STATE OF SOUTH CAROLINA
IN THE SUPREME COURT

APPEAL FROM RICHLAND COUNTY
Court of Common Pleas

Honorable 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.

Amici Curiae Brief by Pharmaceutical Manufacturers

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I. Introduction.

Pharmaceutical Manufacturers, as amicus curiae, hereby provide their brief to assist this Court in considering the matters set forth in the Brief of Respondents-Appellants.

Amici curiae are manufacturers of medicines that are listed in lethal injection execution protocols across the United States and in South Carolina[1] ("the Manufacturers"). On October 31, 2023, this Court issued an order requesting additional briefing on the effect of the recent amendments to Section 24-3-580 of the South Carolina Code (the "Secrecy Law") on the merits in this case.

The Manufacturers take no position on the propriety of capital punishment. However, they share a commitment to providing South Carolina with safe and reliable medicines of the highest quality for the care of critically and chronically ill patients. Oncologists, anesthesiologists, pediatric specialists, nurses, and hospital-based pharmacists all rely on their medicines, as do patients and their families. The Manufacturers have invested substantial effort and resources to foster corporate cultures, corporate brand awareness, and contractual relationships that further this mission.

The Manufacturers have unique expertise with, and knowledge of, the conditions that must be met to guarantee the safety and quality of the medicines they manufacture, including those drugs that states have used in lethal injection executions. Their respective business models and

[1] South Carolina law allows the South Carolina Department of Corrections ("SCDC") to choose which drugs to use in its lethal injection protocol without requiring legislative approval. This means that any drug might at any moment be identified by the state and purchased in secrecy for use in executions. The concerning lack of transparency around the purchase, distribution, and use of controlled substances implicates important public health, safety and commercial interests. The Manufacturers concerns are based on experience with some state Departments of Correction that have added (or attempted to add) dangerous drugs of abuse to their execution protocols, as well as shortage drugs that are needed for critical patient care.

commercial practices are shaped by the U.S. drug regulatory system, which is designed to ensure patient access to reliable medicines by assuring transparency and accountability throughout the supply chain. As such, the Manufacturers are well-placed to assist the Court in understanding and evaluating the impact of the Secrecy Law on drug safety and the wider drug monitoring system. They are also well-positioned to assist the Court in understanding and evaluating the manner in which the Secrecy Law negatively affects the pharmaceutical market and commercial interests.

The Manufacturers are gravely concerned by the breadth of the Secrecy Law, and by the dangerous implications of the SCDC's interpretation of the statute. If allowed to stand, the Secrecy Law would undermine the closed control system in which the Manufacturers and members of the supply chain within the drug distribution space participate to prevent diversion, ensure quality, and provide access for patients. The Secrecy Law not only compromises the safety and quality of medicines, including drugs used in lethal injection executions; it also threatens public health, and undermines the commercial interests of Manufacturers, by exposing them to legal, fiscal, and other harms.

Amicus Manufacturer Fresenius Kabi USA LLC is a health care company that specializes in injectable medicines, biosimilars and technologies for infusion, transfusion, and clinical nutrition. The company's products and services are used to help care for patients with critical and chronic conditions. Fresenius Kabi USA is based in Lake Zurich, Illinois, and the company develops, produces and delivers essential medicines throughout the U.S. via a national R&D, manufacturing and supply chain network with operations in South Carolina, North Carolina, New York, Nevada, Illinois, Pennsylvania and Massachusetts. More than 70 percent of the units shipped by Fresenius Kabi in the U.S. are drugs listed on the U.S. Food & Drug Administration's Essential Medicines list, and all the company's products are regulated by the FDA and other

government agencies for which there are stringent rules for assuring transparency and safety of supply. Hospitals, clinics, and other sites of care throughout the state of South Carolina rely on medicines produced by Fresenius Kabi to treat patients. These medicines are essential to therapies such as oncology, anesthesia and analgesia, anti-infective treatments, and critical care.

Amicus Manufacturer Exela Pharma Sciences, LLC is an award-winning, fast-growing US-based integrated specialty pharmaceutical company, founded in 2005. Exela develops and manufactures proprietary and generic sterile injectable products to address the unique needs of healthcare providers, improve patient experience, and ease drug shortages. Their mission is to provide high-quality affordable medicines that alleviate human pain and suffering while expediting their availability to those in need. Exela's medicines are distributed across the US, including in South Carolina, where patients rely on them for life-enhancing and life-saving care.

Amicus Manufacturer Hikma Pharmaceuticals USA is committed to improving lives by providing patients with access to high quality, affordable medicines. Their medicines are used millions of times each day to treat illness and save lives. This has been their mission for more than 45 years. They develop, manufacture and distribute a broad range of generic and branded medicines across the U.S. including many essential medicines that hospitals, physicians and pharmacists in South Carolina and across the nation need to treat their patients. Hikma is one of the top generic medication providers in the U.S., offering many oral solid, nasal and inhalable medicines and more than 150 injectable pharmaceutical products across a range of therapeutic categories including respiratory, oncology, pain management and many others. They are known for their integrity, quality, respect and transparency. They strive to have a positive impact on all those their work touches – the healthcare providers and patients who use our medicines, their

customers, partners and suppliers, their fellow employees and the wider community – and they reflect this care in everything they do.

