FFCL

DISTRICT COURT

CLARK COUNTY, NEVADA

ALVOGEN, INC.,

Plaintiff,

v.

STATE OF NEVADA; NEVADA DEPARTMENT OF CORRECTIONS; JAMES DZURENDA, Director of the Nevada Department of Corrections, in his Official capacity; IHSAN AZZAM, Ph. D, M.D., Chief Medical Officer of the State of Nevada, in his official capacity; and JOHN DOE, Attending Physician at Planned Execution of Scott Raymond Dozier, in his official capacity;[1]

Defendants.

AND ALL RELATED CLAIMS

Case No. A-18-777312-B
Dept. No. XI

FINDINGS OF FACT AND CONCLUSIONS OF LAW

This matter having come on for an evidentiary hearing on the motions for preliminary injunction brought by Plaintiff Alvogen Inc. ("Alvogen") and Plaintiff-Intervenors Hikma Pharmaceuticals USA Inc. ("Hikma") and Sandoz Inc. ("Sandoz"), which seeks to halt the use of their products by Defendants State of Nevada, Nevada Department of Corrections, James Dzurenda, and Ihsan Azzam (collectively the "Defendants" or the "State"), as part of a cocktail used for lethal injection in carrying out capital punishment. The Court conducted its evidentiary hearing beginning on September 11, 2018, and continuing day to day based upon the availability of the participants and the Courts until its conclusion on September 17, 2018, Plaintiff being represented by its attorneys of record Todd L. Bice, Esq., James J. Pisanelli, Esq., and Emily A. Buchwald, Esq., of the law firm of Pisanelli

[1] The John Doe defendant was voluntarily dismissed on September 10, 2018.

Bice and Kenneth G. Schuller, Esq., Angela Walker, Esq., and Michael J. Faris, Esq., of the law firm of Latham & Watkins LLP; Intervenor Sandoz, Inc. being represented by its attorneys of record Colby Williams, Esq., and Philip R. Erwin, Esq., of the law form of Campbell & Williams and Andrew Kantra, Esq., of the law firm of Pepper Hamilton, LLP; Intervenor Hikma Pharmaceuticals, Inc. being represented by its attorneys of record Josh M. Reid, Esq., David McElhinney, Esq., and Kristen L. Martini, Esq. of the law firm of Lewis Roca Rothberger Christie; Defendants being represented by their attorneys of record Jordan T. Smith, Esq., Randall Gilmer, Esq., Steven Shevorski, Esq., and Theresa Haar, Esq., of the Office of the Attorney General; the Court having considered the papers and pleadings on file herein and the oral argument of counsel, listened to the testimony of the witnesses, reviewed the evidence attached to the briefing and introduced during the hearing, and considered the oral and written arguments of counsel, and being fully advised in the premises and with the intent of deciding solely the issue of injunctive relief[2] the Court makes the following findings of fact and conclusions of law:[3]

FINDINGS OF FACT

FACTS COMMON TO ALL PLAINTIFFS

1. This case arises from Defendants' proposed use of three drugs manufactured and/or sold by Alvogen, Hikma, and Sandoz (collectively hereinafter "Plaintiffs") in the lethal injection execution of Scott Raymond Dozier ("Dozier"), originally scheduled for July 11, 2018, in Nevada's Ely State Prison.

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[2] This matter is still at the pleading stage with a motion to dismiss various causes of action pending supplemental briefing on federal preemption. The hearing on that issue is scheduled for October 2, 2018. By this decision, the Court makes findings on those property claims which the Court believes relate to the requested injunctive relief. The Court does not intend to make any findings or legal conclusions which would impact that motion. Given the adverse inference relied upon for purposes of this hearing only, this decision may not be used for any other purpose.

[3] On July 11, 2018, after granting the temporary restraining order, the Court consulted with the parties and granted limited discovery related to the issues relevant to the motion for preliminary injunction. The Court shortened certain deadlines for discovery in order to meet an expedited schedule. The Court notes that these findings are preliminary as they are based on the limited evidence presented in conjunction with the preliminary injunction hearing after limited discovery conducted by the parties on an expedited basis. The parties raised additional discovery disputes during the evidentiary hearing which the Court was unable to resolve due to time constraints prior to the conclusion of the hearing. These disputes included an additional *in camera* review of documents over which the State claimed privilege and issues related to the testimony of NRCP 30(b)(6) designees.

2. In 2007, Dozier was sentenced to death by lethal injection. Dozier waived all appeals and agreed to be executed.

3. In November 2017, in *Dozier v. State*, Case No. 05-C-215039 (8th Jud. Dist.), the State filed a redacted version of NDOC's Executional Manual, dated November 7, 2017, which confirmed that fentanyl was one of the three drugs[4] consisting of Nevada's new lethal injection cocktail. This was the first time any state in the country included fentanyl as part of its lethal injection cocktail.

4. On July 6, 2018, in *American Civil Liberties Union of Nev. Found.* v. *State,* Case No. 18 OC 00163 1B (1st Jud. Dist.)("the ACLU litigation") the court ordered the Nevada Department of Corrections ("NDOC") to disclose certain information related to the procedures it planned to implement in Dozier's execution.

5. On July 10, 2018, Alvogen filed the instant litigation and requested a temporary restraining order ("TRO") and preliminary injunction with respect to midazolam distributed by Alvogen ("Alvogen Midazolam Product").

6. On July 25, 2018, Hikma moved to intervene in this action to enjoin the State from using its fentanyl ("Hikma Fentanyl Product"); the Court granted Hikma's motion on July 30, 2018.

7. On August 3, 2018, Sandoz moved to intervene in this action to enjoin Defendants from using its cisatracurium ("Sandoz Cisatracurium Product"); the Court granted Sandoz's motion on August 21, 2018.

8. Hikma and Sandoz have also joined in the request for injunctive relief and seek to prohibit the State from using their products in capital punishment.

9. The Alvogen Midazolam Product, Hikma Fentanyl Product and Sandoz Cisatracurium Product are proposed as part of a cocktail by the State to be used for lethal injection under NRS 176.355[5] (collectively the "Lethal Injection Drugs") under the State's current execution protocol.

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[4] The term "drugs" as used in these FFCL refers to all of those products with the same molecular combination. As the Plaintiffs' each distribute generic versions of the combination, their respective products when appropriate, are specifically identified. Each version of a drug has a distinct NDC code; this identifies the manufacturer and/or distributor of as well as the size.

[5] That statute provides in pertinent part:

NRS 176.355 Execution of death penalty: Method; time and place; witnesses.

10. Defendant Ihsan Azzam, the Chief Medical Officer ("Azzam"), has given his opinion to the Director of NDOC, James Dzurenda ("Dzurenda"), that the Lethal Injection Drugs would be appropriate and effective medications.

11. All of the Lethal Injection Drugs were acquired from Cardinal Health, Inc. ("Cardinal"), a health services company that specializes in distribution of pharmaceuticals.[6]

12. In September 2016, the State issued a request for bids which specifically asked drug companies to supply products that could be used in carrying out capital punishment. In its 2016 request for bids, the drug manufacturer would be required to represent and warrant appropriate title in the products such that they could be used for capital punishment. The State acknowledged that the drug sales to the State would be controlled through the Uniform Commercial Code and that title to the drugs would pass to the State upon delivery. The State solicited over 200 drug companies with this proposal.[7] No responses to the request for bid were received by the State for such purposes.

13. The State's request for proposal stated in Section 1.1 that "Nevada State Purchasing, on behalf of the Nevada Department of Corrections is seeking responsible vendors to supply pharmaceutical drugs which will be used for lethal injections."

14. The State's request for proposal stated in Section 9.5.3.8 "Title," which fell under Section 9.5.3 "Express Warranties," that "[t]he vendor has exclusive title to the goods and shall pass title to the State free and clear of all liens, encumbrances, and security interests."

15. The State's request for proposal stated in Section 9.5.3.9.B. "Infringement; Indemnity," which fell under Section 9.5.3 "Express Warranties," that "[i]f the State is enjoined from using such goods, the vendor shall re-purchase such goods from the State at the original purchase price."

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1. The judgment of death must be inflicted by an injection of a lethal drug.
2. The Director of the Department of Corrections shall:

* * *

(b) Select the drug or combination of drugs to be used for the execution after consulting with the Chief Medical Officer.

[6] Although each Plaintiff has a contractual relationship with Cardinal, no testimonial evidence from Cardinal was offered during the evidentiary hearing via deposition, video-conference, or live testimony.

[7] Notably Cardinal, the wholesaler from whom the State acquired all three drugs, did not respond to the solicitation although it was sent to them. The State also knew that Hikma and Sandoz were not interested in providing lethal injection drugs to NDOC, as both were a direct recipient of the State's September 2016 request for bids, and failed to respond.

16. The State's request for proposal stated in Section 9.6.1 that "[t]he vendor agrees to deliver the goods as indicated in the NOA/contract, and upon acceptance by the State, title to the goods shall pass to the State."

17. Attachment C to the State's request for proposal stated that "[t]he Department of Corrections is seeking a vendor that will supply one or both drugs to the Department's licensed pharmacy for use in scheduled executions." Attachment C went on to state that "[p]roposing vendors must provide certification that the drug is authorized for use in an execution."

18. In 2016, the State was aware that drug manufacturers objected to the use of their products in capital punishment and objected to the use of their drugs in Nevada's executions.

19. As a result of the lack of response to the RFP, the State looked for other alternatives.

20. Nevada, like other death-penalty states, was well-aware of certain drug manufacturers' restrictions on the use of their drugs in lethal injection executions.

