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S.C. SUPREME COURT

**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.

Motion for Leave to File Amicus Brief by Pharmaceutical Manufacturers

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Pursuant to Rule 213, South Carolina Appellate Court Rules (“SCACR”), a group of pharmaceutical manufacturers hereby moves for leave to file an amicus curiae brief in the above matter to assist the 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 (“the Manufacturers”). 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.

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.

DESIRABILITY OF BRIEF OF AMICUS CURIAE

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 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 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. Finally, the Manufacturers are well-positioned to help the Court understand how the Secrecy Law, particularly as interpreted by South Carolina Department of Correction, would interfere with their regulatory obligations of monitoring, investigating, and reporting on supply-chain-related problems and create a disincentive not to investigate because of potential civil and criminal liability.

INTEREST OF AMICUS CURIAE

The Manufacturers are gravely concerned by the breadth of the Secrecy Law, and by the dangerous implications of the South Carolina Department of Correction's interpretation of the statute. As the Manufacturers set out in their brief, 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, reputational, and other harms.

For the foregoing reasons, the Manufacturers respectfully request that the Court grant leave to present an amicus curiae brief. A copy of the Manufacturers' proposed amicus curiae brief is attached hereto as **Exhibit A** and is being conditionally filed with this motion in accordance with Rule 213, SCACR.

Dated: January 31, 2024

Respectfully submitted,

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Exhibit A