

THE STATE OF SOUTH CAROLINA  
In the Supreme Court

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APPEAL FROM RICHLAND COUNTY  
Court of Common Pleas

S.C. SUPREME COURT

Honorable Jocelyn Newman, Circuit Court Judge

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Appellate Case No. 2022-001280

Case No. 2021-CP-40-02306

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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.

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RESPONSE OF APPELLANTS-RESPONDENTS TO  
BRIEF OF *AMICI CURIAE* CONCERNED HEALTH PROFESSIONALS, *ET AL.*, AND  
BRIEF OF *AMICI CURIAE* PHARMACEUTICAL MANUFACTURERS

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## INTRODUCTION

After Respondents insisted for years that their preferred method of execution is lethal injection using a single dose of pentobarbital, the State enacted the Shield Statute to help SCDC obtain lethal injection drugs. Now that SCDC has informed this Court that lethal injection is available, Respondents have questioned the very law that made it so.

They are not, however, the only ones to challenge the Shield Statute. But Amici attack the Shield Statute in an entirely different way than Respondents do. According to Amici, the Shield Statute (if not lethal injection generally) is preempted by federal law and endangers the public. Even if the Court were willing to cast aside its own unambiguous rule that amici “*shall* be limited to argument of the issues on appeal as presented by the parties,” Rule 213, SCACR (emphasis added); *see also Ex parte Wilson*, 367 S.C. 7, 15, 625 S.E.2d 205, 209 (2005) (“If a rule’s language is plain, unambiguous, and conveys a clear meaning, interpretation is unnecessary and the stated meaning should be enforced.”), Amici are still wrong for at least two reasons. First, the FDA has no jurisdiction to regulate drugs intended to be used for lethal injection, much less to dictate the State’s execution of criminal judgments. Statutory text, history, and logic all support this conclusion. Second, even if the FDA did have such jurisdiction, Amici overread the scope of the Shield Statute in their effort to portray their abstract arguments and speculative commercial concerns as obvious legal obstacles.

If the Court disagrees with both of these arguments, holding the Shield Statute unconstitutional would necessarily impact the Court’s analysis of the merits of Respondents’ article I, section 15 claim. Holding the Shield Statute unconstitutional won’t, of course, suddenly make capital punishment unconstitutional. But it would effectively eliminate lethal injection as a method of execution in South Carolina. There must, however, “be a constitutional means of

carrying . . . out” a death sentence. *Glossip v. Gross*, 576 U.S. 863, 869 (2015) (internal alteration omitted). So, at a minimum, electrocution or the firing squad must therefore be constitutional, since Respondents did not identify some other alternative method that they admit is constitutional. Whatever the constitutional method for carrying out a death sentence, one thing is clear: A method-by-method attack on various methods of execution cannot leave the State without any way to carry out a “legislatively approved” and “constitutional” punishment. *State v. George*, 323 S.C. 496, 514, 476 S.E.2d 903, 914 (1996).

## ARGUMENT

### **I. The FDA has no authority to regulate lethal injection drugs.**

Tellingly, Amici Health Professionals relegate a critical point to a footnote: The Department of Justice’s Office of Legal Counsel (“OLC”)—in a detailed, 26-page opinion—carefully explained why the FDA lacks authority to regulate drugs intended to be used for lethal injection. *See* Health Profs. Amici Br. 7–8 n.2. The OLC opinion analyzed in great detail why the text and structure of the Food, Drug, and Cosmetic Act (“FDCA”), which is consistent with historical practice, does not give the FDA authority to regulate such drugs. *See Whether the Food and Drug Administration Has Jurisdiction Over Articles Intended for Use in Lawful Executions*, 43 Op. O.L.C. \_\_\_ (May 3, 2019), slip. op., 2019 WL 2235666 (“OLC Op.”). Instead of even trying to rebut OLC’s thoughtful analysis, Amici Health Professionals point to a single paragraph from the D.C. Circuit that said no more than “we’re bound by circuit precedent” and an older D.C. Circuit case that was ultimately reversed by the U.S. Supreme Court. *See* Health Profs. Amici Br. 7.