21. On April 21, 2017, Linda Fox, the chief pharmacist for NDOC ("Fox") received an email from a representative of the Conference on Correctional Health Care which included a list of drugs for which purchase was restricted. The email stated:

> We had, as part of our discussion at the National Member Conference, talked about the current restrictions placed on Correctional facilities in ordering certain products. We received the attached notice from West-Ward the very next week. While this is nothing new to us, it does include actionable steps if you choose to pursue them.
>
> Cardinal was also nice enough to provide the listing of all products that have such a restriction on them. As you can imagine, this list is ever changing.

The list included midazolam as well as other drugs manufactured or distributed by one or more Plaintiffs. A copy of the West-Ward notice dated April 2017 was included as well.

22. On May 22, 2017, Fox provided the communication from the Conference on Correctional Health Care to Dzurenda.

23. In 2017, Dzurenda, Mr. John DiMuro, Nevada's then-Chief Medical Officer, and Fox, had a conference to discuss what drugs were both potentially useful for lethal injection and available to

the State for purchase. As a result of these conversations, the State approved an execution protocol using a three drug cocktail consisting of fentanyl, cisatracurium, and diazepam.

24. Dozier, through his federal public defender, challenged that cocktail as cruel and unusual. Although the Nevada Supreme Court ultimately approved the cocktail, the diazepam in the State's possession expired during the pendency of those proceedings.

25. Dzurenda requested that Fox research potential alternatives to diazepam for use in the execution cocktail that were available for purchase.[8] After two hours of research, Fox determined that midazolam was available and would be an acceptable substitute in the protocol.

26. Following Fox's suggestion of midazolam, on or about May 24, 2018, Dzurenda sent the new protocol to Azzam for approval. Azzam concluded that, based on his review of adverse events, the dosages in the protocol would be sufficient to cause Dozier's death.

27. Azzam does not believe that any of the Lethal Injection Drugs are meant to kill people.

28. Azzam is not aware of any physician in Nevada who administers lethal doses of medication in the usual course of their practice.

29. Azzam, as Nevada's Chief Medical Officer, approved the Lethal Injection Drugs for use in the June 11, 2018, execution protocol.

30. Azzam's job involves promoting public health and welfare. He has no particular expertise in executions. Azzam will have no role in supervising Dozier's execution and will not be attending the execution.

31. Fox is responsible for ordering the drugs to be used for the execution of Dozier.

32. It is Fox's obligation to make sure that the Department of Corrections is in compliance with federal Drug Enforcement Administration (DEA) regulations in the purchase and transport of the drugs to be used for the execution of Dozier.

33. Fox used the same procedure in making each of the online orders with Cardinal for the Lethal Injection Drugs as is utilized for other online orders of pharmaceuticals.[9]

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[8] By this time Cardinal had blocked Fox from purchasing additional diazepam.

34. Fox bypassed no ordering restrictions.

35. Fox was unaware of the manufacturer at the time she placed the online orders for drugs.

36. Fox and Dzurenda did not discuss the manufacturer or distributor in deciding which drugs to order.

37. Fox is concerned about availability and price when ordering drugs.

38. All Cardinal shipments of the Lethal Injection Drugs ordered by Fox were delivered to the NDOC pharmacy in Las Vegas.

39. The Hikma Fentanyl Product is a Schedule II controlled substance.

40. Fox used NDOC's DEA Controlled Substance Registration Certificate when she ordered Plaintiffs' drugs from Cardinal.

41. NDOC's DEA Controlled Substance Registration Certificate lists "Hospital/Clinic" as NDOC's approved business activity.[10]

42. Plaintiffs' drugs were delivered by Cardinal to NDOC's central pharmacy located in Las Vegas.

43. The State intends to use these drugs, including a Schedule II controlled substance, by directing NDOC employees to administer them to Dozier. These NDOC employees are not licensed medical practitioners nor registered to handle controlled substances pursuant to the Federal Controlled Substances Act.

44. Cardinal has never contacted the State seeking return of the drugs or otherwise suggesting that the drugs should not have been sold to the State.

45. Cardinal has never informed the State that it was a mistake to allow NDOC to order the drugs at issue in this case.[11]

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[9] As part of the purchasing process, Fox also purchased drugs manufactured or distributed by other entities than these Plaintiffs.

[10] Execution does not appear to fall within the scope of the description of "Hospital/Clinic".

[11] While it is certainly not legal authority, it is timely that Scott van Pelt, SportsCenter SVP on ESPN remarked on two issues related to mistakes during the September 18, 2018 broadcast. Citing to the two different approaches -- Fleetwood's return of prize winnings he didn't earn, http://www.espn.com/golf/story/_/id/24326742/tommy-fleetwood-120000-open-winnings-sent-wrong-tommy-fleetwood , and a fan trying to collect on a mistakenly priced bet,

46. Cardinal does not require NDOC to identify the intended patient end user of any drug that is ordered.

47. Cardinal did not require NDOC to notify Cardinal of what the intended use of the purchased drug was and for what inmate.

48. Cardinal has contacted the State in the past when it wished to have an ordered drug returned.

49. Cardinal has contacted the State prior to permitting NDOC to complete the order of particular drugs.

50. Cardinal delivered each of the drugs ordered by NDOC consistent with the normal delivery process.

51. Cardinal issued invoices to NDOC for the purchase of the drugs at issue in this case.

52. It is unclear when the State paid the invoices for the drugs.[12]

53. None of the Lethal Injection Drugs are approved by the U.S. Food and Drug Administration ("FDA") for the State's planned use. The State's planned use is an off label use.

54. Plaintiffs' request for preliminary injunctive relief is based upon a series of claims. All three of the Plaintiffs assert claims for replevin and conversion. Alvogen and Sandoz assert claims for false pretenses. All three common law claims are predicated upon Plaintiffs recovering their drugs from the State due to the manner and means by which the State acquired the Plaintiffs' products. Additionally, Plaintiffs Alvogen and Hikma assert certain statutory-based claims predicated upon the fact that their drugs are "controlled substances" and the handling and disbursement of their two drugs is regulated under the law. They allege the State is violating these various restrictions.

55. As part of the execution protocol, the State selected certain personnel to be members of the execution team. The State has resisted publication of the identities of these individuals on the basis

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https://profootballtalk.nbcsports.com/2018/09/19/fanduel-mistakenly-takes-a-long-shot-bet-refuses-to-pay-off/ , illustrates in simplest terms the divergent viewpoints presented to this Court.

[12] Fox did not know when the payment was made.

that associating them with capital punishment could damage their reputations, including subjecting them to potential threats of harm and loss of business or social standing.

56. Under the State's policy, as implemented by Dzurenda, no person can be compelled to participate in carrying out capital punishment, including the attending physician and execution team personnel, or any employee of the State, irrespective of whether that person has already entered into a contractual agreement to do so; all must be volunteers. In fact, even Dozier, who has abandoned his appeals and volunteered to be executed, will not be executed if he expresses a desire not to be executed at any time. Similarly, the jurors who are tasked with sitting on a death penalty case must be able to participate in imposing that sentence.

57. Dzurenda knew when the drug manufacturers discovered that the State obtained their drugs to be used in Dozier's lethal injection, that the manufacturers would take action. He was not surprised that the drug manufacturers took action to stop their drugs from being used in Dozier's lethal injection "because you're going to have activist groups wanting money back from those companies or threaten them with loss of money" and noted that "once it goes public, just like when you produce and publicize people's names, those companies and people get harassed or could get harassed or letters." Hr'g Tr. 65:9-11, 71:16-19, 90:14-19, 71:20-24 (portion of deposition transcript read into hearing record), 195:14-17 and 203:21-204:1 (Sept. 11, 2018).

58. Plaintiffs' experts explained the claim of irreparable harm; testified about the reputational damage due to product misuse[13] in the lethal injection protocol; and, the inability to calculate the impact and damages due to the proposed misuse of the drugs by the State.

59. Plaintiffs offered the expert testimony of Dr. Keith Candiotti, an anesthesiologist, on the impact of association with executions on the attitudes of patients and medical professionals and the business and reputational harm that Plaintiffs will suffer. Dr. Candiotti is qualified to give his opinion.

60. Plaintiffs also offered the expert testimony of Dr. Sean Nicholson, a Professor in the Department of Policy Analysis at Cornell University, on the impact of association with executions on

[13] One example of the impact on a pharmaceutical, was that of propofol and the negative patient reactions following the misuse of this drug in Michael Jackson's death.

Plaintiffs' investor and customer relations, and the financial harm that Plaintiffs will suffer. Dr. Nicholson is qualified to give his opinion.

61. 21 CFR 7.46 permits a pharmaceutical company to remove or withdraw a product by initiating a firm-initiated recall or withdrawal.[14]

62. The State has a contract with Cardinal. Despite formal discovery requests, the contract was not supplied by the State.

63. In addition to requesting the State's contract with Cardinal, Plaintiffs' requested that the State prepare a NRCP 30(b)(6) witness to discuss certain issues related to the purchase, but the State did not.[15] In fact, the representative on those issues did not prepare on the designated topics.

64. Based upon the failure to provide a knowledgeable NRCP 30(b)(6) witness, Plaintiffs have requested an adverse inference that the State's contract with Cardinal modified the title upon delivery provision such that title transferred to the State on payment, rather than delivery.[16]

65. At the request of the parties, the Court excluded witnesses who were not party representatives or experts following opening statements. When a witness was called out of order, Dzurenda spoke to Fox about his completed testimony and the issues he anticipated would be asked of her. Plaintiffs requested the State's examination of Fox be limited as a result. The Court declined that request, but indicated it would take the violation into consideration in assessing credibility of Fox and judging the weight to be given to Fox's testimony.