Amicus Manufacturer Sagent Pharmaceuticals is a specialty pharmaceutical company that develops and sources products that it sells primarily in the United States. Initially founded in 2006, Sagent is based in Schaumburg, Illinois, and has established a growing and diverse product portfolio and product pipeline. Sagent's product portfolio can generally be classified into the following three product categories: anti-infective, oncology and critical care. Its anti-infective products assist in the treatment of various infections and related symptoms, its oncology products are used in the treatment of cancer and cancer-related medical problems and its critical care products are used in a variety of critical care applications and include anesthetics, cardiac medications, steroidal products, and sedatives. Sagent's products are distributed throughout the United States, including to hospitals and clinics in South Carolina.

Amicus Manufacturer Sandoz is a global leader in generic, biosimilar, and other value-added medicines that are developed, manufactured, and distributed for use by the healthcare community. Their mission is to improve and extend people's lives and to ensure their drugs are available for critical patient care. Sandoz has a long history of innovating to increase access to high-quality, affordable medicines to millions of patients around the world.

This brief begins by explaining the closed control system that is essential for the safety and reliability of all drugs that move through the supply chain in South Carolina, including those drugs potentially used in executions. It then demonstrates how the Secrecy Law undermines this system, detailing the consequences of secrecy on the quality and safety of drugs moving through the supply chain on broader public health, and on the business interests of the Manufacturers.

II. The Secrecy Law undermines the system safeguarding the safety and efficacy of drugs, including drugs used in executions, leading to adverse consequences for public health.

The legal framework created by the Secrecy Law and the SCDC's broad interpretation of the same effectively exempt medicines used in lethal injection executions from the regulatory framework governing the production, distribution, and use of drugs. Moreover, the Secrecy Law, particularly as interpreted by the SCFC, adopts an expansive definition of "execution team" in a way that appears to include manufacturers of drugs used in lethal injection executions, even if they are unaware that their products are used for this purpose. According to the SCDC, manufacturers are members of the "execution team," and, therefore, any information that could speculatively lead to their identification, or the identification of others in the supply chain, is subject to "absolute" confidentiality, including basic information about the medicines. Violations of the Secrecy Law trigger civil and criminal penalties. This framework endangers the regulatory safeguards that ensure the quality of medicines, undermines contracts in place to protect medicines from diversion and abuse, and exposes manufacturers to potential conflicts with their regulatory disclosure obligations.

Transparency in the pharmaceutical supply chain is vital to ensure that each member of the chain can effectively monitor the distribution of medicines to prevent drug diversions that lead to misuse, abuse, and public health disasters. The Manufacturers have corresponding regulatory, legal, commercial, and medical responsibilities, alongside other participants in the supply chain who handle the products, such as re-packagers, re-labelers, wholesale distributors, and dispensers (primarily pharmacies), to take steps to ensure the safety and quality of drugs. Members of the supply chain rely on each other to adhere to and fulfill their obligations to the regulatory authorities and uphold their corresponding responsibility for the provision of high-quality medicines. The Secrecy Law, as discussed below, jeopardizes their ability to perform those functions, with

potentially grave consequences for the safety and quality of all drugs, including drugs used in executions both in South Carolina and elsewhere.

A. Drug manufacturing and distribution are governed by a detailed and complex regulatory system in the United States.

A complex regulatory system involving both federal and state laws and agencies governs the production, distribution, and use of controlled substances. That system relies on a closed distribution network to guarantee the safety and quality of drugs. *See* Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. § 360eee–1 (2013); *see also* Drug Enforcement Administration, Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16235, 16237 (Mar. 31, 2010).[2] This closed system is intended to prevent unreliable drugs from entering the supply chain through diversions and to enable a rapid response if such drugs are found. *See, e.g.*, DSCSA, 21 U.S.C. § 360eee–1. Drugs handled outside of this tightly regulated federal framework are not protected by these safeguards. A full description of these mechanisms lies beyond the scope of this brief, but the Manufacturers mention here some of these standards to highlight the interdependence between drug monitoring systems, drug safety, the Manufacturer's commercial interests, and broader public health interests. Also outside the scope of this brief is the question of whether this federal framework pre-empts the Secrecy Law under the Supremacy Clause of the U.S. Constitution. The

[2] "Under the framework of the CSA, all controlled substance transactions take place within a 'closed system' of distribution established by Congress. Within this closed system, all legitimate handlers of controlled substances--manufacturers, distributors, physicians, pharmacies, and others--must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions." U.S. Dep't of Just., Drug Enf't Admin., Diversion Control Div., Practitioner's Manual 8 (2023), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf.

