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DISTRICT COURT

CLARK COUNTY, NEVADA

ALVOGEN, INC., Plaintiff, vs. STATE OF NEVADA; NEVADA DEPARTMENT OF CORRECTION; JAMES DZURENDA, Director of the Nevada Department of Correction, 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; Defendants.	Case No. A-18-777312-B Dept. No. XI **HIKMA PHARMACEUTICALS USA INC.'S MOTION TO INTERVENE ON ORDER SHORTENING TIME** Date of Hearing: Time of Hearing:

Intervenor Hikma Pharmaceuticals USA Inc. ("Hikma"), through its counsel of Lewis Roca Rothgerber Christie LLP, moves to intervene in this action as a matter of right pursuant to NRCP 24(a). Alternatively, Hikma moves for permissive intervention under NRCP 24(b). This

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Motion is made in accordance with EDCR 2.20 and 2.26, and based upon the following Memorandum of Points and Authorities, the attached Exhibit, and the pleadings and paper on file herein.

DATED this 24th day of July, 2018.

LEWIS ROCA ROTHGERBER CHRISTIE LLP

By: /s/ *Josh M. Reid*
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DECLARATION OF JOSH M. REID IN SUPPORT OF APPLICATION FOR ORDER SHORTENING TIME

I, Josh M. Reid, Esq., hereby declare as follows:

1. I am admitted to practice law in the State of Nevada and the courts of Clark County.

2. I am counsel of record for Hikma in the above-referenced action and make this Declaration in support of Hikma's Motion to Intervene on Order Shortening Time ("Motion").

3. I have personal knowledge of the facts stated herein, except those stated upon information and belief, which I believe to be true. I am competent to testify to the facts stated herein.

4. As set forth in the Motion, and as alleged in the proposed Complaint in Intervention, attached hereto as **Exhibit A**, on July 10, 2018, Plaintiff Alvogen, Inc. ("Alvogen") filed its Complaint for Emergency Injunctive Relief and Return of Illegally-Obtained Property ("Alvogen Complaint"), and *Ex Parte* Application for Temporary Restraining Order and Motion for Preliminary Injunction; *Ex Parte* Motion for Order Shortening Time. Through this action Alvogen seeks to enjoin Defendants from using Alvogen's Midazolam Product in capital punishment until further order of this Court.

5. I am informed and believe that on or about July 10, 2018, Hikma received notice that the State of Nevada had confirmed its intention to execute Scott Raymond Dozier, scheduled for July 11, 2018, using the drug fentanyl in its lethal injection protocol. Hikma manufactures fentanyl, but at the time that Hikma received notice of Defendants' planned use for the Dozier execution, it remained unclear whether Defendants were in possession of Hikma's fentanyl product ("Hikma's Fentanyl").

6. This Court heard argument on Alvogen's *Ex Parte* Application for a Temporary Restraining Order at 9 a.m. on July 11, 2018. This Court issued the Temporary Restraining Order ("TRO") the same day, prohibiting and enjoining Defendants from using Alvogen's Midazolam Product in capital punishment until further order of the Court. This Court further ordered that the "TRO will remain in effect pending the preliminary injunction hearing completion," and

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scheduled a status check for September 10, 2018, related to the discovery being conducted in preparation for the preliminary injunction hearing.

7. As a result of the Court's issuance of the TRO, the State of Nevada postponed the execution of Scott Raymond Dozier until further notice.

8. After the Court's issuance of the TRO and the State of Nevada's postponement of the execution, Hikma was able to confirm that Defendants are in possession of Hikma's Fentanyl. Hikma also manufactures midazolam, although it does not appear that Defendants are in possession of any Hikma product besides Hikma's Fentanyl that may be used in its lethal injection protocol. As articulated in the instant Motion, Hikma has an interest in the property and transactions that are at issue in this action concerning Defendants' acquisition of medicines for the purpose of executing Scott Raymond Dozier, and others.

9. As a practical matter, if Hikma's request for intervention is denied, Hikma's ability to protect its interests may be impaired, for any relief afforded to Alvogen will pertain to Alvogen's products, not Hikma's. And, Hikma's request is timely. While the existing parties to this action are about to begin the discovery process in preparation for the preliminary injunction hearing, they have yet to do so. Hikma intends to join in Alvogen's motion for preliminary injunction, but with respect to Hikma's products, and will seek to participate in the discovery process and preliminary injunction hearing if allowed by this Court. Hikma seeks shortened time on its Motion to Intervene as a result.