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[14] That regulation provides in pertinent part:

Sec. 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. . . .

[15] In addition to the failure to provide a NRCP 30(b)(6) witness prepared to discuss the noticed issues at the time of the deposition, when questioned by the Court during the preliminary injunction hearing, Dzurenda deferred all contract questions to Fox. When questioned by the Court during the preliminary injunction hearing, Fox denied knowledge of the contents of the State's contract with Cardinal. She also denied any knowledge of the payment process. As a result, the Court infers the Contract, if it had been produced or a knowledgeable witness provided, would be adverse to the State on the issue of whether title passes upon payment or delivery.

[16] NRCP 37 provides a wide array of sanctions for this situation. See Great American Ins. Co. of New York v. Vegas Const. Co. Inc., 251 F.R.D. 534, 542-543 (D. Nev. 2008).

FACTS REGARDING ALVOGEN

66. Alvogen is a Delaware corporation with its principal place of business located at 10 Bloomfield Avenue, Pine Brook, New Jersey.

67. Alvogen distributes midazolam hydrochloride ("midazolam") injection, solution (Abbreviated New Drug Application number 090696).

68. The Alvogen Midazolam Product is an injectable medication approved by the FDA for use in inducing general anesthesia and preoperative sedation/anxiolysis/amnesia. Midazolam is a Schedule IV controlled substance.

69. In addition to its uses by physicians, midazolam has been used by some state correctional facilities as a component of those states' and facilities' capital punishment regimens. Midazolam acts as a sedative to render the condemned prisoner unconscious, at which time other drugs are administered to stop the prisoner's breathing and heart.

70. Midazolam is not approved by the FDA for use in lethal injection executions.

71. The use of midazolam in executions is alleged to have played a role in various executions the media has described as "botched."

72. Alvogen began distributing the Alvogen Midazolam Product in August 2017.

73. Prior to Alvogen's distribution of the Alvogen Midazolam Product, Alvogen had not distributed any drugs that were used in lethal injection executions.

74. Alvogen distributed under its own label, but did not manufacture, the midazolam that the State acquired from Cardinal.

75. Prior to beginning to distribute the Alvogen Midazolam Product, Richard Harker, Vice President of Sales for Alvogen's Injectables division (designated as Alvogen's NRCP 30(b)(6) representative) ("Harker") met with representatives of each of its four major distributors and believed he had reached oral agreements regarding controls to be placed on the sale of the Alvogen Midazolam Product to departments of corrections.

76. The first distributor Harker met with was Cardinal.

77. Alvogen had previously entered into a Generic Wholesale Distribution Agreement with Cardinal on March 1, 2010 (GWDA). The agreement did not prohibit sales to departments of correction or restrict the uses of end users.

78. Cardinal informed Harker that, for a fee, it had a program under which sales of certain products, like midazolam, could be blocked to departments of corrections. ("Controlled Distribution Program").

79. Harker also met with Alvogen's other distributors, AmerisourceBergen, Morris Dixon, and McKesson, prior to beginning to distribute the Alvogen Midazolam Product. AmerisourceBergen and Morris Dixon each agreed to block sales of the Alvogen Midazolam Product to departments of corrections without requiring Alvogen to enter into a written contract or to pay an additional fee.

80. McKesson agreed to restrict the sale of the Alvogen Midazolam Product to a specific list of customers to be provided by Alvogen. Alvogen provided such a list prior to the purchases at issue in this case after it had established a sufficient sales history to do so.

81. Alvogen initially declined to pay a fee to Cardinal for the Controlled Distribution Program. Harker reviewed certain sales reports and spot checked to track sales of the Alvogen Midazolam Product by the wholesalers.

82. Prior to beginning to distribute the Alvogen Midazolam Product, Alvogen put in place controls to prevent the direct sale by Alvogen to any department of corrections, or any sale that Alvogen believed could be diverted to be used in an execution. Alvogen controlled direct sales by designating the Alvogen Midazolam Product as a "Managed Hold Product" which cannot be sold without prior authorization by Harker. Harker received a listing of every order of a Managed Hold Product at least once daily. Harker reviewed that listing and had to approve each sale before the Managed Hold Product could be shipped. In the event that a proposed sale of the Alvogen Midazolam Product to a department of corrections appeared on the Managed Hold Product listing, it was Harker's practice to decline such sale.

83. The Managed Hold Product process did not apply to products distributed by the wholesalers.

84. Harker only checked for departments of corrections sales a few times in Fall 2017 and once in 2018.

85. When Harker reviewed Alvogen's records of midazolam sales through February 2018, Harker determined that no sales to departments of corrections had occurred.

86. Alvogen does not audit its midazolam sales through wholesalers, but relies solely on the wholesaler to block sales to departments of corrections.

87. Alvogen had the ability to do daily "spot checks" of its sales to determine whether there were any sales to prisons or departments of corrections.

88. In early 2018, two events occured that prompted Harker to modify the controls that were in place with Cardinal.

89. First, an anti-death-penalty organization called Reprieve began a concerted effort to engage Alvogen in discussions over its controls. Reprieve contacted one of Alvogen's private equity firm investors. That investor suggested Alvogen management meet with Reprieve.

90. Harker met with representatives of Reprieve in April 2018. Alvogen was advised it could suffer business and reputational harm if it was associated with lethal injections, and could lose sales and investments. Reprieve discussed industry best practices to avoid that sort of harm in the future, including the types of policies and controls that other pharmaceutical companies employed.

91. Second, in March of 2018, when Harker inquired of Cardinal, he learned that the Alvogen Midazolam Product was not "on control."

92. In spite of Harker's confirmation that Cardinal had not made any sales as of February 2018, the knowledge that the Alvogen Midazolam Product was not "on control" with Cardinal concerned Harker.

93. As a result of the controversy over the use of midazolam in lethal injections, the statements made by Reprieve regarding the potential injury Alvogen could suffer from the misuse of midazolam and the suggestion that Cardinal might not control distribution of midazolam, Alvogen took additional steps to control distribution of the Alvogen Midazolam Product.

94. On April 20, 2018, Alvogen sent letters to the Governors, Attorneys General, and Department of Corrections Directors in every state that has a death penalty, including Nevada (the "April 20 Letters").

95. The April 20, 2018 letter was sent to 31 states. Alvogen received no response from any of those states.

96. The State of Nevada was one of those 31 states to receive the letter.

97. In the April 20 Letters, Alvogen stated "Alvogen strongly objects to the use of its products in capital punishment." Alvogen specifically identified the Alvogen Midazolam Product as one that should not be used in executions, and noted that use of midazolam or other products in executions "clearly runs counter to the FDA-approved indication for these products."

98. In the April 20 Letters, Alvogen informed the State that Alvogen does not accept orders directly from correctional institutions and that Alvogen had controls in place and directed its distributors not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions.

99. In its April 20 Letters, Alvogen specifically instructed the State that if it had somehow obtained Alvogen products for execution, it must return them immediately for a full refund.

100. The April 20 Letters also warned the State against attempting to obtain the Alvogen Midazolam Product for executions surreptitiously, illicitly, and/or by subterfuge, or otherwise attempting to circumvent Alvogen's distributor controls.

101. NDOC received that letter no later than April 24, 2018. NDOC never responded to Alvogen's letter and demand for the surrender and return of any of its products. Dzurenda acknowledged that he personally became aware of Alvogen's letter no later than May 11, 2018, and that he simply ignored its terms. Since he had no contract with Alvogen, he believed it had no import. He handled the letter like other letters he had received from other drug companies; he placed the letter in a file.

102. The April 20 letters to the State assert an ongoing interest in the Alvogen Midazolam Product. The letters state that "Alvogen objects to the use of ***its products*** in executions." This

possessive language is used repeatedly throughout the letter, *e.g.* ("our products" and "our medicines.") Further, the letters state: "If your state has purchased [Alvogen products] for use in capital punishment procedures – either directly or indirectly – we ask that you ***immediately return our products*** in exchange for a full refund."

103. Although Alvogen was aware of Cardinal's Controlled Distribution Program in May 2017, Alvogen did not request documentation about the program until March 2018. An agreement was reached between Alvogen and Cardinal regarding the Controlled Distribution Program which became effective on May 28, 2018.

104. The Third Amendment to the GWSA provides in pertinent part:

> Cardinal Health agrees to restrict the distribution and sale of certain Products in accordance with the terms and in exchange for the Service Fees described in the Controlled Distribution Program Schedule attached to this Agreement.

105. The Controlled Distribution Program Schedule provides in pertinent part:

> 1. ***Services.*** In consideration for the Service Fees described in this Controlled Distribution Program Schedule, Cardinal Health will provide the following services (collectively, the "Controlled Distribution Program Services"):
>
> ***c. order blocking/restriction of sales to ineligible customers***
>
> * * *
>
> ***f. restrict sales to all prison and retail customers***
>
> * * *
>
> 3. ***Products subject to the Controlled Distribution Program Agreement.*** Cardinal Health will perform the Controlled Distribution Program Services with respect to the following Products (collectively, the "Controlled Distribution Products"). . .
>
> Various sizes and concentrations of midazolam are identified.
>
> (Emphasis in original.)

106. Alvogen admitted through its 30(b)(6) representative, Harker, that because there were no controls in place on May 9 and May 11, 2018, NDOC was not trying to evade the Controlled Distribution Program. Alvogen admitted that Cardinal had no written obligation to ask the State why it was purchasing the Alvogen Midazolam Product.