Manufacturers understand that this issue is covered in detail in a separate Amicus Brief filed by Concerned Professionals.[3]

The Manufacturers' have a commercial and medical interest in closely tracking the distribution of their products from the first point of sale to final delivery. DSCSA, 21 U.S.C. § 360eee–1; *see also Combating Counterfeit Medicine*, PFIZER, https://www.pfizer.com/products/medicine-safety/counterfeiting#:~:text=Pfizer's%20Anti%2DCounterfeiting%20Program,distributors%20of%20counterfeit%20Pfizer%20medicines (last visited Jan. 24, 2024).[4] Tracking helps ensure that medicines remain within the closed system of distribution and can be identified and located should the Manufacturers need to intervene to safeguard their reliability through procedures like product recalls and investigations into new adverse patient reactions.

Other aspects of tracking and monitoring are also federally mandated responsibilities. These include disclosures to federal agencies, including the Drug Enforcement Administration ("DEA") and the Food and Drug Administration ("FDA") of specific drug-related data to enable these agencies to oversee the safe distribution and use of drugs across the U.S. under the Federal

[3] This Amicus Brief from Concerned Professionals is being submitted by a group of medical professionals, scientists, regulators, and educators who 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.

[4] "It is precisely because of the threat that counterfeit medicines pose to patients that Pfizer has implemented an aggressive and focused campaign to detect, disrupt and deter major manufacturers and distributors of counterfeit Pfizer medicines. We work with wholesalers, pharmacies, customs offices, and law enforcement agencies worldwide to increase inspection coverage, monitor distribution channels, and improve surveillance of distributors and re-packagers. Most significantly, we conduct and manage pro-active investigations and refer the cases we develop to enforcement authorities."

Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.*[5]

The regulatory framework for drugs increasingly requires rigorous tracking (monitoring the product through the supply chain) and tracing (gathering information about product's journey through the supply chain) records for controlled substances to safeguard public health. Congress enhanced reporting obligations in 2013 by enacting the DSCSA, 21 U.S.C. § 360eee–1, to more tightly regulate the supply chain and thereby address unsafe, ineffective, and counterfeit drugs. The DSCSA establishes a federal system for tracing prescription drug products at the package level through the pharmaceutical supply chain. Manufacturers and other members of the supply chain are required to provide, receive, and maintain product and distribution information. *See, e.g.*, *id.* § 360eee-3(b). This system helps to protect patients from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful, and to improve detection and removal of potentially dangerous drugs from the drug supply chain to protect public health.[6]

The success or failure of the closed monitoring system is predicated upon the participation of all members of the supply chain, with whom the Manufacturers work closely. Re-packagers, wholesale distributors, third-party logistics providers, and dispensers must meet similar tracking

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[5] *See, e.g.*, DSCSA, 21 U.S.C. § 360eee–1(b)(1)(B) ("Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product."); *see also* CSA, 21 C.F.R. § 1310.76(b) ("The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant must also file a complete and accurate DEA Form 106 with the Administration through DEA's Diversion Control Division secure network application within 45 days after discovery of the theft or loss.").

[6] Drug Supply Chain Security Act (DSCSA), FDA (Dec. 13, 2023), https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

and reporting obligations on issues relating to drug production, distribution, and dispensing. The DSCSA imposes additional duties on them to report instances where they believe drug diversions may have taken place. They must establish systems to determine whether a product is "illegitimate"[7] and notify the FDA and all appropriate immediate trading partners within 24 hours if a drug diversion has taken place. 21 U.S.C. § 360eee–1(b)(4)(B)(ii).

The ability to track drugs as they move through the supply chain is essential for battling public health harms such as the opioid epidemic. This tracking ability is also necessary to avoid the risk that contaminated, substandard, or counterfeit drugs will enter and/or circulate within the U.S. *See, e.g.*, Henry N. Njuguna et al., *Hepatitis C Virus Potentially Transmitted by Opioid Drug Diversion from a Nurse—Washington, August 2017–March 2018*, U.S. DEP'T OF HEALTH & HUM. SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION ("CDC") (Apr. 26, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6816a3-H.pdf; *see also* Jillianna Wasiura et al., *Correspondence: Cluster of Sphingomonas paucimobilis Bacteremias Linked to Diversion of Intravenous Hydromorphone*, NEW ENG. J. MED. (2019), https://www.nejm.org/doi/10.1056/NEJMc1902973. When contaminated drug products reach the wider market—either directly through drug diversion or indirectly through substandard supply channels—the results can be catastrophic. The world learned of these consequences firsthand in 2012 when medicines from a New England compounding pharmacy were contaminated with fungus, causing an outbreak of meningitis that caused the death of over 100 people and sickened

[7] 21 U.S.C. § 360eee(1)(8) defines an illegitimate product as a product for which credible evidence shows that the product is (A) counterfeit, diverted, or stolen; (B) intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

nearly 800 in 20 states.[8] In the case of the opioid crisis, nearly 1,500 people were killed and another 10,000 hospitalised in a single year in South Carolina alone due to diversions and misuse of the synthetic opioid Fentanyl.[9]

In order to further safeguard the quality of drugs throughout the distribution stream, manufacturers enter into agreements with other members of the supply chain, such as wholesalers and pharmacies. These agreements, in conjunction with federal regulation, dictate the terms upon which certain drug products may be distributed along the supply chain, in order to ensure that products are used safely, in the course of professional practice, to promote patient health and wellbeing. Particular restrictions are implemented for high-risk products, products with a heightened risk of abuse or misuse, and products with a niche patient population. Manufacturers periodically audit wholesalers to ensure the terms of these agreements are followed. *See, e.g.*, Agata Dabrowska, CONG. RSCH. SERV., R44810, *FDA Risk Evaluation and Mitigation Strategies (REMS): Description and Effect on Generic Drug Development* 6 (2018), https://sgp.fas.org/crs/misc/R44810.pdf.