OLC’s analysis is thorough and compelling, and there is no need to regurgitate it all here. Instead (and particularly given the condensed timeframe, with Amici filing their briefs less than a

week before oral argument and more than a month after Respondents filed their amended merits brief), four points are worth highlighting. *First*, the FDA cannot regulate lethal injection drugs consistent with the plain text of the FDCA. The FDA’s mission is to ensure that a drug “is ‘safe’ and ‘effective’ for its intended use.” *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quoting 21 U.S.C. § 393(b)(2)). A drug intended for use in lethal injection could never satisfy the requirement that the drug’s “potential for inflicting death or physical injury is . . . offset by the possibility of therapeutic benefit.” *Id.* at 134. The process is, after all, intended to end the condemned inmate’s life. This is why the U.S. Supreme Court held that, under the FDCA, the FDA could not regulate tobacco, which also does not have a therapeutic benefit that outweighs the risks. *See id.*; *see also* OLC Op., 2019 WL 2235666, at \*7–9.

*Second*, the structure of the FDCA doesn’t permit the FDA to regulate drugs intended for use in lethal injection. Many provisions in that law “would make no sense” if the FDCA applied to lethal injection drugs. OLC Op., 2019 WL 2235666, at \*9. How could the FDA “assess ‘the seriousness of the disease or condition that is to be treated with the drug’ or ‘the expected benefit of the drug with respect to such disease or condition’”? *Id.* (quoting 21 U.S.C. § 355-1(a)(1)(B)–(C)). How could the FDA “provide for review of scientific disputes by a ‘panel of experts’ that includes members with ‘expertise in *the particular disease or condition* for which the drug is proposed to be indicated.”? *Id.* (cleaned up) (quoting 21 U.S.C. § 355(n)(1), (3)(D)). Or how could the FDA consider “patient experience data”? *Id.* at \*10 (quoting 21 U.S.C. § 360bbb-8c).

*Third*, Amici Health Professionals’ argument conflicts with decades of history. “[F]or nearly 80 years after the FDCA’s enactment, [the] FDA had never asserted jurisdiction over articles intended for use in capital punishment, notwithstanding thousands of cases that would have implicated [the] FDA’s enforcement discretion under such a theory,” as both the federal

government and States carried out executions. *Id.* at \*14. Although it has never squarely addressed the question of the FDA’s jurisdiction over lethal injection drugs, the U.S. Supreme Court has called the idea that “the FDA is required to exercise its enforcement power to ensure that States only use drugs that are ‘safe and effective’ for human execution” “implausible.” *Heckler v. Chaney*, 470 U.S. 821, 827 (1985). Shedding even more light on the history of the FDA’s authority over lethal injection drugs is the federal government’s repeated and unequivocal disclaimer of the authority to regulate drugs used for capital punishment. *See, e.g.*, OLC Op., 2019 WL 2235666, at \*13 n.11 (collecting briefing from the federal government in *Heckler*). Such an about-face suggested by Amici concerning the alleged scope of the FDA’s jurisdiction should rightly provoke skepticism from this Court.

*Fourth*, Amici Health Professionals’ argument is irreconcilable with logic. The federal government has used lethal injection as its only method of execution for the past three decades. *See* Federal Bureau of Prisons, *Capital Punishment: Historical Information* (last visited Jan. 31, 2024), <http://tinyurl.com/26rx5w62>; *see also* OLC Op., 2019 WL 2235666, at \*12 (discussing the statutory history of the federal death penalty). Amici’s position would mean that the federal government, between the Bureau of Prisons and the FDA, has been violating the FDCA.

In the face of these four points (as well as the rest of the OLC Opinion), Amici Health Professionals’ invocation of a few D.C. Circuit cases falls flat. *See* Health Profs. Amici Br. 7. For one, in *Chaney v. Heckler*, the D.C. Circuit (over a dissent from then-Judge Scalia) held that the FDA acted arbitrarily and capriciously in its “decision to take *no* action . . . against the unapproved use of approved drugs in state capital punishment systems.” 718 F.2d 1174, 1177 (D.C. Cir. 1983). Then-Judge Scalia observed that the majority had, “by rewriting the law,” reached an “implausible result” that “convert[ed] a law designed to protect consumers against drugs that are unsafe or

ineffective for their represented use into a law not only permitting but mandating federal supervision of the manner of state executions.” *Id.* at 1192 (Scalia, J., dissenting). Ultimately, the U.S. Supreme Court did not take up the question of the FDA’s jurisdiction, as that Court concluded that the FDA’s decision not to exercise such jurisdiction was not subject to judicial review under the APA. 470 U.S. at 837–38. Treating the D.C. Circuit’s opinion as definitively resolving the question of the FDA’s jurisdiction over lethal injection drugs is therefore a stretch, to put it mildly.