107. Alvogen now pays Cardinal a fee to block purchases to departments of correction under the Controlled Distribution Program.

108. Alvogen delayed entering into the Controlled Distribution Program because Harker considered the fee to participate excessive.

109. NDOC had no agreement or contract with Alvogen.

110. NDOC did not purchase the Alvogen Midazolam Product from Alvogen.

111. Alvogen had no firsthand knowledge of the interaction between the State and Cardinal when the State acquired the Alvogen Midazolam Product from Cardinal.

112. Alvogen has no firsthand knowledge of any representations that the State did or did not make to Cardinal.

113. Alvogen never asked Cardinal if it would have shipped the Alvogen Midazolam Product to the State if it had known the State's intended use.

114. Despite the contract being finalized on May 28, 2018, Cardinal did not block or restrict the sale of the Alvogen Midazolam Product on May 29, 2018, as NDOC was able to order another order of the Alvogen Midazolam Product from Cardinal on that date.

115. NDOC had no knowledge of the terms of the Controlled Distribution Agreement finalized between Alvogen and Cardinal on May 28, 2018.

116. The State did not acquire any additional Alvogen Midazolam Product after May 29, 2018.

117. In June 2018, Alvogen placed a disclaimer regarding not accepting orders directly from departments of correction and that it is working with wholesalers to prevent such resales.

118. There is no evidence that the State ever saw Alvogen's Website before or after its acquisitions from Cardinal.

119. Despite these controls, the State placed three orders for the Alvogen Midazolam Product on May 9, May 11, and May 29, 2018. Payment for these shipments was not due or made until June 2018.

120. The first order was placed on May 9, 2018. That morning, at a 6:41 a.m., Fox texted Dzurenda announcing that she had made a "discovery" regarding potential available drugs that she wanted to discuss promptly. Following a discussion with Dzurenda, Fox placed an order for midazolam from Cardinal.

121. The State knew that the availability of midazolam through Cardinal was not allowed and its availability was an oversight.[17] On the morning of May 9, shortly before placing the first order, Fox acknowledged that she discovered this oversight by Cardinal and was very surprised that the drug was identified as being available. Fox informed Dzurenda that she thought Cardinal had made a "mistake" in allowing her to order the midazolam.[18]

122. At the direction of Dzurenda, she promptly placed the order hoping to acquire the drugs before the purpose of the acquisition was discovered. That first order was received on May 10, 2018, but the State did not pay for those drugs until sometime later in June.

123. Following receipt of the midazolam that was the subject of the May 9th order, Fox and Dzurenda determined to quickly issue another order before their acquisition of midazolam was discovered.

124. The second order was placed on May 11, 2018, because Fox believed that the State would not be able to place additional orders for the midazolam once Cardinal figured out what was occurring. She wanted to place more orders quickly to avoid detection. The second order that the State placed was received on May 12.

125. After the receipt of the first order, Dzurenda inquired as to whether the midazolam was Alvogen's. Fox confirmed that it was. Dzurenda then revealed his receipt of the Alvogen April 20th letter, to which Fox replied "Oh shit."

126. Following the "Oh shit" comment, Fox then asked Dzurenda if he would like her to acquire more midazolam because she was "certain once it's in the press that we got it [she] will be cut off." In response, she then ordered three more boxes, despite expecting that Alvogen "will be calling

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[17] Midazolam appears in several lines on the list provided by Cardinal to the Conference on Correctional Health Care.

[18] Fox had been unable to purchase midazolam up until May 9.

next week asking for it back." Fox then texted Dzurenda that once the acquisitions were discovered, it would look "contrived" that they ordered the product just a day after the Dozier execution was allowed to move forward.

127. The State placed another order of midazolam on May 29, 2018.

128. Alvogen never told the State the acquisitions of the Alvogen Midazolam Product from Cardinal was a mistake.

129. The State did not produce documentation concerning payment for the orders despite such documents being responsive to Alvogen Document Request No. 1. Fox, who was designated as the State's NRCP Rule 30(b)(6) witness on Alvogen's Topic No. 2 which encompasses the dates of payment, was not adequately prepared on said topic[19] and was unable to identify the date(s) of payment. Given the adverse inference,[20] the Court infers that the invoices for the Alvogen Midazolam Product were paid after the effective date of the Controlled Distribution Amendment.

130. With the adverse inference, for purposes of this hearing only,[21] the Court finds that the sales of the Alvogen Midazolam Product were not fully consummated and/or performed until after the restriction on the sale of the Alvogen Midazolam Product to correctional institutions was memorialized in writing by the Controlled Distribution Agreement.

131. All three of the Cardinal orders indicate that the transactions were to be completed by the provision of payment by the State to Cardinal, which was due in June 2018.

132. None of these orders were paid for until later in June 2018.

133. Pursuant to the orders themselves, the purchases were to be completed by payment from the NDOC, which was not due until June 2018. Given the adverse inference, each of the three sales actually occurred after the date of the Controlled Distribution Agreement executed between Cardinal and Alvogen on May 28, 2018.

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[19] Fox made no investigation in preparation for her appearance as the NRCP 30(b)(6) designee on those topics.

[20] See footnote 15.

[21] See footnote 15.

134. Since each of the sales of the Alvogen Midazolam Product occurred after the effective date of the Controlled Distribution Agreement, Cardinal obtained, at most, voidable title to the Alvogen Midazolam Product. The State, in turn, could only have acquired voidable title as well pursuant to NRS 104.2403(1).

135. The State's knowledge at the time of the ordering of the Alvogen Midazolam Product, the Controlled Distribution Agreement between Cardinal and Alvogen, and the circumstances surrounding the text messages between Fox and Dzurenda do not demonstrate the qualities of a good faith purchaser.

136. As Alvogen asserted its property interest to the State, prior to the State's order, the State, given its knowledge and conduct, could not be a good faith purchaser for value[22] and could only have acquired voidable title.

137. NDOC was not a good faith purchaser for value of the Alvogen Midazolam Product. It knew that it was not allowed to acquire this product for use in capital punishment. NDOC knew and acknowledged that the product's availability through Cardinal was an obvious error, and it acted with speed in order to seize upon that error and acquire the Alvogen Midazolam Product despite Alvogen's express warnings and restrictions.

138. Despite knowing that Alvogen had forbidden the State from acquiring the Alvogen Midazolam Product or using it for lethal injection, the State nevertheless intended to use the Alvogen Midazolam Product in Dozier's execution, which was scheduled to proceed on July 11, 2018.

139. Alvogen learned that the State intended to use the Alvogen Midazolam Product to execute Dozier through a press inquiry on July 7, 2018, and acted to obtain return of its property through this action.

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[22] The Nevada Supreme Court has identified this as a factual determination.

> . . . [W]hether or not a purchaser had notice of an outstanding claim or was buying in good faith is a factual determination. (citations omitted.) . . .

Cooper v. Pacific Auto. Ins. Co., 95 Nev. 798, 801 (1979).

140. Alvogen admitted that it cannot measure any economic loss due to the Dozier execution, as those losses are based on product availability and inventory.

141. Alvogen has not noticed any increase in employee turnover since July 2018.

142. Harker is unaware of any customer complaints or threats to stop doing business with Alvogen as a result of the Dozier execution.

143. Since July 2018, Harker was unaware of any investor concerns or threats to divest if Alvogen's drugs are used in Dozier's execution.

144. Harker is not aware of any lenders or bankers threatening to cease business with the company if the company's drugs are used in Dozier's execution.

145. Harker did not know of any financing opportunities that the company lost as a result of being associated with Dozier's execution.

146. Alvogen has not lost any opportunities to enter into other markets for generic drugs as a result of being associated with Dozier's execution. Nor has Alvogen lost opportunities to develop new branded drugs as a result of being associated with Dozier's execution.

147. Harker could not testify about reputational harm or business good will injury that Alvogen claims occurred as a result of its product associated with the Dozier execution but relied upon experts.

148. Alvogen's reputational harms are reasonably ascertainable future adverse effects arising out of the State's illegitimate acquisition and use of Alvogen's drugs. Both experts testified to the concrete harms that can and will arise out of damage to Alvogen and its Midazolam Product as a result of association with the death penalty, including patient aversion, doctor boycotts, and investor divestment.

FACTS REGARDING HIKMA

149. Hikma is a wholly owned subsidiary of Hikma Pharmaceuticals PLC, which is publicly traded on the London Stock Exchange. If Hikma suffers reputational harm and harm to its goodwill, Hikma Pharmaceuticals PLC and its stockholders and investors suffer adverse effects as a result.

150. Capital punishment is prohibited in the United Kingdom.

151. Hikma is a manufacturer and provider of oral, liquid, inhalant, and injectable branded and non-branded generic medicines in the United States.

152. The Hikma Fentanyl Product is in the narcotic (opiate) analgesics class of medications and was originally developed in or around 1960 as a powerful intravenous anesthetic for surgery. It has been approved by the FDA since 1972 for use in as an analgesic (pain relief) and anesthetic.

153. Until recently, Hikma was known as "West-Ward Pharmaceuticals."

154. West-Ward entered into a Generic Wholesale Service Agreement (GWSA) with Cardinal Health in June 1998.

155. In an attempt to ensure that the Hikma Fentanyl Product, among its other drugs, is used responsibly, Hikma has placed controls on the purchase and use of its drugs. Those controls include internal policies and procedures with its customers to restrict the supply of Hikma drugs for the distribution and use in lethal injection protocols. Hikma has refused the direct sale of its drugs to United States departments of corrections for use in capital punishment, and works directly with its distribution partners to add restrictions for unintended use to its distribution contracts.

