IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

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| FRESENIUS KABI USA, LLC,<br><br>Plaintiff,<br><br>vs.<br><br>STATE OF NEBRASKA; THE NEBRASKA DEPARTMENT OF CORRECTIONAL SERVICES; and SCOTT FRAKES, in his Official Capacity as Director of the Nebraska Department of Correctional Services,<br><br>Defendants. | CASE NO. 18-cv-3109<br><br>COMPLAINT |

COMES NOW Plaintiff, Fresenius Kabi USA, LLC ("Fresenius Kabi"), and for its causes of action and claims for relief states and alleges as follows:

**PARTIES AND JURISDICTION**

1. Fresenius Kabi is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, IL 60047. Fresenius Kabi is a leading manufacturer and supplier of intravenous generic drugs. Fresenius Kabi manufactures and markets more than 120 drugs in over 400 dosages and formulations. Fresenius Kabi drugs are used in every area of clinical care, including cardiac care, dialysis, emergency, intensive care, OB/GYN, operating room, oncology, orthopedics, pediatrics, psychiatry, and radiology.

2. The Nebraska Department of Correctional Services is a Nebraska state agency established in 1973 with its principal place of business in Lincoln, NE. It is charged with carrying out the executions of those who have been sentenced to death.

3. Scott Frakes is the Director of the Department of Correctional Services of the State of Nebraska. Defendant Frakes' office is located at 801 W. Prospector Place, Lincoln, NE 68522 in Lancaster County, Nebraska. Nebraska statutes specifically

authorize and direct Defendant Frakes to prescribe and direct the means by which the Department of Correctional Services carries out executions.

4. Defendant State of Nebraska ("Nebraska") is the sovereign government of Nebraska.

5. In the six months ending June 30, 2018, Fresenius Kabi's net sales of Potassium Chloride ("KCL") total more than $1.5 million; in the twelve months ending June 30, 2018, Fresenius Kabi's net sales of KCL total more than $4.3 million; and in the twelve months ending December 31, 2017, Fresenius Kabi's net sales of KCL total more than $4.8 million.

6. The losses to Fresenius Kabi's net sales that will result if it does not obtain the injunctive relief it seeks is greater than $75,000.

7. This Court has subject matter jurisdiction in this action under 28 U.S.C. §§ 1331 and 1332.

8. Venue is proper in the District of Nebraska pursuant to 28 U.S.C. § 1391.

**ALLEGATIONS**

9. Defendants have scheduled the execution of Carey Dean Moore to take place on Tuesday, August 14, at 10:00 a.m. in the Nebraska State Penitentiary. A copy of the Execution Warrant issued by the Supreme Court of the State of Nebraska is attached hereto as Exhibit A.

10. Defendants have adopted an execution protocol that utilizes four drugs to be administered by lethal injection, Diazepan, Fentanyl Citrate, Cisatracurium Besylate, and Potassium Chloride. On information and belief, this combination of drugs has never before been used for an execution. Two of those drugs,

Cisatracurium Besylate ("Cisatracurium") and Potassium Chloride ("KCL") are manufactured by Fresenius Kabi.

11. The drugs Fresenius Kabi manufactures are supplied to health care professionals primarily through authorized wholesalers and distributors. Because its products are injectables, rather than oral solids, topicals or other forms used or administered directly by patients themselves, Fresenius Kabi's drugs are typically purchased and administered to patients by institutional end use customers such as hospitals and clinics and administered in in-patient or out-patient settings.

12. While Fresenius Kabi takes no position on capital punishment, Fresenius Kabi opposes the use of its products for this purpose and therefore does not sell certain drugs to correctional facilities. Since at least 2012, Fresenius Kabi has maintained a policy of not allowing the drugs it manufactures to be used in connection with lethal injections and has established special and specific distribution controls for a select group of products it manufactures and sells that have been identified from time to time for possible use, or been used, by one or more state governments for lethal injection executions, drugs it refers to as Restricted Products. Eight (8) drugs are currently listed on the Fresenius Kabi's Schedule of Restricted Products, a copy of which is attached as Exhibit B. Both Cisatracurium and KCL are listed on the Schedule of Restricted Products.