10. Moreover, because this Court's TRO extends only to Alvogen's Midazolam Product, Hikma's products are still at risk to be used in the State of Nevada's execution of Scott Raymond Dozier, which may occur upon the issuance of a new death warrant. Thus, Hikma seeks a decision on its request to intervene on shortened time so that Hikma may seek immediate temporary relief from this Court to protect Hikma's products—the request of which would raise the same legal issues and substantially similar facts as those presented in Alvogen's request—should the need arise. If intervention is allowed on shortened notice, the scenario requiring Hikma to initiate a new, separate action—thereby creating the risk of inconsistent decisions, or delay as a result of subsequent consolidation—to obtain such immediate relief is avoided altogether.

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11. For these reasons, good cause exists to shorten time and hold the hearing on Hikma's Motion to Intervene as soon as possible.

I declare under penalty of perjury under the laws of the State of Nevada, that the foregoing is true and correct.

DATED this 24th day of July, 2018.

JOSH M. REID, ESQ.

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ORDER SHORTENING TIME

TO: ALL PARTIES AND THEIR ATTORNEY OF RECORD:

IT IS HEREBY ORDERED that the time for hearing on Hikma Pharmaceuticals USA Inc.'s Motion To Intervene is hereby shortened and shall be heard on the 30 day of July, 2018, at 9, p.m./a.m., in Department XI in the above-entitled court, or, alternatively, as soon thereafter as counsel may be heard.

IT IS FURTHER ORDERED that the briefing schedule concerning Hikma Pharmaceuticals USA Inc.'s Motion to Intervene be set as follows:

Defendants shall have up to and including _____, 2018, by 5:00 p.m. to file a response to the Motion. Plaintiff Hikma Pharmaceuticals USA Inc. shall have up to and including _____, 2018, by 5:00 p.m. to file a reply.

DATED this 25 day of July, 2018.

DISTRICT COURT JUDGE

LEWIS ROCA ROTHGERBER CHRISTIE LLP

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Hikma, as a pharmaceutical company that manufactures medicines to promote the well-being of patients in need, seeks to intervene in this action to protect its interests. This action involves Defendants' illegal and unauthorized acquisition and possession of medicines that make up the novel, three-drug protocol that Defendants intend to use to execute Scott Raymond Dozier, and potentially other condemned inmates. Plaintiff Alvogen, Inc. ("Alvogen"), is a manufacturer of midazolam—a one-third component to the new lethal injection protocol—and has alleged various statutory and common law claims against Defendants, further seeking to preliminarily and permanently enjoin Defendants from using its products for executions. Hikma is a manufacturer of both fentanyl and midazolam and, like Alvogen, only recently discovered through media sources that Defendants illegally obtained possession and intend to use one of its products, Fentanyl Citrate Injection, USP C-II ("Hikma's Fentanyl"), in an illegal manner as one of the other one-third components to the protocol for Scott Raymond Dozier's execution. Defendants' actions and intended use of Hikma's Fentanyl are contrary to Hikma's express admonitions, made both publicly and directly to Defendants, the U.S. Food and Drug Administration's approved use of the drug, and Nevada law.

If Defendants are permitted to retain their unlawful possession of Hikma's Fentanyl and proceed with their wrongful use of Hikma's products, Hikma will suffer irreparable damage including, but not limited to, reputational injury arising out of (i) association with the manufacture of drugs used for executions, (ii) the corresponding damage to business and investor and prospective investor relationships, (iii) damage to goodwill, and (iv) other irreparable harm to be proven at trial. Hikma seeks to raise substantially the same legal issues and claims as those raised by Alvogen in this matter, which are based on a substantially similar set of facts.

Thus, Hikma has a compelling interest in the property and transactions that are the subject of this lawsuit. Resolution of this action as a practical matter, based on the factual and legal issues and claims raised herein, will affect Hikma's substantial interests. Hikma is entitled to protect those interests and will be harmed if precluded from doing so because, while adjudicating the

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overarching legal and factual issues in the case, Alvogen seeks to protect its specific property rights, not Hikma's. Consequently, in the absence of Hikma's intervention in this action, a decision in favor of Alvogen will not extend to prevent Defendants from illegally obtaining and misusing Hikma's products, including Hikma's Fentanyl, in the upcoming execution of Scott Raymond Dozier. For these reasons, Hikma is entitled to intervene as a matter of right, pursuant to Nevada Rule of Civil Procedure 24(a).