156. Upon learning that some states, including the State of Nevada, were considering new compounds to use in their lethal injection protocols, Hikma took steps to prevent its drugs from being used for such purpose.

157. As of October 2016, Hikma published on its Website its policy on states' uses of Hikma's drugs in capital punishment regimes, voicing its strong objection to any department of corrections' acquisition and use of its drugs for such purpose.

158. On December 20, 2016, Hikma sent letters to Nevada's Attorney General, Adam Laxalt, Governor Brian Sandoval, and Dzurenda, in which Hikma vehemently objected to any of its drugs being used for lethal injection ("December 2016 Letters"). In the December 2016 Letters, Hikma stated, "We object in the strongest possible terms to the use of any of our products for lethal injection," and again made clear that its objection should be applied to all of its drugs, including Hikma's Fentanyl Product. Hikma notified the recipients that such use was

> [n]ot only an off-label use and inconsistent with the FDA indication and contrary to [Hikma's] intention of manufacturing the product for health and well-being of patients in need, but also it is completely counter to [Hikma's] values as an organization.

159. Hikma further explained,

> In the event that we were forced to implement additional controls to prevent these uses, it may have the unintended consequence of potentially preventing certain patients from receiving these medicines despite having a genuine need. This outcome would not be beneficial for anyone, particularly the people of Nevada. We believe that Nevadans deserve high quality, generic medicines and we are very pleased to continue to play a role in manufacturing much needed products to improve health. As such, we hope that you will give serious consideration to the positions that we have set forth in this letter and be our partner in furthering our values and policy.

160. Dzurenda admitted that he recalled receiving the December 2016 Letter in which Hikma specifically objected to the State using any of its products in lethal injection. The State received this letter and had knowledge that Hikma prohibited the State's use of its drugs in executions prior to the State ordering any of Hikma's products to use in the State's lethal injection protocol.

161. Some of Hikma's drugs (listed as West-Ward) appear on the listing provided by Cardinal to the Conference on Correctional Health Care.

162. By the end of September 2017, Hikma continued to publish on its Website its policy on states' uses of its products in capital punishment regimes, which read:

> We object in the strongest possible terms to the use of any of our products for the purpose of capital punishment. Not only is it contrary to the intended label use(s) for the products, but it is also inconsistent with our values and mission of improving lives by providing quality, affordable healthcare to patients.

163. Hikma's Website further explains the various controls it has in place to "to prevent these products from being used for the purpose of capital punishment," including that Hikma "will not accept orders for these products directly from any Departments of Correction or correctional facilities in the United States unless accompanied by an original, raised seal copy of an affidavit signed by the state attorney general (or governor), certifying under penalty of perjury that the product(s) will not be used for capital punishment," and that Hikma "will only sell these same drugs to pre-selected commercial customers who agree that they will not then sell them to Departments of Corrections/correctional facilities, or to secondary distributors or retail pharmacies." Hikma also restricted particular drugs that

have a heightened potential of misuse for lethal injection protocols and published them on Hikma's restricted list.

164. NDOC did not purchase any fentanyl directly from Hikma.

165. Hikma did not add fentanyl to its Website statement regarding drugs that may be used in lethal injection until on or after September, 29, 2017.

166. When the State disclosed its execution protocol via public disclosure in August 2017, the State was not in possession of the Hikma Fentanyl Product.

167. The State ordered the Hikma Fentanyl Product on September 28, 2017, one day before the Hikma Fentanyl Product was placed on the restricted list.

168. Although Hikma claims to have had an understanding with Cardinal on blocking purchases to departments of correction for execution dating back to 2013, Hikma never formalized any terms to block fentanyl from being purchased by prisons until December 2017.

169. By December 2017, Hikma had executed a Controlled Distribution Program amendment to its wholesale contract with Cardinal. Cardinal had requested additional resources for a more robust control system. Hikma agreed to pay Cardinal for its services, and the payment for those services included the entire year of 2017 and 2018.

170. In December 2017, Hikma sent letters to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Dzurenda, in which Hikma again vehemently objected to any of its products being used for lethal injection ("December 2017 Letters"). In the December 2017 Letters, Hikma restated that such use of any Hikma products is "off label" and contrary to the FDA indication, in addition to being contradictory to the intended use of the products and Hikma's organizational values.

171. The State admitted that by December 2017, it was in receipt of two letters from Hikma objecting to the State's use of any of its products for execution and knew that Hikma protested such use of its products.

172. On or about July 10, 2018, Hikma learned through a public interest organization that the State had confirmed its intention to execute Dozier on July 11, 2018, using fentanyl and midazolam in

its three-drug cocktail. At that time it was unclear whether these drugs were manufactured by Hikma (who manufactures a midazolam drug product, as well as the Hikma Fentanyl Product).

173. Hikma obtained copies of documents produced as a result of a court order in the ACLU litigation. The documents disclosed by the State in the ACLU litigation included a list of the drugs to be included in the lethal injection cocktail, along with the invoices related to NDOC's purchase of those specific drugs. These invoices identified the States' receipt of the Hikma Fentanyl Product, identified as NDC/UPC 0061-6027-25. The invoices further showed that NDOC placed multiple small orders of the drugs over a number of months, with some orders following the previous order by only one day.

174. NDOC ordered the Hikma Fentanyl Product from Cardinal on September 28, 2017, for shipment the next day, and addressed to be billed and shipped to NDOC Pharmacy.

175. Prior to NDOC ordering the Hikma Fentanyl Product, NDOC had received and read Hikma's December 20, 2016 letter and was on notice that Hikma objected to the use of any of its products for lethal injection.

176. Upon confirming that the State intended to use the Hikma Fentanyl Product in the scheduled lethal injection of Dozier on July 11, 2018, Hikma hand-delivered a third set of notices to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Dzurenda ("July 11, 2018 Letters"). In the July 11, 2018 Letters, Hikma reminded these recipients of Hikma's position on the misuse of its medicines in executions:

> Despite our best efforts to ensure our medicines are used only for their intended medicinal purposes—including a requirement that these products are only supplied to pre-authorized customers who agree in writing not to sell them to Departments of Corrections or other entities that intend to use them for lethal injection -- some states continue to attempt to procure our products from distributors and other intermediaries for use in lethal injection. Not only is this inconsistent with the FDA indication and contrary to our intention of manufacturing the product for the health and well being of patients in need, but it is also completely counter to our company values.

177. Hikma demanded that NDOC immediately return all of the Hikma Fentanyl Product, and other products, intended for use in executions. Hikma specifically requested that Dzurenda and other NDOC officials not circumvent Hikma's controls or potentially undermine these specifically

drafted legal provisions in its agreements. Defendants have not responded to Hikma's July 11, 2018 Letters.

178. Dzurenda admitted he received Hikma's July 11, 2018 Letter, objecting to the State's use of its products in execution and demanding return of all Hikma products in the State's possession that it intended to use in lethal injection. He knew that Hikma did not want the State using its products, and he told the pharmacist not to return any fentanyl. The State admitted that it was on notice of Hikma's objections.

179. Fentanyl has anesthetic properties when administered in the doses contemplated by the June 11, 2018, execution protocol.

180. Azzam testified that using fentanyl for lethal injections is an off label use of fentanyl and is not recommend by the manufacturer because its intended use pertains to medical or surgical instances.

181. Hikma never informed NDOC that Cardinal sold the fentanyl by mistake.

182. NDOC has no contract with Hikma.

183. NDOC does not purchase any drugs directly from Hikma.

184. Hikma, like Alvogen, also sent letters to all states that allow capital punishment.

185. Hikma admitted that the letters are non-binding and do not require NDOC or any other state to comply with its desire.

186. The circumstances surrounding the ordering of the Hikma Fentanyl Product are much less egregious than the circumstances surrounding the acquisition of the Alvogen Midazolam Product. Fentanyl had not been previously unavailable to the State from Cardinal. While letters from West-Ward and Hikma had been previously received by NDOC, the evidence is dissimilar than that reflected in the text messages related to the the acquisition of the Alvogen Midazolam Product in May 2018.

187. Hikma learned that the State intended to use the Hikma Fentanyl Product to execute Dozier through a press inquiry on July 10, 2018, and acted to obtain return of its property through this action.

188. Hikma admitted that there are factors other than being associated with executions that could contribute to a diminution in value of fentanyl. These factors include fentanyl's role in the opioid epidemic. Hikma admitted it is impossible to determine whether it was the lethal injection or the opioid epidemic that caused the recent diminution in value to its fentanyl product.

189. Despite those concerns, Hikma acknowledged year-to-date fentanyl sales, as compared to the same time period in 2017, are up.

190. Hikma's reputational harms are reasonably ascertainable due to future adverse effects arising out of the State's illegitimate acquisition and use of Hikma's Fentanyl Product. Both experts, as well as Mr. Rosenstack, testified to the concrete harms that can and will arise out of damage to Hikma and its Fentanyl Product as a result of association with the death penalty, including patient aversion, doctor boycotts, and investor divestment.

FACTS REGARDING SANDOZ

191. Sandoz is a Colorado corporation with its principal place of business located at 100 College Road West, Princeton, New Jersey. Sandoz is an indirect subsidiary of Novartis AG ("Novartis"), which trades on the SIX Swiss Exchange under the ticker symbol NOVN and whose American Depository Shares are publicly traded on the New York Stock Exchange under the ticker symbol NVS.

192. Sandoz is a licensed wholesaler in the State of Nevada.

193. Sandoz is a generic pharmaceutical company. Among its products in the United States, Sandoz manufactures and distributes Cisatracurium Besylate Injection (Abbreviated New Drug Application Number 200154).