Neither of the other cases Amici Health Professionals cite bolsters their position. For instance, *Cooke v. Food & Drug Administration* addressed the FDA’s duty to regulate the importation of drugs. *See* 733 F.3d 1 (D.C. Cir. 2013). That decision did not address the broader question of the FDA’s authority to oversee (or, effectively, invalidate) States’ use of drugs for lethal injection more generally. And neither did *In re Federal Bureau of Prisons’ Execution Protocol Cases*, which relied on what the court claimed was “binding circuit precedent” to hold that the FDCA applied to the federal government’s use of lethal injection drugs, without the majority even citing, much less engaging in any of the analysis of, the OLC Opinion. 980 F.3d 123, 137 (D.C. Cir. 2020) (*per curiam*).

On the subject of cases from other jurisdictions, it’s worth noting what Amici Health Professionals omit: the cases holding that federal law does not preempt state lethal injection laws. The Southern District of Ohio rejected a preemption argument, observing that, “if [the] preemption argument were accepted, it would be impossible to implement the lethal injection protocol of Ohio and every other state that uses the method. Yet, not only has States’ use of lethal injection been upheld repeatedly, the federal government has evinced its intent to resume executions via lethal injection.” *Davis v. Shoop*, No. 16-CV-495, 2020 WL 3255145, at \*50 (S.D. Ohio June 16, 2020), *report and recommendation adopted as modified*, No. 16-CV-495, 2021 WL 1172048 (S.D. Ohio

Mar. 29, 2021), *aff'd in part, rev'd in part on other grounds and remanded sub nom. Davis v. Jenkins*, 79 F.4th 623 (6th Cir. 2023), *reh'g en banc granted, opinion vacated*, 86 F.4th 733 (6th Cir. 2023).

Similarly, a Delaware court recognized that “Delaware’s Lethal Injection Statute’s single goal is merely to effect the execution of lawfully-condemned inmates.” *Delaware v. Deputy*, 644 A.2d 411, 419 (Del. Super. Ct.), *aff'd*, 648 A.2d 423 (Del. 1994). To that end, “[t]he statute permits one narrow and well-defined usage of certain controlled substances by state officials,” so it did “not, by its terms or its intent, permit individuals to abuse controlled substances with impunity, nor does it endanger public health.” *Id.* Therefore, “the statute in no way conflicts with the federal purposes behind the DAPCA and FDCA.” *Id.*

Both the federal district court in Ohio and the Delaware court recognized what OLC explained in depth in its 2019 opinion. Allowing the FDA to regulate lethal injection drugs would effectively outlaw lethal injection. Yet the U.S. Supreme Court has repeatedly upheld that method of execution, which Respondents here claim to prefer. *See Bucklew v. Precythe*, 139 S. Ct. 1112 (2019); *Glossip*, 576 U.S. 863; *Baze v. Rees*, 553 U.S. 35 (2008). Moreover, lethal injection has a fundamentally different purpose than the FDCA, which is designed to protect consumers. Cases like those from Ohio and Delaware are thus more compelling than the D.C. Circuit cases Amici Health Professionals cite.

## **II. Amici overread the Shield Statute in seeking to create a conflict that does not exist.**

Amici Health Professionals’ preemption argument hinges largely on their misreading of “[n]otwithstanding any other provision of law” in section 24-3-580(B) as encompassing not only state law but also federal law. *See* Health Profs. Amici Br. 8. That is an implausible reading of the Shield Statute.

Federal law is “the supreme Law of the Land.” U.S. Const. art. VI, cl. 2. This is a well-established legal rule going back to at least *McCulloch v. Maryland*, 17 U.S. (4 Wheat) 316 (1819). *See City of Cayce v. Norfolk S. Ry. Co.*, 391 S.C. 395, 400, 706 S.E.2d 6, 8 (2011). The General Assembly is presumed to be aware of such legal rules. *See, e.g., State v. McKnight*, 352 S.C. 635, 648, 576 S.E.2d 168, 175 (2003).