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[8] The New England Compounding Center was not accredited and produced large quantities of drugs for hospitals across the country, rather than the traditional compounding practice of producing small quantities in response to individual needs. An FDA investigation found mold and bacteria in areas that should have been sterile and discovered microbial growth in all 50 tested vials of methylprednisolone acetate, an injectable pain medication that was linked to the meningitis outbreak. The New England Compounding Center voluntarily recalled all of its products, ceased operations, and handed its license over to the Massachusetts Board of Registration in Pharmacy in October 2012, and former employees were convicted on criminal charges. *See* Press Release, FDA, *Owner and Four Former Employees of New England Compounding Center Convicted Following Trial* (Dec. 13, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/december-13-2018-owner-and-four-former-employees-new-england-compounding-center-convicted-following; *see also* CDC, *Multistate Meningitis Outbreak*, https://www.cdc.gov/hai/outbreaks/meningitis.html (last visited Jan. 24, 2024).

[9] State health authorities believe that the true number of casualties is even higher. *See* Ali Rockett & Zharia Jeffries, *SC may be undercounting overdoses from the deadliest drug*, POST & COURIER (July 1, 2023), https://www.postandcourier.com/news/sc-may-be-undercounting-overdoses-from-the-deadliest-drug/article_aec0b786-ffc2-11ed-8d8d-b381d4c12f00.html.

In sum, each participant in the drug supply chain relies on the transparent cooperation and compliance of others within the chain to carry out their responsibilities for drug safety and quality. Without transparency across the supply chain and adherence to proper safeguards and controls, the protections built into the drug monitoring system will fail.

B. The South Carolina Secrecy Law risks undermining the safety controls provided by this regulatory framework.

The Secrecy Law, and the SCDC's extremely broad interpretation of that law, has the dangerous consequence of impeding the Manufacturers' ability to monitor the supply chain and ensure that their products are safe and reliable. It deliberately undermines both the drug monitoring system and the Manufacturer's commercial interests. The effect of this secrecy regime is to interfere with professional and regulatory oversight of medicines at every stage of the supply chain, undermining the systems that ensure the safety and quality of medicines in South Carolina.

The Secrecy Law explicitly allows the Appellants to procure drugs for use in lethal injection executions without regard to "the entirety of the South Carolina Procurement Code." S.C. Code Ann. § 24-3-580(D) (2023). A pharmacy or pharmacist involved in supplying, manufacturing, or compounding any drug used for executions is not bound by any of the licensing, dispensing, and possession laws, processes, regulations, and requirements of the Department of Labor, Licensing and Regulation, the Board of Pharmacy, or any other state agency. *Id.* § 24-3-580(F). Likewise, no physician's prescription is required for any drug intended for use in executions, meaning that the record documenting the procurement and use of these drugs is compromised. *Id.* Moreover, any out-of-state acquisition of drugs is exempt from all licensing processes and requirements administered by the Department of Health and Environmental Control or by any other department or Agency. *Id.* § 24-3-580(E). These provisions remove safeguards

that would otherwise protect the quality and reliability of medicines circulating in South Carolina and more widely.

The Secrecy Law, as interpreted by the SCDC, incorporates an expansive definition of the "execution team" that covers the entire drug supply chain, potentially including entities who are unaware that South Carolina has purchased their drugs for execution purposes. According to the SCDC, *any* person or entity involved however tenuously in the planning or administration of the execution of a death sentence is deemed a member of the team and restricted by secrecy, regardless of their wishes or indeed their awareness of their status. This includes "any person or entity that prescribes, compounds, tests, uses, manufactures, imports, transports, distributes, supplies, prepares, or administers the drugs." S.C. Code Ann. § 24-3-580(A)(1). This definition, particularly under SCDC's broad interpretation, could be construed to mean that the "execution team" includes a doctor, pharmacist, importer, supplier, wholesaler, manufacturer, or other healthcare sector participant—a wide array of entities who may have no knowledge they have been—and no desire to be—included in an "execution team."