194. The Sandoz Cisatracurium Product is a nondepolarizing skeletal muscle relaxant for intravenous administration approved by the FDA for inpatients and outpatients as an adjunct to general anesthesia to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation in the ICU.

195. Sandoz's position is that its drugs should only be used for therapeutic purposes (*e.g.*, purposes medically approved by FDA), and that it has the right to prevent use inconsistent with such purposes.

196. Sandoz has expressed an interest in not allowing its drugs to be used as part of a lethal injection protocol.

197. Sandoz has placed controls on the purchase and use of certain of its products that states have publicly identified may be used in connection with lethal injection. Those controls include internal policies and procedures, contracts, and other agreements with its customers to restrict the supply of Sandoz products for distribution and use in lethal injection protocols.

198. Sandoz has refused the direct sale of its products to departments of corrections for use in capital punishment, and works directly with its distribution partners to add restrictions for unintended use to its distribution contracts.

199. Sandoz has repeatedly expressed its position from 2011 to the present against the use of any of its products in lethal injection and has implemented controls to prevent its products from being misused in connection with capital punishment.

200. On July 1, 2006, Sandoz signed a GWSA with Cardinal, appointing Cardinal as a "non-exclusive, authorized distributor of all generic pharmaceutical products manufactured and/or marketed" by Sandoz, and setting forth the terms and conditions governing the Agreement.

201. Sandoz and Cardinal have a GWSA which governs the terms of their contractual relationship. Terms of that contract have been amended over time.

202. In 2006, Sandoz first entered into an agreement with Cardinal to restrict sales of rocuronium bromide to prisons. In August 2017, Sandoz and Cardinal agreed to restrict sales of anectine to departments of correction. Under the 2017 agreement the parties agreed Sandoz would pay Cardinal 1.5% of net sales to prevent sales to prisons, but the amount was capped at $100,000 per calendar year. "Net sales" is defined as the "time of each sale."

203. In 2012, after Sandoz received FDA approval for its Abbreviated New Drug Application (ANDA) regarding the Sandoz Cisatracurium Product, Sandoz started selling its cisatracurium under the terms of its GWSA with Cardinal.

204. In 2013, Sandoz implemented restrictions on the distribution of Sandoz's Rocuronium Bromide to prevent its use in capital punishment, including amending agreements with distributors to prohibit its sale to United States prison hospitals.

205. Consistent with this position, Sandoz did not respond to a request for proposal issued by the State of Nevada in September 2016 to supply drugs required for lethal injection.

206. In August 2017, Sandoz implemented restrictions on the distribution of Anectine, at its launch, to prevent its use in capital punishment, including amending agreements with distributors to prohibit its sale to United States prison hospitals, including all State and Federal Prisons in the United States.

207. In August 2017, Cardinal signed amendments implementing restrictive use programs for Anectine and Rocuronium, less than four months before Sandoz requested that its Cisatracurium Product also be subject to a restrictive use program.

208. By August 2017, Sandoz's policy required that restrictive use agreements be implemented in all Anectine and Rocuronium contracts with (a) group purchasing organizations (GPOs), (b) wholesale distributors, and (c) end-line purchasing hospitals.

209. Cardinal was responsible for communicating any restrictions to the end user.

210. Sandoz first began working with Cardinal to add cisatracurium to the restrictive use agreement in November 2017. The agreement preventing cisatracurium sales to prisons was not executed until five months later, on May 15, 2018.

211. NDOC has no contractual relationship with Sandoz.

212. NDOC has never purchased any product, including cisatracurium, from Sandoz.

213. NDOC purchased the Sandoz Cisatracurium Product from Cardinal on December, 14, 2017.

214. There was no restrictive agreement in place between Sandoz and Cardinal governing cisatracurium sales when NDOC purchased the product from Cardinal.

215. The expiration date for the Sandoz Cisatracurium Product purchased on December 14, 2017, is November 30, 2018.[23]

216. Two other manufacturers (AbbVie and Fresenius Kabi) currently manufacture Cisatracurium Besylate in the United States.

217. The State currently has possession of unexpired Nimbex (branded cisatracurium) manufactured by Abbvie.

218. The Storage section of the product labeling for the Sandoz Cisatracurium Product states:

> Cisatracurium besylate injection should be refrigerated at 2° to 8°C (36° to 46°F) in the carton to preserve potency. Protect from light. DO NOT FREEZE. Upon removal from refrigeration to room temperature storage conditions (25°C/77°F), use cisatracurium besylate injection within 21 days even if rerefrigerated.

219. There is no evidence that NDOC stored the Sandoz Cisatracurium Product that it purchased on December 14, 2017, in compliance with the storage instructions contained in the product labeling.

220. In August 2017, Sandoz became aware that Nevada created a new execution protocol that included cisatracurium. This was the first time any State had included cisatracurium in a lethal injection protocol; since then, only one state has used cisatracurium in carrying out an execution.

221. Cisatracurium is one of three drugs, along with midazolam and fentanyl, which the State plans to use to execute Dozier by lethal injection.

222. When NDOC announced in August 2017 that cisatracurium was part of its revised lethal injection protocol, NDOC did not have the Sandoz Cisatracurium Product.

223. Also in August 2017, Sandoz learned that the NDOC had not purchased any Sandoz-manufactured drugs, including the Sandoz Cisatracurium Product, for use in executions.[24]

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[23] The batch with this expiration date, appears, according to the evidence adduced during the preliminary injunction hearing to be "missing".

[24] The NDOC had purchased cisatracurium from another manufacturer, Fresenius Kabi, in May 2017.

224. Upon becoming aware of cisatracurium's inclusion in the Nevada execution protocol, Sandoz immediately began a due diligence process to determine whether the Sandoz Cisatracurium Product should be added to applicable restrictive use programs. This process involved review by Medical, Regulatory, Legal, and Customer Services Operations.

225. Following completion of the due diligence process in November 2017, Sandoz began to add distribution restrictions for the Sandoz Cisatracurium Product to its customer agreements as they came up for renewal. These restrictions were designed to prevent customers from selling the Sandoz Cisatracurium Product to state and federal prisons.

226. NDOC ordered Sandoz Cisatracurium Product from Cardinal in October 17, 2017; November 2, 2017; and December 14, 2017.

227. In November 2017, Sandoz began implementing controls to restrict distribution and usage of the Sandoz Cisatracurium Product for capital punishment.

228. Implementation of the restrictive use program for the Sandoz Cisatracurium Product required that all hospitals purchasing the medication from Cardinal also sign a restrictive use agreement.

229. The formal written amendment adding the Sandoz Cisatracurium Product to the restrictive use program in the GWSA was signed in May 2018.

230. As part of the Sandoz restrictive use program, a service fee is paid to Cardinal to administer the program.

231. The first time Sandoz paid Cardinal a fee for administration of the restrictive use program was in August of 2017.

232. This service fee does not reflect the value of the restrictive use program to Sandoz, but rather the cost that Cardinal incurs to implement the program.

233. The State only disclosed the identities of the manufacturers of the medications to be used in Dozier's lethal injection execution a week before the scheduled execution pursuant to a court order in to an order in the ACLU litigation.

234. On or about July 7, 2018, Sandoz learned that NDOC had acquired the Sandoz Cisatracurium Product from Cardinal in December 2017 and intended to use it in Dozier's execution Sandoz obtained copies of the documents produced as a result of the ACLU litigation, which included a list of the drugs to be included in the lethal injection protocol, along with the invoices related to NDOC's purchase of those specific drugs. These invoices identified the Sandoz Cisatracurium Product.

235. The invoice for the Sandoz Cisatracurium Product was from Cardinal and documented an order placed on December 14, 2017, to be billed and shipped to the Nevada Department of Correction Center Pharmacy located at the NDOC's administrative building in Las Vegas.

236. Based on this purchase order, Cardinal shipped a total of 20 vials of 2mg/ml 10X5ML Cisatracurium.

237. NDOC acquired the Sandoz Cisatracurium Product from Cardinal aware that its planned use of the product in a lethal injection was contrary to therapeutic and medical uses, and contrary to Sandoz's intention of manufacturing products for the health and well being of patients in need.

238. On July 10, 2018, Sandoz wrote a letter to the State making clear its position against misuse of the Sandoz Cisatracurium Product for capital punishment:

> . . .We strongly object to the misuse of any of our medicines for purposes of lethal injection. Our products are developed, manufactured and distributed to help save and improve people's lives. Their use in connection with executions, many of which have gone horribly wrong in recent years, is fundamentally contrary to this purpose.
>
> To ensure our products are not purchased for this purpose, Sandoz has imposed a system of strict distribution controls designed to prohibit the sale of its medicines to correctional facilities or otherwise for the use in connection with lethal injection executions. These controls align with prevailing industry standards in the pharmaceutical sector and reflect our company's strict policy on ensuring the appropriate use of our medicines.
>
> We write to communicate in the clearest possible terms that Sandoz objects to the misuse of Sandoz Cisatracurium or any other Sandoz product in the administration of capital punishment. We request the NDOC immediately return Sandoz's Cisatracurium that it purchased from Cardinal Health along with any other Sandoz products that Nevada may have obtained for use in lethal injection executions in exchange for a full refund.

239. Sandoz demanded that NDOC immediately return all of Sandoz's Cisatracurium Product and other drugs, intended for use in executions in exchange for a full refund, for such use would represent a serious misuse of life-saving medicines.

240. Counsel for Sandoz attended the July 11, 2018 hearing on Alvogen's TRO application to make a formal objection to the use of Sandoz's Cisatracurium Product for the non-approved use of lethal injection.