13. Fresenius Kabi only sells these Restricted Products to a limited number of its wholesalers and distributors who have been contractually convenanted (a) to abide by requirements that the products not be sold to prisons, (b) that the products be sold only to end use customers (and not distributors, retailers or other resellers), and (c) on the condition that the customers not resell or otherwise transfer the products to any other person or party. These provisions are for the express purpose to

prohibit the sale of these drugs to federal or state prisons, penitentiaries, jails or other incarceration facilities. The majority of other manufacturers or sellers of these drugs have instituted similar controls.

14. On information and belief, prior to November, 2017 Defendants had never taken the position that the identity of an execution drug manufacturer or supplier was not a matter of public record. They routinely and without objection provided records in response to public record requests for documents related to their efforts to purchase drugs for executions. The records produced included invoices, purchase orders, communications with drug suppliers, etc. In November, 2017 Defendants began taking the position that a statute enacted in 2009 amounted to an exception to the public records statutes. Defendants have been sued in the District Court of Lancaster County, Nebraska by media entities and the ACLU seeking orders mandating the release of records which would reveal the manufacturers of the drugs that the state intends to use to execute Carey Dean Moore. The District Court of Lancaster County has ordered Defendants to release documents and records showing communications with supplier(s), DEA records, invoices, inventory logs and photographs of packaging. Defendants have appealed from that Order.

15. Defendants have obtained inventories of the drugs specified in their execution protocol. Included in those inventories is KCL, according to the inventory listing, attached hereto as Exhibit C. The KCL inventory list indicates the Defendants have in their possession 25 vials of KCL. The unit of measure for these vials is 30 ml. On information and belief, Fresenius Kabi is the only manufacturer of KCL in 30 ml vials. Attached hereto as Exhibit D is Defendants' inventory listing for Cisatracurium.

16. Defendants could not have acquired the drugs manufactured by Fresenius Kabi from an authorized distributor or in accordance with Fresenius Kabi

policies. These drugs, if manufactured by Fresenius Kabi, could only have been obtained by Defendants in contradiction and contravention of the distribution contracts the Company has in place and therefore through improper or illegal means. Defendants are well aware that Fresenius Kabi opposes the use of its drugs as part of any state's lethal-injection protocol. On July 24, 2018 Fresenius Kabi sent the Honorable Pete Ricketts, Governor of Nebraska, a letter emphasizing that Fresenius Kabi opposes the use of its life saving products as part of the state's lethal-injection protocol and requesting that any Fresenius Kabi drugs the state has acquired for use in connection with executions be returned without delay. Fresenius Kabi offered a full refund. A copy of said letter is attached hereto as Exhibit E. To this day, Defendants have not returned the Fresenius Kabi drugs and have not provided a substantive response to this correspondence.

17. In addition to the above-referenced letter, Fresenius Kabi has previously and specifically corresponded with the Nebraska Department of Corrections about its possession of previous stores of the Company's KCL (a different lot which would since have expired). That is, in 2015 Fresenius Kabi had learned that one of its distributors had mistakenly sold KCL to the Nebraska Department of Corrections. A representative of the Fresenius Kabi distributor contacted a representative of the Nebraska Department of Corrections and requested that the KCL be returned. The Fresenius Kabi distributor representative explained the Company's position that its drugs could not be used for executions by lethal injection. The representative of the Department of Corrections advised that Nebraska had repealed the death penalty and there were no scheduled executions. He refused to return the KCL and said he was using the product to treat the state's patients. On December 27, 2016 Fresenius Kabi sent Mr. Mark Boyer, Associate Legal Counsel of the Nebraska Department of Correctional

