethal injection in South Carolina *at all*. At a minimum, because the secrecy law “frustrate[s]” the federal government’s ability to enforce the laws under its charge, it is straightforwardly preempted. *Priester v. Cromer*, 401 S.C. 38, 59, 736 S.E.2d 249, 260 (2012).

South Carolina’s secrecy law particularly stands as an obstacle to federal enforcement of federal drug laws, because it is among – if not *the* – most draconian of all the states’ laws on this topic. South Carolina is one of only four states that impose criminal penalties for disclosure, and one of only two that prompt significant jail time. While many other states make exceptions for the discovery process in litigation with protective orders or requests from government agencies, South Carolina’s law explicitly forbids those disclosures in state proceedings, at least for the identity of the execution team. *See* S.C. Code Ann. § 24-3-580(B) (2023).

To be sure, the provision of the secrecy law that arguably most directly comes into play in this appeal is the just-mentioned provision for disallowing discovery in state court and agency proceedings. While that provision, in isolation, might not at first blush overtly appear to implicate federal enforcement authority or a contrary federal regulatory requirement, it is not “wholly independent” of the rest of the secrecy law and, therefore, cannot survive on its own. *See Doe v. State*, 421 S.C. 490, 509, 808 S.E.2d 807, 817 (2017) (quoting *Thayer v. S.C. Tax Comm’n*, 307 S.C. 6, 13, 413 S.E.2d 810, 814-15 (1992)). Moreover, the federal drug regulatory scheme does, in fact, call for partnership in federal enforcement between federal regulatory and state authorities, *see* 21 U.S.C. § 372, which South Carolina, through the secrecy law’s instructions against disclosure in the state court and agency context, not only abdicates but affirmatively undermines

with respect to lethal injection drugs. And finally, as Respondents have noted, this part of the secrecy law (*i.e.*, the part limiting disclosure or discovery in state proceedings) protects only the identities of the execution team “not information regarding the drug itself or quality controls surrounding the drug.” Am. Final Br. of Respondents-Appellants at 47 (Dec. 27, 2023). Thus, only the rest of the secrecy law – if any of it – could prevent the disclosure Respondents seek, and those aspects are directly unconstitutional under the Supremacy Clause, as explained above.³

D. Federal Oversight over Lethal Injection Drugs Is Critically Necessary, and Compromising It Through State Secrecy Laws Threatens the Public’s and Incarcerated Individuals’ Health and Safety

Federal oversight and enforcement concerning lethal injection drugs, which secrecy laws (including South Carolina’s) impede, is critically necessary both to protect public health generally and to protect incarcerated individuals from harm. The examples are numerous of dangerous situations created by lethal injection drugs; federal regulation of the procedures and methods associated with lethal injection – as Congress intended – offers the best route to avoid future hazards from lethal injection.

One example illustrating threats to the public health involved, in 2010, ten states acquiring supplies of sodium thiopental for use in their lethal injection protocol from a pharmacy in England operating out of a back room in a driving school. *See* John Schwartz, *Seeking Execution Drug, States Cut Legal Corners*, N.Y. Times (Apr. 13, 2011), <https://www.nytimes.com/>

³ Nor does the proviso in the secrecy law that “[t]he Department of Corrections shall comply with federal regulations regarding the *importation* of any execution drugs” save the statute from the Supremacy Clause. S.C. Code Ann. § 24-3-580(J) (2023) (emphasis added). Federal regulations do not cease to apply once a drug enters the country. If anything, this provision of the secrecy law illustrates its collision with federal law. Whereas the legislature has instructed compliance by the Department of Corrections with federal laws concerning drug *importation*, its contrasting silence on compliance with federal regulations for drugs acquired in-state or from another state reads as an indication that the Department (wrongly) need not comply with applicable federal law.

[2011/04/14/us/14lethal.html](https://www.cbsnews.com/news/drug-company-driving-school-its-all-the-same-in-the-lethal-injection-business/); Jim Edwards, *Drug Company? Driving School? It's All the Same in the Lethal Injection Business*, CBS News: MoneyWatch (Jan. 6, 2011, 6:09 PM), <https://www.cbsnews.com/news/drug-company-driving-school-its-all-the-same-in-the-lethal-injection-business/>. The drug product was not FDA-approved, and its importation was illegal. The states acted covertly to obtain the drugs, outside of the protections provided by a closed-system supply chain, and the products entered the United States despite their unapproved status. Some of the thiopental was ultimately sold to at least one pharmacy servicing the general public, and “substantial quantities” of the medicine went “missing” from San Quentin prison in California. *Beatty*, 853 F. Supp. 2d at 34-35, 42 n.8. It turned out that the person responsible for maintaining custody of the drug at that California prison was an “illicit drug smuggler.” *See id.* at 42 n.8.