The implications of this expansive secrecy framework, especially if mis-interpreted by implementing agencies, are draconian. The Secrecy Law imposes significant penalties for the disclosure of "identifying information" relating to a member of the execution team. S.C. Code Ann. § 24-3-580(A)(2). It grants "absolute confidentiality" status to "any record or information that reveals a name, date of birth" or other "personal identifying information" in relation to an execution team member (emphasis added). *Id.* § 24-3-580(A)(2), (I). Accordingly, if their products were, unbeknownst to them, used in an execution, the Manufacturers, and any of the other members of the supply chain with whom the Manufacturers work, could be found to have run afoul of these provisions simply by carrying out their ordinary reporting, monitoring, investigating, or

tracking duties as part of their public health mandate, and particularly under the SCDC's expansive view of the Secrecy Law.

Further exacerbating these risks, the Secrecy Law instructs that the term "identifying information" is to be "broadly" construed. S.C. Code Ann. § 24-3-580(I). The SCDC has taken this instruction to an extreme, concluding that even basic information about the drugs to be used in lethal injection (such as the date of manufacture, the batch number, or the expiration date) is confidential under the Secrecy Law, because it speculatively could reveal identifying information.[10] This overreaching interpretation of the Secrecy Law far exceeds what is required to protect the identity of individuals and entities who participate in planning and carrying out executions and aggravates the risk to healthcare sector entities who act to protect the integrity of the supply chain.

The Secrecy Law further imposes both civil and criminal penalties for violating its provisions, penalties up to and including a term of imprisonment of three years (in fact, the statutory language ("must be imprisoned") appears to be an attempt to require incarceration conviction). S.C. Code Ann. § 24-3-580(C). The Secrecy Law even purports to make criminally liable any person who "knowingly" discloses confidential information to incur criminal liability, even if they did not *intend* to reveal information that could lead to the identification of an execution

[10] Appellants have stated that:

> … information such as the date when the drugs were manufactured or compounded or any procedures used in manufacturing or compounding the drugs could result in identifying the source, particularly when considered alongside any additional information Respondents may be able to gather from other sources.

Reply in Supp. of Mot. to Lift Abeyance, Dismiss Appeal, & Vacate Circuit Ct. Order 9–10 (Oct. 2, 2023).

team member.[11] A person acts "knowingly if he is aware 'that the result is practically certain to follow from his conduct, whatever his desire may be as to that result.'" *State v. Jefferies*, 316 S.C. 13, 20 n.8, 446 S.E.2d 427, 431 n.8 (1994) (quoting *United States v. Bailey*, 444 U.S. 394, 404 (1980)). By contrast, a person acts "purposefully if 'he consciously desires that result, whatever the likelihood of that result happening from his conduct.'" *Id.* at 19 n.7, 446 S.E.2d at 431 n.7 (quoting *Bailey*, 444 U.S. at 405).

A manufacturer, in the course of filing mandatory drug disclosures to an administrative agency (documents that are generally available to the public through public records requests), may inadvertently include information that, combined with otherwise available information, leads to the identification of a member of the execution team. Under the SCDC's interpretation of the Secrecy Law, the state could argue that the manufacturer "knew" that it was disclosing information about a drug that is or has been listed in a state's execution protocol. Even if the manufacturer had no way to know, let alone intend, that this information would lead to the identification of an execution team member (including its own identification), and even if the disclosure was mandated by law, nothing in the Secrecy Law, particularly as interpreted by the SCDC, appears to protect the manufacturer from criminal responsibility. Let us consider another example: if a manufacturer is made aware that some of its product has been contaminated, counterfeited, or otherwise diverted

[11] In relevant part, S.C. Code Ann. § 24-3-580(C) provides:

> *A person shall not knowingly disclose the identifying information of a current or former member of an execution team or disclose a record that would identify a person as being a current or former member of an execution team. Any person … or entity whose identity is disclosed in violation of this section shall have a civil cause of action against the person who is in violation of this section and may recover actual damages and, upon a showing of a wilful violation of this section, punitive damages. A person who violates the provisions of this subsection also must be imprisoned not more than three years.*

S.C. Code Ann. § 24-3-580(C) (emphasis added).

from the regulated supply chain, any investigation it launches risks violating the Secrecy Law, particularly as construed by the SCDC, potentially triggering civil and criminal penalties. This would force the manufacturer to weigh risks to patients and its own business reputation against the risk that its inquiry would uncover an unregulated, unsafe supply chain leading to an execution chamber, arguably in violation of the Secrecy Law. These provisions thus create a situation where it may be effectively impossible for the Manufacturers and other members of the supply chain to carry out activities that are necessary to safeguard the integrity of drugs through the supply chain, creating a potential conflict of law between state and federal regulations.