Services, a letter advising of Fresenius Kabi's concern regarding the potential use of certain of its products in lethal injections and that it had put in place distribution controls to prevent the sale or distribution of certain drugs for use in carrying out executions. Fresenius Kabi requested assurance that Nebraska would not use Fresenius Kabi medicines as execution agents and invited the opportunity to discuss the matter with Mr. Boyer or any Nebraska officials. A copy of said letter and the documents that accompanied the letter is attached hereto as Exhibit F. From this correspondence and the letter sent in July, 2018, the Defendants clearly know that Fresenius Kabi strongly opposes the use of its drugs in executions.

18. The ultimate customers of Fresenius Kabi are pharmacists, physicians and other health professionals who provide Fresenius Kabi drugs to patients for life sustaining or life saving purposes. The professional associations of those ultimate customers have uniformly adopted policies against capital punishment and lethal injection including the American Medical Association (Code of Ethics Opinion 9.7.3, attached as Exhibit G), the American Society of Anesthesiologists (See Statement on Physician Nonparticipation in Legally Authorized Executions approved 10/18/06 and reaffirmed 10/26/16, attached hereto as Exhibit H), the American Board of Anesthesiology, Inc. (See Commentary, May, 2014, attached as Exhibit I), the American Nurses Association (See Position Statement dated January 28, 2010, attached as Exhibit J), the American Pharmacists Association (See March 30, 2015 news release, attached hereto as Exhibit K), the American Public Health Association (See Policy 8521, attached as Exhibit L), the International Academy of Compounding Pharmacists (See 2018 statement, attached as Exhibit M), the American College of Physicians (See excerpt from Ethics Manual, attached as Exhibit N), and the World

Medical Association (See WMA Resolution on Physician Participation in Capital Punishment, attached hereto as Exhibit O).

19. Fresenius Kabi is an affiliate of a German group company—Fresenius SE & Co. KGaA—focused in healthcare, including the manufacturing of medicines and medical technologies used worldwide, including in the United States and Europe. European Union Regulation 1352/2011 authorizes the European Union ("EU") to prevent export from the EU of products that could be used in capital punishment. (See Commission Implementing Regulation (EU) No 1352/2011, attached as Exhibit P.) The list of products already subject to export restrictions includes anesthetic agents (e.g. Sodium Thiopental and Phenobarbital) that were added by the EU specifically because they were used in lethal injections in the United States.

20. Fresenius Kabi and the companies with which it is affiliated across the globe will suffer great reputational injury in the event its drugs are used for the administration of capital punishment. This injury will cause corresponding damage to business and investor relationships.

21. Drugs manufactured by Fresenius Kabi have been subjected to a rigorous testing and approval process mandated by the United States Food and Drug Administration ("FDA"). That process is vital to ensuring the safety of and efficacy of medicines for patients, physicians and public health. Fresenius Kabi drugs that have been approved by the FDA, including KCL and Cisatracurium, have not been tested or approved for use in lethal injection protocols.

22. Cisatracurium is a non-depolarizing skeletal muscle relaxant for intravenous administration. It acts on cholinergic receptors, blocking neuromuscular transmission. It is used to maintain neuromuscular relaxation during major surgical procedures, primarily to facilitate endotracheal intubation. It is typically administered

by an anesthesiologist or certified registered nurse anesthetist. Its use is contraindicated in patients with known hypersensitivity to the product and its components. Severe anaphylactic reactions to neuromuscular blocking agents, including Cisatracurium, have been reported. Precautions should be taken in individuals who have had previous anaphylactic reactions to other neuromuscular blocking agents since cross-reactivity between neuromuscular blocking agents, both depolarizing and non-depolarizing has been reported in this class of drugs. It should be refrigerated at 36-46 °F in the carton to preserve potency. It will lose potency if not properly refrigerated. Defendants' Execution Protocol provides that the drugs used for lethal injection shall be maintained under "room temperature storage conditions". See Title 29, Nebraska Administrative Code, Chapter 11, 008.03. Use of this drug not stored under proper labeled conditions could lead to adverse consequences for the person to whom the drug is administered.