To the extent any question remains as to Hikma's intervention right, Hikma alternatively seeks leave for permissive intervention under Rule 24(b). Permissive intervention is proper for the reasons that Hikma has alleged the same claims for relief, predicated on the same legal and similar factual bases, as those alleged by Alvogen in this case. Moreover, Hikma seeks to preliminarily and permanently enjoin Defendants from using its products, including Hikma's Fentanyl and midazolam, for executions conducted by the State of Nevada, including the execution of Scott Raymond Dozier. Alvogen has already requested that Defendants be preliminarily and permanently enjoined from using Alvogen's Midazolam Product in executions, and specifically the Dozier execution.

Because of the (1) similar legal questions; (2) substantially similar factual underpinnings surrounding Defendants' unlawful acquisition and use of the drugs, and these manufacturers' public and direct notices to Defendants that these products could not be used in executions; and (3) timeliness of the instant Motion, no existing party will suffer prejudice as a result of Hikma's intervention. Accordingly, an order allowing Hikma to intervene in this action is warranted.

II. FACTUAL BACKGROUND

Hikma's mission is to treat illnesses and save lives by providing patients with access to high-quality and affordable medicines. To maintain Hikma's reputation for producing safe, high-quality products, Hikma has always been and is committed to going beyond mere compliance with the law and strives to uphold the highest ethical standards in everything it does.

In an attempt to ensure that its products are used responsibly, Hikma has placed controls on the purchase and use of its products. Such controls include internal policies and procedures, and contracts with its customers to restrict the supply of Hikma products for the distribution and

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use in lethal injection protocols. Hikma states its policy against the use of any of its products in capital punishment on its website:

> 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.

Ex. A at Ex. 2 (*Use of Products in Capital Punishment*, HIKMA, http://www.hikma.com/about/our-policies/use-of-products-in-capital-punishment (last accessed July 24, 2018)). Hikma has also refused the direct sale of its products 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. Hikma's website further publishes 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." *Id.* Hikma also restricted particular drugs that have a heightened potential of misuse for lethal injection protocols, publishing them on Hikma's restricted list. *See id.* These drugs include Hikma's Fentanyl and midazolam products. *Id.*

Upon learning that some states, including the State of Nevada, were considering new medicines to use in their lethal injection protocols, Hikma exercised its rights and took proactive action to prevent its medicines from being used in this inappropriate use that violates Hikma's policy and values and is counter to Hikma's interests.

In 2016, for example, Hikma exercised its right not to sell its products to Defendants for use in lethal injection, and gave Defendants written notice that Hikma vehemently objected to the use of any of its products for lethal injection. On December 20, 2016, in confirming this policy, Hikma sent letters to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and

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Defendant Dzurenda, in which Hikma stated, "We object in the strongest possible terms to the use of **any of [its] products** for lethal injection," including Hikma's Fentanyl, and again made clear that its objection should be applied to all of its products ("2016 Letters"). *See* **Ex. A** at Ex. 3 (emphasis added). Hikma notified these recipients that such use of any of its products was

> 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 [its] values as an organization.

Id.

Hikma stated that it was not aware of Defendants having possession of any of its products at that time, but noted that its objection was made because it had become aware that some states were considering new compounds to use in lethal injections. *Id.* Hikma further stated,

> 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.

Id. By the end of September 2017, after discovering that fentanyl was being considered for use in lethal injections, Hikma specifically named its Fentanyl and midazolam products on the restricted list.

In November 2017, in Scott Raymond Dozier's habeas corpus case (*Dozier v. State*, Case No. 05C21503, Notice of Redacted Version of the State of Nev.'s Execution Protocol (Nev. Dist. Ct. Nov. 11, 2017)), the State filed a redacted version of NDOC's Executional Manual, dated November 7, 2017, wherein it confirmed that fentanyl was one of the three drugs consisting of Nevada's new lethal injection cocktail. This decision was extremely controversial because it represents the first time any state in the country included the already-controversial drug fentanyl as

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part of its lethal injection protocol. The State's novel misuse of the drug in executions renders it experimental, and thus exacerbates the already existing controversy.

Again in 2017, Hikma took proactive action to enforce its rights and provided another written notice to Defendants to restate its policy and position on the use of its drugs. On December 17, 2017, Hikma sent letters to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Defendant Dzurenda, in which Hikma again vehemently objected to any of its products being used for lethal injection ("2017 Letters"). *See* **Ex. A** at Ex. 4. Hikma restated that such use of any Hikma products is contrary to its therapeutic purpose and FDA approved-use, in addition to being contradictory to the intended use of the products and Hikma's organizational values. *Id.* Hikma echoed its 2016 Letters in stating that it has certain controls in place to prevent departments of corrections from using its products for lethal injection, "including the restriction of any direct sales to Departments of Corrections of restricted products, or sales to customers." *Id.*

Although Hikma at the time was not aware of the State being in possession of Hikma products for such purpose and communicated the same, to be sure, Hikma reiterated,

> [W]e are writing again to restate our policy and our position on the use of these drugs: We object in the strongest possible terms to the use of any of our products for lethal injection.
>
> We wrote to you on this same topic this time last year, and are reaching out to advise you that we have had to extend the restriction of products to include additional drugs, as states continue to experiment with new cocktails. There is a list of restricted products on our website which we keep current.
>
> To this point, we would like to make clear that our objection should be applied to any and all West-Ward and Hikma products, not just those on our restricted list.