Each actor in the healthcare sphere relies on other actors carrying out their responsibilities transparently and consistently. Yet, South Carolina would apply the Secrecy Law to obscure portions of the supply chain from those entities, hindering their ability to adhere to the law and undertake these responsibilities. The consequences of such a policy are potentially devastating: by undermining the very system that protects the safety of drugs, the Secrecy Law risks counterfeit or contaminated products entering the market. This policy not only raises the specter of a botched lethal injection execution from unreliable drugs[12] but it also poses direct harms to South Carolina patients. Research shows that once drugs enter the market from outside the closed system of distribution, there is a real risk that these unapproved drugs will ultimately reach the general patient population. *See* Prashant Yadav et al., *When government agencies turn to unregulated drug*

[12] As noted by the Association for Accessible Medicines, the largest industry association of generic and biosimilar manufacturers and distributors in the country, "Operating without the benefit of rigorous scientific research, states may be forced to proceed through trial and error. And the errors can be ghastly: uncertainty about a drug's efficacy and dosing appear to have contributed to "horrific execution[s]" in which a prisoner appears "to be in great pain" because the drug did not work to anesthetize the prisoner in the way corrections officials intended." Brief for the Association for Accessible Medicines, as Amicus Curiae, in Support of Neither Party ("AAM Amicus Brief") at 10, *Bucklew v. Precythe,* 139 S. Ct. 1112 (2019) (No. 17-8151).

sources: Implications for the drug supply chain and public health are grave 3, J. AM. PHARMACISTS ASS'N (July 5, 2018), *available at* https://www.japha.org/article/S1544-3191(18)30336-4/fulltext. In 2010, for example, ten states acquired supplies of sodium thiopental from Dream Pharma, a pharmacy in England apparently operating out of a back room in a driving school, for the purpose of using them in executions. The drug product was not FDA-approved and its importation was illegal. But the states acted covertly, outside of the protections provided by the closed system supply chain, and the products entered the United States despite their unapproved status. *See* Jim Edwards, *Drug Company? Driving School? It's All the Same in the Lethal Injection Business*, CBS NEWS (Jan. 6, 2011), https://www.cbsnews.com/news/drug-company-driving-school-its-all-the-same-in-the-lethal-injection-business. Some of these driving school products eventually found their way to hospital shelves. This led a federal judge to opine that allowing such drugs into the country "threaten[ed] the public health by creating a risk that thiopental could incorrectly end up in the hands of the general public." *Beaty v. FDA*, 853 F. Supp. 2d 30, 42 & n.8 (D.D.C. 2012), *aff'd in part, vacated in part sub nom Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013); *see also Cook*, 733 F.3d 1.

The Secrecy Law's obstruction of the federally regulated drug control regime raises an important question as to whether the Secrecy Law is pre-empted by the extensive federal drug-regulation regime under the Supremacy Clause of the U.S. Constitution. Consideration of this is outside of the scope of this brief but is set out in detail in an Amicus Brief from Concerned Professionals which details the pre-emption doctrine applying where state law (here the Secrecy Law) conflicts with federal law (here the federal drug-regulation regime) and the ensuing invalidity of the relevant state law.

III. By undermining manufacturers' ability to take action to safeguard drug quality, the Secrecy Law harms the Manufacturers' business interests in South Carolina and beyond.

As discussed above, the Secrecy Law severely compromises the Manufacturers' closed monitoring systems that safeguard the quality of medicines, including those drugs used in executions. Its far-reaching scope harms business practices adopted by the Manufacturers to protect the quality of their products. One of these practices, the implementation of distribution agreements, is at particular risk, thereby impairing the Manufacturers' ability to deploy freedom of contract for the purpose for which it was intended in commercial contexts: to enhance business prospects and to mitigate business risks.

The Manufacturers have obligations to track and trace their products throughout the supply chain. 21 U.S. Code § 360eee–1. They have both a regulatory and commercial interest in ensuring the proper distribution of their products. *See, e.g.*, *Combating Counterfeit Medicine*. Accordingly, manufacturers can enter into agreements with their distributors that specify and limit how the drugs they manufacture are to be distributed. In the context of drugs used in executions, the Manufacturers—like other major drug companies—have specific agreements in place with other members of the supply chain, such as wholesalers and pharmacies to protect their drugs from misuse in executions. These agreements "further drug manufacturers' legitimate business interest to reduce the "reputational, fiscal, and legal risks" associated with the misuse of drugs in executions. AAM Amicus Brief at 15, *Bucklew*. These agreements also implement legal rights that courts have found that to apply in this context. *See, e.g.*, Notice of Entry of Order & Findings of Fact and Conclusions of Law ("Mem. Op.") ¶¶ 258–59, *Alvogen v. Nevada*, No. A-18-777312-B (Nev. Dist. Ct. Sept. 28, 2018) ("Because of the highly regulated nature of their products, all pharmaceutical companies retain a property interest in their products subject to FDA regulations for the purpose of quality control and potential removal from the marketplace … [manufacturers

and distributors] of pharmaceutical products necessarily retain some ownership rights in their products in order to comply with FDA rules and regulations, such as for purposes of implementing product recalls.")

The Secrecy Law, particularly as interpreted by the SCDC, undermines the Manufacturers' ability to monitor and oversee the distribution of their drugs through its overbroad definition of the execution team and by rendering confidential information that may be necessary for Manufacturers to track and trace their products and, where necessary, enforce their contracts. Indeed, under such an interpretation, even carrying out an investigation into a potential breach of contract risks triggering the civil and criminal penalties of the Secrecy Law. S.C. Code Ann. § 24-3-580I.