23. The potassium chloride listed on Defendants' inventory document is an injectable concentrate. Potassium chloride for injection is a parenteral fluid and electrolyte replenisher. Potassium is the chief cation of body cells and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve condition and muscle contraction, particularly in the heart. Chloride, the major extra cellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration. Potassium chloride for injection concentrate is indicated for the treatment of potassium deficiency when oral replacement is not feasible. Potassium chloride for injection concentrate is contraindicated in diseases where high potassium levels may be encountered and in patients with hyperkalemia, renal failure and in

conditions in which potassium retention is present. The dose and rate of administration are dependent upon (and adjusted for) the specific condition of each patient.

24. Potassium chloride for injection concentrate is on the FDA drug shortage list and has been since May 15, 2012. Its current status is "Currently in Shortage". Acquisition and stock piling KCL for use in executions by Defendants and other departments of correction contributes to this shortage and may impair the ability of health care providers to obtain the drug for its intended use. Use of any quantity for lethal injection execution inevitably denies that quantity to an ill patient who needs the drug.

**COUNT I**

**REQUEST FOR TEMPORARY RESTRAINING ORDER, PRELIMINARY INJUNCTION AND PERMANENT INJUNCTION**

25. Paragraphs 1 through 24 are incorporated by reference as if fully set forth herein.

26. Fresenius Kabi seeks a temporary restraining order, a preliminary injunction and a permanent injunction because absent same, Fresenius Kabi will suffer irreparable harm and Fresenius Kabi lacks an adequate remedy at law to compensate Fresenius Kabi for Defendants' conduct in obtaining KCL and Cisatracurium by improper or illegal means and Defendants' intent to use the improperly/illegally obtained KCL and Cisatracurium in the execution of Carey Dean Moore. Fresenius Kabi does not seek a monetary judgment, only protection from the Defendants' improper/illegal conduct.

27. Fresenius Kabi will suffer grave reputational harm by being associated with the planned execution of Carey Dean Moore using products that were never designed or intended to be used for such a purpose. Said reputational harm will

impact Fresenius Kabi's relationships with its contractual partners and its customers. Fresenius Kabi has a significant commercial interest in ensuring that its drugs are only used for their intended purpose. Fresenius Kabi will also suffer harm to its property interests and right to due process. Such harms cannot be adequately remedied later through a monetary judgment against Defendants.

28. Defendants bear no corresponding risk. A temporary restraining order and injunction would not bar Defendants' efforts to put its inmates to death. Defendants can use other means to complete these executions. Further, Defendants' interests bear no urgency. It has taken decades to schedule executions and Defendants have not conducted an execution since 1997. Defendants can wait longer to identify a method to put inmates to death without using deceit, or illegal and improper means to obtain pharmaceuticals.

29. Fresenius Kabi has demonstrated a likelihood of success on the merits as discussed above.

**COUNT II**

**TORTIOUS INTERFERENCE WITH A BUSINESS RELATIONSHIP**

30. Paragraphs 1 through 29 are incorporated by reference as if fully set forth herein.

31. Fresenius Kabi maintains a business relationship with medical-professionals, distributors, the organizations identified in paragraph 12 of this Complaint, and members of those organizations, and it expects those business relationships to continue into the future.

32. Through its communications to Governor Ricketts, the previous communications with Fresenius Kabi regarding the Department of Corrections' possession of the Company's KCL, and through these allegations, Defendants are or

should be aware of Fresenius Kabi's business relationships and expectancies alleged in the preceding paragraphs.

33. Defendant's knowing, intentional use in the administration of its lethal-injection protocol of Cisatracurium and KCL sourced from Fresenius Kabi and improperly and illegally obtained in contravention of Fresenius Kabi's policies and distribution agreements is unjustified.