241. On August 24, 2018, Sandoz sent a follow-up email to the NDOC, Attorney General Adam Laxalt, and Governor Brian Sandoval, reiterating Sandoz's objection to the use of any of its medications in executions, and again requesting a response.

242. The State has not responded to the July 10, 2018 Letter or follow-up email, nor have they returned Sandoz's Cisatracurium Product acquired for use as part of the lethal injection protocol for Dozier.

243. Only one other state has ever carried out a lethal injection using Cisatracurium. Nebraska utilized the drug in the execution of Carey Dean Moore on August 14, 2018. Sandoz believes that Nevada's proposed misuse of the drug in executions is experimental and without substantial precedent establishing that it can be administered without causing unconstitutional suffering.

244. The State's use of the Sandoz Cisatracurium Product in the lethal injection protocol for Dozier is for a non-therapeutic purpose.

245. The State is currently able to purchase cisatracurium made by manufacturers other than Sandoz.

246. The State's Narcotics and Controlled Drugs Perpetual Inventory forms do not include record of the Sandoz Cisatracurium Product with an expiration date of November 30, 2018.

247. The State's Narcotics and Controlled Drugs Perpetual Inventory forms do not reflect that NDOC has any unexpired cisatracurium manufactured by Sandoz in its possession.

248. On July 12, 2018, Fox texted Dzurenda data regarding "total quantities and all the expiration dates" for cisatracurium in NDOC's possession. This list does not include the Sandoz

Cisatracurium Product with an expiration date of November 30, 2018. All of the Sandoz Cisatracurium Product on this list is currently expired.

249. There is no evidence that NDOC currently has possession of unexpired cisatracurium manufactured by Sandoz.

250. While Anthony Wallace provided undisputed testimony that given the transport and storage of the Sandoz Cisatracurium Product, the product had "been compromised," and Sandoz would destroy the product if it was in the company's possession, the decision on effectiveness of the drug for lethal injection remains with Dzurenda and Azzam.

251. Cardinal did not object to or challenge adding cisatracurium to the restrictive use program.

252. Sandoz requested that the State prepare a 30(b)(6) witness to discuss the contract, but the State did not.[25] Sandoz has requested an adverse inference that the State's contract with Cardinal modified this provision such that title transferred to the State on payment, rather than delivery.[26]

253. Even with that adverse inference,[27] the Court finds, for purposes of this hearing only, that the sales of the Sandoz Cisatracurium Product were fully consummated and/or performed prior to the restriction on the sale of the Sandoz Cisatracurium Product by Cardinal to correctional institutions. The Court concludes that Cardinal had clear title, not voidable title at the time of the sale.

254. The circumstances surrounding the ordering of the Sandoz Cisatracurium Product are much less egregious than the circumstances surrounding Alvogen Midazolam Product. Cisatracurium had not been previously unavailable to the State from Cardinal. While letters from Sandoz had been previously received by NDOC, the evidence is dissimilar than that reflected in the text messages related to the Alvogen Midazolam Product order in May 2018.

255. If any findings of fact are properly conclusions of law, they shall be treated as if appropriately identified and designated.

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[25] See footnote 15.

[26] See footnote 16.

[27] See footnote 15.

CONCLUSIONS OF LAW

256. "Before a preliminary injunction will issue, the applicant must show (1) a likelihood of success on the merits; and (2) a reasonable probability that the non-moving party's conduct, if allowed to continue, will cause irreparable harm for which compensatory damage is an inadequate remedy." *Univ. & Cmty. Coll. Sys. of Nev. v. Nevadans for Sound Gov't*, 120 Nev. 712, 721, 100 P.3d 179, 187 (2004) (quotations omitted); NRS 33.010(1). Courts also weigh the relative hardships and the public interest. *Univ. & Cmty. Coll. Sys. of Nev.*, 120 Nev. at 721, 100 P.3d at 187.

257. In early May 2018, it appeared that the State would have to procure midazolam for the potential execution of Dozier. Several facts indicate that the State did so by way of a scheme or plan involving evasion. The three purchases of the Alvogen Midazolam Product occurred weeks after the State was placed in actual and/or constructive notice by Alvogen that the State could not legitimately acquire the drug, whether "directly or indirectly." The text messages between Fox and Dzurenda also support Alvogen's allegation of a scheme. The question for the Court is whether this scheme was legally permissible under the circumstances.

258. 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.

259. The evidence showed that pharmaceuticals such as those at issue,are unique products. Certain of them (fentanyl and midazolam) are controlled substances subject to strict controls and regulations designed to avoid their diversion and misuse. As Mr. Rosenstack testified, for instance, 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 manufacturers and distributors are responsible for such efforts, not wholesalers like Cardinal.

260. The Plaintiffs claim they retain the right to "recall" their products at any time for any reason.

261. The Court takes judicial notice of 21 CFR § 7.46(a),[28] which provides that "[a] firm may decide of its own volition and under any circumstances to remove or correct a distributed product." This provision reflects pharmaceutical companies' retention of some ownership rights in their distributed drugs even after those products come into the possession of others, including prospective end users like Defendants.

262. No evidence of the compliance with 21 CFR 7.46 was presented during the preliminary injunction hearing.

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[28] The CFR relied upon provides:

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER A--GENERAL
PART 7 -- ENFORCEMENT POLICY
Subpart C--Recalls (Including Product Corrections)--Guidance on Policy, Procedures, and Industry Responsibilities
Sec. 7.46 Firm-initiated recall.
(a) ***A firm may decide of its own volition and under any circumstances to remove or correct a distributed product.*** A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:
(1) Identity of the product involved.
(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
(3) Evaluation of the risk associated with the deficiency or possible deficiency.
(4) Total amount of such products produced and/or the timespan of the production.
(5) Total amount of such products estimated to be in distribution channels.
(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.
(7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
(8) Proposed strategy for conducting the recall.
(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.
(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.
(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

263. While the Court recognizes the importance of the rights under 21 CFR 7.46 where there are product deficiencies, tampering or impurities, here the Plaintiffs seek to remove the distributed product to prevent its misuse by the end user.

264. While 21 CFR 7.46 reflects a retained interest in the pharmaceutical, no evidence that Plaintiffs relied upon that provision in demanding return of the Lethal Injection Drugs was presented during the preliminary injunction hearing.

265. This retention of a property interest is one that has requirements of notification to the FDA. As no evidence of any notification to the FDA was admitted during the hearing, Plaintiffs cannot rely upon 21 CFR 7.46 for injunctive relief.

266. The Nevada Supreme Court has also recognized a continuing duty to warn on the part of drug manufacturers.

> . . . FDA warnings are generally viewed as establishing minimum standards for product design and warning. (citations omitted.) Thus, if a drug manufacturer knows, or has reason to know, of increased dangers that are not already identified in its drug's label, compliance with the FDA's minimal standard may not satisfy its duty to warn. (citations omitted.)

Wyeth v. Rowatt, 126 Nev. 446, 468 (2010).

267. Replevin is a common law cause of action to recover personal property or goods wrongfully detained. *Perkins v. Barnes*, 3 Nev. 557, 559-60 (1867). To state a cause of action for replevin, a plaintiff must plead and prove the following elements: (1) plaintiff's ownership, either general or special, of the property, describing it; (2) his right to its immediate possession, and the wrongful taking and detention thereof by defendants; and (3) a demand for possession in certain instances. *Johnson v. Johnson*, 55 Nev. 109, 27 P.2d 532 (1933).

268. Similarly, to state a cause of action for conversion, the plaintiff must show "a distinct act of dominion wrongfully exerted over another's personal property in denial of, or inconsistent with his title or rights therein or in derogation, exclusion, or defiance of such title or rights." *Evans v. Dean Witter Reynolds, Inc.*, 116 Nev. 598, 606, 5 P.3d 1043, 1048 (2000) (quotations omitted).

269. The Plaintiffs assert that they each retained a property interest in the drugs sold through Cardinal because they each purportedly placed "controls" or use restrictions on the drug that attached to the product and ran with it down the stream of commerce and prevented the State from obtaining title.

270. Plaintiffs assert this retained property interest along with the belief that Cardinal would not sell their respective products to departments of corrections was sufficient to create an interest subject to evaluation of the State's conduct and knowledge as a good faith purchaser for value.

271. The State's conduct regarding the drug purchases qualifies as subterfuge. "In ordinary parlance, and in dictionary definitions as well, a subterfuge is a scheme, plan, stratagem, or artifice of evasion." *See United Airlines, Inc. v. McMann*, 434 U.S. 192, 203 (1977). The State engaged in such a stratagem.

272. Fox and Dzurenda were aware when purchasing Alvogen's drugs that Plaintiffs objected to their use in lethal injection and that they had controls in place to prevent sales for such use. Yet Dzurenda merely filed those objection letters and never acted upon them. Indeed, when purchasing the Alvogen Midazolam Product, Fox's response to Alvogen's objections was "Oh shit." She then asked Mr. Dzurenda if he would like her to order more because she was "certain once it's in the press that we got it [she] will be cut off." In response, she then ordered three more boxes despite expecting that Alvogen "will be calling next week asking for it back," with the acknowledgement that it would look "contrived" that they ordered the product just a day after the Dozier execution was allowed to move forward.

273. The State's conduct in acquiring midazolam stands in stark contrast to the State's prior unsuccessful attempt to obtain lethal injection drugs via a transparent RFP in which the State disclosed the purpose of the drugs and asked any seller submitting a bid for a certification that the drugs could be used in an execution. When the State's attempt at transparency failed, they resorted to subterfuge.