There is no reason to believe or presume that the General Assembly intended to pass a law that purported to override federal law and flout the Supremacy Clause. *See Hodges v. Rainey*, 341 S.C. 79, 85, 533 S.E.2d 578, 581 (2000) (“The cardinal rule of statutory construction is to ascertain and effectuate the intent of the legislature.”). After all, a State cannot nullify federal law, so there was no reason or need for the General Assembly to try to do so here. *See Cooper v. Aaron*, 358 U.S. 1, 17–19 (1958); *see also* Walter Edgar, *South Carolina: A History* 330–38 (1998) (discussing the nullification crisis in the 1830s related to federal tariffs); *cf. Curtis v. State*, 345 S.C. 557, 569, 549 S.E.2d 591, 597 (2001) (“all statutes are presumed constitutional and, if possible, will be construed to render them valid”).

Nor is there any evidence that the General Assembly made such an attempt. Everything in the Shield Statute is focused on state law. It exempts obtaining lethal injection drugs from the State’s Procurement Code. *See* S.C. Code Ann. § 24-3-580(D). It exempts out-of-state acquisitions of lethal injection drugs from DHEC regulations. *See id.* § 24-3-580(E). It exempts a pharmacist who supplies lethal injection drugs from LLR and Board of Pharmacy regulations. *See id.* § 24-3-580(F). And it exempts documents that identify execution team members from South Carolina’s Freedom of Information Act. *See id.* § 24-3-580(G). With all this focus on various state law, it would defy credulity to treat section 24-3-580(B)’s “[n]otwithstanding any other provision of law” as an implicit attempt to disregard whatever applicable federal law existed. *Cf. id.* § 24-3-580(J)

(requiring compliance with federal regulations for importing drugs).

With that cleared up, turn to the supposed conflicts that Amici claim exist. For example, Amici Health Professionals claim that a prescription is required for pentobarbital. *See* Health Profs. Amici Br. 9 (citing 21 U.S.C. § 828(a)). Although that might generally be true for the public’s use of this drug, that ignores the fact that the Controlled Substances Act (“CSA”) is about the “illegal importation, manufacture, distribution, and possession” of controlled substances. 21 U.S.C. § 801(2). As the Tennessee Supreme Court succinctly put it, “[s]tate-sanctioned executions do not fall within the ambit of the legislative purpose embodied in the CSA.” *West v. Schofield*, 519 S.W.3d 550, 571 (Tenn. 2017). Moreover, the federal government requires federal executions to be carried out “in the manner prescribed by the law of the State in which the sentence is imposed,” which Congress knew was lethal injection in many States when it enacted that statute in 1994. 18 U.S.C. § 3596(a).

As yet another flaw in Amici Health Professionals’ argument, 21 U.S.C. § 828(a) doesn’t even apply in the lethal injection context. That provision relates to DEA Form 222, which is about transferring controlled substances. *See* S.C. Code of Regulations R. 61-4.901. Plus, for purposes of the CSA, a prescription “does not include an order for medication which is dispensed for immediate administration to the ultimate user,” which is the situation with lethal injection. 21 C.F.R. § 1300.01.

More generally on this front, the repeated concern about the supposed harm to the public from the Shield Statute is overblown. Amici Health Professionals claim their interest here is the “serious consequences for the general public health” that may follow from the Shield Statute. Health Profs. Amici Br. 3. Even more dramatically, Amici Manufacturers repeatedly insist that the Shield Statute threatens the safety of medicine for the public generally. *See, e.g.,* Manuf. Amici

Brief 5, 9, 11, 15. It's not at all clear what impact the Shield Statute has on the public health or medicines at large, and Amici fall far short of connecting the dots for this parade of horrors. The Shield Statute is *very* specific: It applies only to the acquisition of drugs for use in lethal injection. *See* S.C. Code Ann. § 24-3-580(D), (E), (F), (G). Nothing more. The Shield Statute has no effect on the general public health. Drugs obtained under the Shield Statute will be used for one purpose and one purpose only: executions by lethal injection. There is no reason that other inmates at SCDC, much less the general public, will have any contact with these drugs.

Take another example that confirms the Shield Statute does not conflict with federal law. Amici Health Professionals say the Shield Statute prevents the State from working with the federal government to enforce federal law. *See* Health Profs. Amici Br. 10. But the statute they cite does not impose any specific obligation on state officials. *See* 21 U.S.C. § 372. And even if it did, "Congress cannot compel the States to enact or enforce a federal regulatory program." *Printz v. United States*, 521 U.S. 898, 935 (1997).