34. Use of Fresenius Kabi's products in the administration of a lethal-injection protocol will cause irreparable harm to the business relationships and expectancies alleged in the preceding paragraphs, including but not limited to:

a. Harm to the reputation and goodwill of Fresenius and its parent company;

b. Harm to the commercial and investment interests of Fresenius and its parent company;

c. Harm to the willingness of medical-professionals, distributors, and other customers to maintain a business relationship now or in the future with Fresenius Kabi;

d. Such use substantially increases the likelihood that the European Union would apply trade restrictions to Fresenius Kabi's export from Europe of its products, such as Diprivan, under Regulation 1352/2011;

e. Given the limited supply of Fresenius Kabi's products, including the inclusion of Fresenius Kabi's 30-mL vials of potassium chloride on the Food and Drug Administration's Drug Shortages list, Defendant's retention of Fresenius Kabi's products for use in its lethal-injection protocol will reduce the availability of such products with which Fresenius Kabi expects to maintain

and expand business relationships based on federally approved product uses in the future.

35. Such harm will result in the termination of any number of Fresenius Kabi's above-alleged business relationships or expectancies.

**COUNT III**

**SECTION 1983 CLAIM FOR VIOLATION OF COMMERCE CLAUSE**

36. Paragraphs 1 through 35 are incorporated by reference as if fully set forth herein.

37. Defendants' procurement and threatened use of Fresenius Kabi's KCL and Cisatracurium is made under color of state law and will proximately cause an interference in interstate commerce that will harm Fresenius.

38. The availability of KCL and Cisatracurium in their respective national markets is predicated on their approval for certain uses by the FDA.

39. The supply of KCL and Cisatracurium in their respective national markets for the use of those products in a manner approved by the FDA is limited, as evidenced in part by KCL's inclusion on the FDA's Drug Shortages list.

40. The Defendants' use of KCL and Cisatracurium, and specifically its procurement of Fresenius Kabi's KCL and Cisatracurium for a non-FDA approved use, interferes with interstate commerce by reducing the limited availability of those products for their federally approved purposes.

41. The Defendants' use of KCL and Cisatracurium substantially increases the likelihood that the EU will enforce regulation 1352/2011, limiting the supply of other limited products manufactured by Fresenius Kabi, such as Diprivan.

42. The Defendants' have other, equally if not more feasible methods for conducting executions that will not burden and interfere with the interstate markets for KCL and Cisatracurium.

**COUNT IV**

**SECTION 1983 CLAIM FOR VIOLATION OF DUE PROCESS**

43. Paragraphs 1 through 42 are incorporated by reference as if fully set forth herein.

44. Defendants' threatened use of Fresenius Kabi's KCL and Cisatracurium is made under color of state law and will proximately cause a deprivation of Fresenius Kabi's goodwill, settled business relations, expectancies, future profits, and other commercial interests.

45. Defendants' refusal to respond to Fresenius Kabi's demand for return of its products and the lack of any state-law procedure for Fresenius Kabi to contest Defendants' use of its products in an execution deprives Fresenius Kabi of its right to due process.

**COUNT V**

**REPLEVIN**

46. Paragraphs 1 through 45 are incorporated by reference as if fully set forth herein.

47. Defendants have circumvented Fresenius Kabi's controls and distribution agreements which prohibit the use of its drugs in connection with executions of the sale of its drug to correctional facilities. The KCL in the possession of the Defendants was manufactured by Fresenius Kabi.

48. As set forth above, Defendants knew or should have known that distributors of KCL manufactured by Fresenius Kabi are not permitted, allowed or

authorized to sell Fresenius Kabi products to the Department of Corrections and the remaining Defendants, let alone for the purpose of an execution. Indeed, in July of 2018 Fresenius Kabi wrote to the Governor of the State of Nebraska and copied Defendant Frakes and specifically advised that Fresenius Kabi contracts prohibited the sale of its drugs to states for execution and any acquisition by a state for that purpose would be in contravention of those contracts and thus illegal and improper.