274. The Cardinal-Alvogen GDWA expressly provides for Alvogen's ability to recall products even after their transfer to Cardinal.[29]

275. Given the adverse inference,[30] Alvogen had a Controlled Distribution Agreement in place with Cardinal when the State purchased the Alvogen Midozolam Product. This Controlled

[29] Each of the wholesale agreement provides language substantially similar to:

Supplier shall reimburse Cardinal for the full amount of all reasonable costs and expenses incurred by Cardinal in connection with Cardinal's performance of any recall services or assistance relating to the products.

[30] See footnote 15.

Distribution Agreement limited Cardinal's interest in the Controlled Distribution Products. Given the limitation on transfer in the Controlled Distribution Agreement, Cardinal obtained voidable title to the Alvogen Midozolam Product.

276. Pursuant to NRS § 104.9620(1)(a), Alvogen requested the return of its property in its April 20th letters. As Dzurenda admitted, the State never responded to those letters, let alone contested them.

277. Two of the Plaintiffs (Hikma and Sandoz) did not have any restrictive agreements in place with Cardinal when the State placed its orders or when payment was due.

278. The Plaintiffs' letters and Website disclaimer are relevant in evaluating notice to the State.

279. The FDA has no per se rule against off-label uses for drugs. "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient."[31] Alvogen's NRCP 30(b)(6) acknowledged that the FDA has relaxed its stance toward off-label uses. Alvogen does not believe there is a finite list of procedures that midazolam can be legally used in.

280. While NDOC is required by law to carry out an order of execution by lethal injection under NRS 176.355(1), (2)(b), sovereign immunity does not protect Dzurenda from injunctive relief simply because he purchased drugs in order to carry out an execution by lethal injection. NRS 176.355(2)(b). The property interests in the replevin claim are not subject to protection under the immunity doctrines, but are a remedy seeking the return of the Lethal Injection Drugs.

281. The State initially added midazolam to the proposed execution protocol in 2016. After doing so, the NDOC issued a Request for Proposal that was transparent as to the purpose for acquiring the drug – the NDOC asked for a representation from pharmaceutical companies that the midazolam was appropriate for use in a lethal injection. Despite sending the RFP to over 200 pharmaceutical companies, the NDOC received zero responses.

[31] https://www.fda.gov/forpatients/other/offlabel/default.htm.

282. NDOC had actual notice imputed to all of its employees no later than April 27, 2017, the date when Alvogen's April 20 letter to the NDOC was stamped received by NDOC personnel.

283. Hikma requested the return of its property in its July 11 letter. The State did not respond.

284. Sandoz requested the return of its property in its July 10 letter. The State did not respond.

285. Nevada permits replevin to recover property from a third party with whom the plaintiff had no contractual relationship. *See Cooper v. Pacific Auto. Ins. Co.*, 95 Nev. 798, 801-02, 603 P.2d 281, 283 (1979).

286. A buyer in the ordinary course is "a person that buys goods in ***good faith, without knowledge that the sale violates the rights of another person*** in the goods, and in the ordinary course from a person, other than a pawnbroker, in the business of selling goods of that kind." NRS § 104.1201(i) (emphasis added).

287. Here, the State did not acquire the Alvogen Midazolam Product in good faith, and it did so knowing that it violated Alvogen's property rights. Fox knew Cardinal's offering the Alvogen Midazolam Product for sale to the State was a mistake that the State seized on before it could be corrected. This is not good faith.

288. The State was aware of Alvogen's right in their property. Alvogen sent letters to various Nevada officials asserting their property rights and informing the State that they were not authorized to purchase the Alvogen Midazolam Product.

289. In the face of the State's bad faith disregard for Alvogen's rights, the State cannot qualify as a good faith buyer in the ordinary course.

290. Alvogen has demonstrated a substantial likelihood of success on its replevin claim.

291. Hikma sent to various Nevada officials letters notifying the State of its rights in its products by objecting to the use of its products in executions in December 2016, December 2017, and July 2018.

292. Sandoz notified the State of its rights in its product by sending direct communications to Nevada officials asserting the company's property rights and informing the State that it was not authorized to purchase the Sandoz Cisatracurium Product.

293. Plaintiffs did not unduly delay in seeking to enforce their rights.

294. Although the State published its press release disclosing its intention to use fentanyl and cisatracurium in August 2017, the State did not disclose at that time that it intended to use either the Hikma Fentanyl Product or the Sandoz Cisatracurium Product. In fact, the State was not in possession of Hikma's or Sandoz's products at the time.

295. Even though neither Hikma nor Sandoz knew whether the State intended to use their drugs in its lethal injection protocol, both Hikma and Sandoz have specific controls and agreements in place to prevent the State's use of any of their products in connection with lethal injections, and were diligently exercising their rights and interest in their products.

296. The State was specifically aware of Hikma's prohibition directed at the State that the State was not permitted to use any of its products as early as 2016, well before the State updated its lethal injection protocol to include fentanyl.

297. Given the fact that Sandoz had a restrictive use program in place for one of its other medications as early as 2013, the State was aware of Sandoz's prohibition directed at the State that the State was not permitted to use any of its products well before the State updated its lethal injection protocol to include cisatracurium.

298. Dzurenda was certain that even as early as 2016 the drug manufacturers would bring action against the State if they knew that the State possessed and intended to use any of their products in an execution.

299. The State had refused to disclose the manufacturers of the products that the State intended to use in Dozier's execution until July 6, 2018, when the State was compelled to produce the records pursuant to the order in the ACLU litigation.

300. Each of the parties in this case may suffer some harm by the issuance of the injunctive relief. The Court balances these interests and hardships in making a determination on the injunctive relief request.

301. A preliminary injunction may harm the interests of the State, the victims, and the public in timely enforcement of a lawful capital sentence.

302. Since NDOC's declaration of its lethal injection protocol to be used in Dozier's execution, including the use of the midazolam, fentanyl, and cisatracurium in the execution, the NDOC's protocol has been widely publicized and criticized.

303. Plaintiffs have shown a substantial likelihood of establishing that association with the death penalty brought on by the State's intended use of the Alvogen Midazolam Product, the Hikma Fentanyl Product, and the Sandoz Cisatracurium Product will irreparably harm the three companies' reputations.

304. The severe criticism communicated by a vocal minority of the American public, medical and legal professionals, and scholars alike implicates Plaintiffs as the manufacturer of the drugs that the State intends to use in this execution.

305. Investors have already raised concerns about the Plaintiffs' association with the death penalty.

306. Plaintiffs have already seen negative press articles regarding their products involvement with Dozier's execution.

307. As Dr. Candiotti testified, association with the death penalty can result in the removal of a drug product from the marketplace.

308. Hospira previously removed sodium pentothal from the marketplace as a result of its association with the death penalty. Sodium pentothal was previously a useful drug product for anesthesiologists and beneficial to patients, and they now cannot access it.

309. Drugs associated with lethal injection can be removed from the marketplace, as previously happened with sodium pentothal. Such a discontinuation would harm both Plaintiffs and the public, which would no longer have access to valuable medications.

310. The expert testimony of Dr. Candiotti conveyed that patients may form an association between the Plaintiffs' drugs and lethal injection that will make them reluctant to have doctors administer Plaintiffs' drugs, causing a drop in Plaintiffs' sales that would be impossible to calculate.

311. The expert testimony of Dr. Nicholson conveyed that Plaintiffs may also experience reputational harm within the medical community. Many doctors oppose the death penalty. No organization for medical professionals supports the death penalty, and many medical organizations, including the American Medical Association, have taken affirmative positions opposing physician participation in lethal injection. These anti-death-penalty sentiments within the medical community will result in harm to Plaintiffs' respective reputations if the State uses Plaintiffs' property in the execution, because doctors will refuse to purchase or prescribe drugs from companies they perceive as supporting the death penalty.

312. Plaintiffs' reputational harm could result in lost sales, lost licensing opportunities, weakened employee recruitment, divestitures by investors, increased financing costs, lost opportunities to enter the market for generic drugs, and lost opportunities to develop new branded drugs.

313. The aggregate economic harm to Plaintiffs arising from these various factors would be impossible to calculate to a reasonable degree of economic certainty.

314. Given the nature of reputational harm, the impact is largely intangible and occurs over a prolonged period of time.

315. Dzurenda recognized the irreparable harm that would be suffered by the Plaintiffs if their products are misused in the execution over their objection.[32]

316. Given the adverse inference,[33] the Controlled Distribution Program limited Cardinal Health from selling Alvogen Midazolam Product to the State at the time of each of the State's acquisitions.

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[32] The Court has not addressed the immunity arguments raised by the State as this order relates only to an injunctive relief proceeding and the claim on which the Court bases its order does not seek monetary damages, but a return of the Lethal Injection Drugs.

[33] See Footnote 15.

317. While the State was well aware of the objections of these manufacturers to the misuse of their drugs in conjunction with an execution, Sandoz and Hikma's failure to promptly act to impose Controlled Distribution Agreements militates against their request for injunctive relief.

318. While the Court is disturbed by the conduct of the State in this matter, but after weighing the equities and balancing the hardships, the Court denies the motion for Preliminary Injunction as to Hikma and Sandoz.

319. With respect to Alvogen, given the adverse inference,[34] the Court, after balancing the hardships and finding the State not to be a good faith purchaser for value from one with voidable title, grants the preliminary injunction as to Alvogen only.

320. If any Conclusions of Law are properly Findings of Fact, they shall be treated as though appropriately identified and designated.

Dated this 28th day of September, 2018.

DISTRICT COURT JUDGE

[34] See Footnote 15.