By preventing the Manufacturers from enforcing their distribution contracts and stopping diversions of their products, the Secrecy Law conscripts them involuntarily into the execution team. This raises constitutional concerns under freedom of contract principles. The South Carolina Constitution guarantees freedom of contract as a cornerstone principle upholding a business environment where persons have the freedom to pursue an occupation free from unreasonable government interference. Article I, Section 4 of the state constitution provides: "No … law impairing the obligation of contracts … shall be passed …." S.C. Const. art. I, § 4. The federal Constitution's Contract Clause also prohibits the impairment of contracts. U.S. Const. art. 1, § 10. Violations of the Contracts Clause turn, among other factors, on an evaluation of "whether the change in the law impairs that contractual relationship" and "whether the impairment is substantial." *Hodges v. Rainey*, 341 S.C. 79, 93, 533 S.E.2d 57, 585 (2000) (citing *Gen. Motors Corp. v. Romein*, 503 U.S. 181 (1992)). Moreover, "[f]or purposes of Contract Clause analysis, a statute can be said to substantially impair a contract when it alters the reasonable expectations of

the contracting parties." *Id.* at 94, 533 S.E.2d at 585–86 (citation omitted). The expectations of the Manufacturers and their distributors have certainly been altered by the Secrecy Law, which (particularly as interpreted by the SCDC) undermines their ability to turn to contractual agreements as an effective tool to build and protect their business interests, subjects them to potential civil and criminal liability, and exposes them to what one court has identified as potential "irreparabl[e]" reputational harm. Mem. Op. ¶ 303, *Alvogen*, No. A-18-777312-B.

In addition, the Secrecy Law makes it much more likely that drugs used in executions will be obtained from outside controlled supply chains and will bypass the kind of quality assurance that regulatory and contractual controls are designed to ensure. This, in turn, exposes the Manufacturers to increased risk their products will be misused, thwarting the purpose of contractual controls.

Stakeholders in the pharmaceutical industry foresaw these issues and have expressed their concern in various fora. For instance, in an amicus brief before the U.S. Supreme Court in the case of *Bucklew*, the industry association for generics manufacturers (a number of which are amici in this brief), the Association for Accessible Medicines (AAM), explained that "states have […] found ways to secure those drugs for use in capital punishment—sometimes under questionable circumstances." *Bucklew*, AAM Amicus Brief at 17; *see also* Richard A. Oppel Jr., *Nevada Execution Is Blocked After Drugmaker Sues*, N.Y. TIMES (July 11, 2018) (describing a temporary restraining order to block Nevada's use of midazolam in an execution based on the manufacturer's suit alleging that the drug was purchased by Nevada under false pretenses, and in violation of the company's distribution controls); Complaint, *McKesson Med.-Surgical Inc. v. Arkansas*, No. 60CV-17-1921 (Cir. Ct. of Pulaski Cnty. Apr. 14, 2017) (alleging that the Arkansas Department of Corrections purchased vecuronium from McKesson, a leading pharmaceutical distributor, by

concealing its intent to use the drug in executions, which violated the manufacturer's terms of sale). As a result, drugs may be used for purposes that AAM members did not intend." *Bucklew*, AAM Amicus Brief at 15.

The AAM further noted that the use of secrecy to facilitate the illicit procurement of execution drugs "not only conflicts with the policies and values of AAM and its members—and risks significant damage to their reputations—but it also carries the prospect of legal liability. For example, one family of an executed inmate brought a product liability suit against a midazolam manufacturer and a pharmaceutical wholesaler because the manufacturer's product was used in an execution that allegedly caused severe pain and suffering." *See* First Am. Compl. ¶ 162, *McGuire v. Mohr*, No. 14-cv-93 (S.D. Ohio filed Dec. 5, 2014). Continued misuse of drugs by corrections officials may invite future suits against legitimate drug companies, and could ultimately harm patients by contributing to drug shortages."[13]

For all the reasons detailed in this brief, the Manufacturers have consistently opposed the efforts by states—including South Carolina—to introduce secrecy laws and practices, on the basis

[13] Drug shortages represent another public health concern associated with the misuse of drugs intended for use in executions. Drugs listed in lethal injection protocols have critical uses for patients with medical needs. Pentobarbital, for instance, is a barbiturate drug indicated as a sedative, a short-term treatment for insomnia, a pre-anesthetic, and an emergency treatment for some types of acute convulsive episodes, such as those associated with eclampsia, tetanus, or meningitis. *See* Nat'l Library of Medicine, *Pentobarbital sodium, NDC Codes 25021-676-20, 25021-676-50*, DAILYMED, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e9f4b344-b092-4eec-b49d-d8cfe8ebc05d. Reports from other states show that Corrections officials sometimes stockpile drugs in sufficient quantities to create a risk of drug shortages—a practice that has real consequences for public health. *See* Ed Pilkington, *States Are Stockpiling Lethal Injection Drugs That Could Be Used to Save Lives*, THE GUARDIAN (Apr. 20, 2017), https://www.theguardian.com/world/2017/apr/20/states-stockpiling-lethal-injection-drugs-arkansas-execution (last visited Jan. 24, 2024) ("Arkansas has stockpiled sufficient supplies . . . to treat 1,800 patients in potentially life-saving operations. . . . Virginia[] has sufficient stocks of drugs used in its lethal injection protocol to treat almost 5,000 patients in critical operations.").