49. Defendants are not good faith purchasers for value and therefore did not acquire title to the KCL and Cisatracurium.

50. Fresenius Kabi has requested Defendants to return its KCL and Cisatracurium, offering to provide a full refund for the sales price. To date, Defendants have not returned the medications.

51. Fresenius Kabi has a property right in its KCL and Cisatracurium products and its right to deal or refuse to deal with particular prospective customers with respect to said drugs. The Supreme Court of the United States long ago recognized the "right of [a] trader or manufacturer engaged in an entirely private business freely to exercise his own independent discretion as to parties with whom he will deal, and of course, [to] announce in advance the circumstances under which he will refuse to sell." United States v. Colgate & Co., 250 U.S. 300, 307 (1919). Fresenius Kabi has exercised those rights both generally in its statements to the public and to its distributors and specifically in communications with Defendants. Further, in selling its product, Fresenius Kabi has only ever transferred the property right of use in accordance with legitimate medical ends. Fresenius Kabi, as a term of the contract for sale of its products, has never transferred the right of use of its products for the purpose of capital punishment.

52. The Defendants actions are wrongful vis-a-vis Fresenius Kabi because they are inconsistent with Fresenius Kabi's property rights, they do not constitute the appropriate and therapeutic use for KCL and Cisatracurium for a legitimate medical purpose, they are contrary to the therapeutic uses for which the drugs can be utilized, and they risk grave harm to Fresenius Kabi's reputation and good will. Defendants, therefore, have wrongfully detained Fresenius Kabi's property, over which Fresenius Kabi maintains a right of immediate possession.

**COUNT VI**

**REQUEST FOR DECLARATORY JUDGMENT**

53. Paragraphs 1 through 52 are incorporated by reference as if fully set forth herein.

54. As set out above, an actual case or controversy exists between the parties regarding the Defendants' wrongful detainment and improper/illegal intended use of Fresenius Kabi's KCL and Cisatracurium products.

55. Based on the above allegations, and pursuant to 28 U.S.C. § 2201, Fresenius Kabi is entitled to a declaration as to its right of immediate possession of the KCL and Cisatracurium at issue in this dispute; Defendants' obligation to refrain from using said products in the administration of its lethal injection protocol; and Defendants' obligation to return said products to Fresenius Kabi immediately.

**PRAYER FOR RELIEF**

WHEREFORE, Fresenius Kabi requests the Court to issue a temporary restraining order, preliminary injunction, and/or permanent injunction, and declaratory relief, as outlined above and to grant all other just and equitable relief to which it may be entitled. Fresenius Kabi does not seek monetary damages for any of its claims and therefore the relief Fresenius Kabi seeks will not increase the State of Nebraska's financial obligations. Fresenius Kabi further requests an order requiring Defendants to return immediately all of the Fresenius Kabi products to Fresenius Kabi. Fresenius Kabi requests such other and further relief as the Court deems appropriate under the circumstances.

FRESENIUS KABI USA, LLC,
Plaintiff

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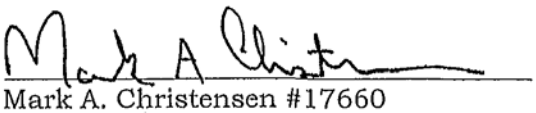
By: 
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VERIFICATION

I hereby declare under penalty and perjury under the laws of the United States of America, and pursuant to Title 28, U.S. Code, Judiciary and Judicial Procedure § 1746 "Unsworn Declarations Under Penalty and Perjury," that the foregoing is true and correct.

Executed on August 7, 2018

Jack Silhavy,
Executive Vice President
Fresenius Kabi USA, LLC

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