### **III. Stretching to strike down the Shield Statute as unconstitutional would have significant consequences.**

If the Court reaches this issue that Amici have raised and concludes that the Shield Statute is preempted or otherwise unconstitutional, at least two things would follow.

The first is that it would be virtually certain that SCDC would not be able to obtain lethal injection drugs. SCDC would have to tell prospective suppliers that South Carolina does not have a Shield Statute and then ask if they would provide or compound lethal injection drugs for SCDC. To be sure, the Court could order another remand, give SCDC more time to again contact the over 1,300 potential suppliers it contacted this past summer (with the benefit of the Shield Statute), and see what the results are. But we know how that would turn out: Everyone would say "no" (if they bothered to respond at all). Thus, under whatever definition of "available" the Court adopts, lethal

injection would again be unavailable in this State. Without the Shield Statute, SCDC could not and cannot obtain lethal injection drugs—and certainly not if it all must be public, as Amici seem to suggest. Indeed, at argument in *Owens I*, Respondents admitted that every State carrying out executions by lethal injection has a shield statute. See Oral Argument Video 2:07:51–2:08:12, *Owens v. Stirling*, No. 2022-001280 (S.C.) (Blume).

The second is that, even if the Shield Statute were unconstitutional, that would not make capital punishment unconstitutional. To the contrary, this Court has definitively held, after the question was “examined by this Court,” that “[c]apital punishment” is “constitutional.” *George*, 323 S.C. at 514, 476 S.E.2d at 914. Respondents have conceded as much. See R. p. 1041. Thus, “it necessarily follows that there must be a constitutional means of carrying it out.” *Glossip*, 576 U.S. at 869 (cleaned up). Eliminating the option of lethal injection would leave electrocution and the firing squad as the State’s two legislatively approved methods. See S.C. Code Ann. § 24-3-530(A); see also *State v. Woomer*, 278 S.C. 468, 473, 299 S.E.2d 317, 320 (1982) (“capital punishment as such and the method of execution are matters of legislative determination”). Therefore, at least one of these methods must be constitutional, particularly since Respondents did not offer another method of execution that they admit is constitutional but which the State has unreasonably refused to adopt. Cf. *Bucklew*, 139 S. Ct. at 1125 (“a prisoner must show a feasible and readily implemented alternative method of execution that would significantly reduce a substantial risk of severe pain and that the State has refused to adopt without a legitimate penological reason”).

At the end of the day, Amici’s attack on the Shield Statute is part of the “guerilla war against the death penalty which consists of efforts to make it impossible for the States to obtain drugs that could be used to carry out capital punishment with little, if any, pain.” Oral Argument

Tr. 14:21–25, *Glossip v. Gross*, No. 14-7955 (U.S.) (Alito, J.). Indeed, not only are Amici challenging the Shield Statute, but at least Amici Health Professionals are also questioning the constitutionality of lethal injection. *See* Health Profs. Amici Br. 12–13. Similarly, Amici Manufacturers say they don’t challenge capital punishment, *see* Manuf. Amici Br. 1, but these manufacturers have been insistent that their drugs should not be used for lethal injection, *see, e.g.*, Hikma Pharm., *Hikma Pharmaceuticals Strongly Objects to the Use of Its Products in Capital Punishment* (May 15, 2013), <http://tinyurl.com/42pd84zt>. All of this stands in stark contrast with Respondents themselves (whom Amici purport to support), who have consistently claimed that lethal injection by a single dose of pentobarbital is the most humane way to carry out an execution. *See, e.g.*, R. p. 113.

Of course, in their opposition to lethal injection, Amici do not seem ready to admit that any other method of execution is constitutional. In other words, Amici seem to want to neuter the State’s authority to carry out a death sentence. The law cannot permit such a result. The decision to have the death penalty rests with the People, through their elected representatives. And if, as here, the People have chosen to permit capital punishment, then (absent executive clemency in a particular case) the State must be able to carry out that sentence in accordance with the constitution—even if lethal injection is not available.

### **CONCLUSION**

For the foregoing reasons, the circuit court’s order should be reversed, and the case remanded with instructions to enter judgment for Appellants.

Respectfully submitted,

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