that these undermine their ability to ensure the safety of drugs and increase the commercial risks that the companies face. Amicus Hikma, explains that "[*t*]*ransparency is one of our core values, and as such* [*we*] *object*[] *to attempts by any entity, person or state to obscure or hide the source of products for lethal injection. It is imperative that we are not impeded from protecting patient health and the integrity of our products and our supply chain.*" *Use of products in capital punishment*, HIKMA, https://www.hikma.com/about/our-policies-and-positions/use-of-products-in-capital-punishment/#:~:text=We%20object%20in%20the%20strongest,quality%2C%20affordable%20healthcare%20to%20patients (last visited Jan. 24, 2024) (emphasis added).

In a joint filing before the Ohio Supreme Court in 2017, amici Fresenius Kabi and Sandoz explained that as manufacturers, they "*have a keen and important interest in knowing whether any department of corrections have obtained their drugs despite and in contravention of their distribution controls and contracts*." Amicus Curiae Brief in Support of Relator on Behalf of Fresenius Kabi USA, LLC and Sandoz Inc. at 2, *State ex rel. Hogan Lovells U.S., L.L.P. v. Dep't of Rehab. & Corr.*, No. 2016-1776 (Ohio filed July 10, 2017) (emphasis added). In so arguing, the companies made clear that:

> *Any refusal by the state to disclose the manufacturers of its lethal injection drugs directly undermines [Fresenius Kabi and Sandoz's] interests, impeding their ability to preserve the integrity of their contracts .... To the extent that these records indicate a violation of manufacturer contracts, release of this information would allow the manufacturers to enforce their contractual rights and take appropriate steps to prevent future diversion of their medicines.*

Id. at 5–6 (emphasis added)

Further, in a letter addressed to South Carolina officials, Sandoz noted that:

> *Public health experts and pharmaceutical companies alike have raised concerns that the use of secrecy and diversion to procure manufactured or compounded medicines for executions can undermine the integrity of the supply chain, creating risks for public health. Our trade association, AAM has made clear—including by way of an amicus curiae brief*

> *in the United States Supreme Court—that the industry is "firmly opposed[d]" to the misuse of medicines in executions, a practice that it says "has real consequences for public health" and which "could ultimately harm patients."*

Although the Secrecy Law purports to "shield" sources of lethal injection drugs from the risks associated with executions, the Manufacturers wish to emphasize that a secrecy regime is more harmful than transparency. Governor McMaster declared that a secrecy law was necessary for execution to resume because potential suppliers of drugs were "afraid that their names will be made known and they don't want to have anything to do with it for fear of retribution or exposure."[14] To the contrary, the Manufacturers have repeatedly and emphatically requested that they *not* be granted cover of secrecy for potentially playing an unwanted role in supplying drugs for executions. In addition to the reasons outlined in this brief, in the event of a failed lethal injection execution, negative attention would likely be redirected towards the supplier. Indeed, Senator Hembree, the lead sponsor of the secrecy bill, conceded as much during debates in the legislature, asserting that if a botched execution were to occur, the courts would likely force the disclosure of drug-related information, despite the Secrecy Law precluding judicial review.[15] To

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[14] *South Carolina Seeks Drug-Secrecy Law to Carry Out Execution that was Never Going to Happen*, DEATH PENALTY INFO. CTR. (Nov. 22, 2017), https://deathpenaltyinfo.org/news/south-carolina-seeks-drug-secrecy-law-to-carry-out-execution-that-was-never-going-to-happen.

[15] During the legislative debates about the Shield Law, the principal sponsor of the secrecy bill, Senator Hembree, repeatedly stated that the General Assembly could simply "trust the judicial system" to assert its authority even without a "good cause" provision expressly permitting disclosure:

> So I think **you're going to have to kind of trust the judicial system to, to deal with that exceptional circumstance, if you had a botched execution,** that a lawyer is going to come in and say, "Hey, I know what the statute says. But this is truly exceptional. And because of this, we need to . . . be able to pierce the shield." And, you know, I think . . . **that's what judges do**.

Hearing Before the Senate Comm. on Corrs. & Penology, 125th Leg.. at 20:11 (S.C. Feb. 2, 2023) (Statement of Sen. Greg Hembree) (emphasis added). *See also* Am. Final Br. of Resp't-Appellants at 51.

preserve the integrity of drug safety mechanisms as well as the Manufacturers' commercial interests, the cure is not more secrecy, the cure is full transparency in the drug supply chain, and freedom of contract underpinned by accessible enforcement mechanisms. If these fundamental business tools are not guaranteed, South Carolina becomes an uncertain, unpredictable business environment for the pharmaceutical industry and a threat to national public health.

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Respectfully submitted,

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