Diversions like this of unauthorized or adulterated drugs into the patient population can quickly expand to larger scale public health crises. Once an illicit supply channel is established with a given supplier, it is extremely challenging to control which drug products move through it, and which customers they reach, particularly in a context where the FDA and DEA are prevented from performing their usual regulatory duties because of secrecy. *See Prashant Yadav et al., When Government Agencies Turn to Unregulated Drug Sources: Implications for the Drug Supply Chain & Public Health Are Grave*, 58 J. of Am. Pharmacies Ass’n 477, 478 (2018), [https://www.japha.org/article/S1544-3191\(18\)30336-4/pdf](https://www.japha.org/article/S1544-3191(18)30336-4/pdf).

As to examples illustrating harm to incarcerated individuals, in 2018, Anthony Shore cried out while being executed by the state of Texas via an injection of pentobarbital, ““I can feel that it does burn. Burning!”” Chris McDaniel, *Inmates Said the Drug Burned as They Died. This Is How Texas Gets Its Execution Drugs.*, BuzzFeed News (Nov. 28, 2018, 5:09 PM), <https://www.buzzfeednews.com/article/chrismcDaniel/inmates-said-the-drug-burned-as-they-died>

[-this-is-how-texas?bfsource=relatedmanual](#). In the following months, four individuals put to death by Texas made similar statements after being injected with pentobarbital, and a fifth writhed on the gurney as he died. The drugs were procured from Greenpark Compounding Pharmacy in Houston, which has been repeatedly cited for dangerous practices and incorrectly compounding medication for children resulting in the need for emergency medical care. *See id.* Michael Lee Wilson similarly screamed, “I feel my whole body burning!” when injected with compounded lethal injection drugs in January 2014 while being executed by the state of Oklahoma. Eric Berger, *Lethal Injection Secrecy and Eighth Amendment Due Process*, 55 B.C. L. Rev. 1367, 1385 (2014), <https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1210&context=lawfacpub>. This response, according to experts, is consistent with a reaction to contaminated pentobarbital. *Id.*

Because of instances like this, state legislatures and governors have begun repealing secrecy laws, initiating investigations, or placing moratoriums on executions until such time that drugs can be legally and transparently obtained. *See, e.g.*, Press Release, Office of Gov. Katie Hobbs, *Governor Katie Hobbs Unveils Executive Action Improving Oversight and Transparency with Arizona’s Death Penalty Process* (Jan. 20, 2023), <https://azgovernor.gov/office-arizona-governor/news/2023/01/governor-katie-hobbs-unveils-executive-action-improving>; Lethal Injection Information Center, *Virginia Repeals Execution Secrecy Law* (Apr. 27, 2020), <https://lethalinjectioninfo.org/virginia-repeals-execution-secrecy-law/>; Lethal Injection Information Center, *Oklahoma Abandons Lethal Injection* (Mar. 1, 2018), <https://lethalinjectioninfo.org/oklahoma-abandons-lethal-injection/>. The *amici* are not aware of similar efforts in South Carolina. Consequently, it falls on this Court to adjudicate the legality of South Carolina’s secrecy law. Because it violates the Supremacy Clause, the law is void and cannot serve as a basis for denying relevant discovery to Respondents.

CONCLUSION

The judgment below should be affirmed, notwithstanding the intervening enactment of the secrecy law in its current form.

January 30, 2024

Respectfully submitted,

/s/ John L. Warren III
John L. Warren III (S.C. Bar #101414)
Law Office of Bill Nettles
2008 Lincoln St.
Columbia, SC 29201
Tel. (803) 814-2826
Email: JW@billnettleslaw.com

Anthony F. Shelley
Kathleen T. Wach
Rachel Mendelson
Miller & Chevalier Chartered
900 Sixteenth St. NW
Black Lives Matter Plaza
Washington, DC 20006
Tel. (202) 626-5800
Email: ashelley@milchev.com
kwach@milchev.com
rmendelson@milchev.com

(Admitted in the District of Columbia)

APPENDIX

List of *Amici Curiae*

Donald F. Downing, Clinical Professor, University of Washington School of Pharmacy

Dr. Leonard L. Edloe, PharmD, Former President of the American Pharmacists Association Foundation

Robert B. Greifinger, M.D., Consultant, Correctional Health Care

Margaret A. Hamburg, M.D., Former Commissioner U.S. Food and Drug Administration

Philip D. Hansten, Professor Emeritus, Department of Pharmacy, University of Washington

James Ruble, PharmD, J.D., Associate Professor, Department of Pharmacotherapy, University of Utah College of Pharmacy

Joshua Sharfstein, Former Principal Deputy Commissioner U.S. Food and Drug Administration

J. Robert Sneyd, Dean and Professor of Anesthesia, Faculty of Medicine and Dentistry, University of Plymouth

Rebecca L. Weintraub, M.D., Assistant Professor, Department of Global Health and Social Medicine, Harvard Medical School

Prashant Yadav, PH.D., Affiliate Professor, Department of Global Health and Social Medicine Harvard Medical School