Id.

Hikma's actions here are consistent with those of other pharmaceutical companies that have taken affirmative action to exercise their rights to not sell their products for use in lethal injection. *See* **Ex. A** at Ex. 1. More than 20 American and European pharmaceutical companies have taken similar action, including Alvogen in this specific case.

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Like Alvogen and other pharmaceutical companies, Hikma has an important interest in protecting its business reputation and meeting its fiduciary duties to its shareholders and investors. Experts have commented that a pharmaceutical company's involvement with lethal injection may open the company to liability, including the loss of large institutional investors and litigation from their shareholders. *See id.* As a U.S. subsidiary of an international pharmaceutical company that is publicly traded on the London Stock Exchange, Hikma has taken multiple proactive actions in order to protect its rights and values, and also to protect its shareholders and investors.

Similar to Hikma, Alvogen sent Defendants letters strongly objecting to the use of Alvogen's products in capital punishment, specifically identifying that Alvogen's Midazolam Product should not be used in executions for running counter to the FDA-approved therapeutic and medical uses for these products. Alvogen Compl. 6-7. Alvogen, too, explained the controls it has in place to ensure that its products are not purchased for use in lethal injections, including that it does not accept orders from any state departments of corrections and prohibits its customers from selling to the same. *Id.* Alvogen's website reiterates that its product should not be used in execution protocols. *See id.* at 7.

Similar to what Alvogen alleges with respect to its Midazolam Product, *e.g.*, *id.* at 7, in spite of Hikma's written demands and warnings to not have its products used in conjunction with lethal injection, Defendants acted to illegitimately obtain Hikma's Fentanyl to use in its lethal injection protocol.

On or about July 10, 2018, Hikma was informed, just as Alvogen was, that the State had confirmed its intention to execute Scott Raymond Dozier on Wednesday, July 11, 2018, using fentanyl and midazolam in its three-drug protocol. At that time, it was unclear whether Defendants were in possession of Hikma's Fentanyl or midazolam products. On July 10, 2018, Hikma was notified of Alvogen's initiation of the instant lawsuit, and Alvogen's request for a preliminary injunction. Through these filings, Alvogen confirmed that Defendants were intending to use Alvogen's Midazolam product in the execution, not Hikma's.

This Court heard argument on Alvogen's *Ex Parte* Application for a Temporary Restraining Order at 9 a.m. on July 11, 2018, and issued the Temporary Restraining Order

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("TRO") the same day. The TRO prohibited and enjoined Defendants from using Alvogen's Midazolam product in capital punishment until further order of the Court. The TRO is specifically limited to Alvogen's Midazolam Product.

After the hearing on Alvogen's *Ex Parte* Application, Hikma obtained copies of documents produced as a result of a court order in litigation initiated by the American Civil Liberties Union of Nevada. *See Am. Civil Liberties Union of Nev. Found. v. State*, Case No. 18 OC 00163 1B, Order Granting In-Part Emergency Pet. Issuing Writ of Mandamus (Nev. Dist. Ct. July 6, 2018). The court order in that case compelled NDOC to disclose the lethal injection procedures it planned to implement in Scott Raymond Dozier's execution. *Id.* The documents 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 Hikma's Fentanyl product, NDC/UPC 00641-6027-25. *See* **Ex. A** at Ex. 5. These invoices further showed that NDOC placed multiple small orders of the drugs over a number of months, with some orders following the last by only one day.

The invoice for Hikma's Fentanyl was from one of Hikma's wholesale distributors, Cardinal Health, placed on September 28, 2017, for shipment the next day, and addressed to be billed and shipped to the Nevada Department of Correction Center Pharmacy, located at the NDOC's administrative building in Las Vegas—not to the Ely State Prison where Nevada's executions take place (over 200 miles away from its Las Vegas building). *See id.* Defendants' purchase of Alvogen's Midazolam Product were placed through the same wholesale distributor, and billed and shipped to the same NDOC's administrative building in Las Vegas. *E.g.*, Alvogen Compl. 11-12.

In order to purchase Hikma's Fentanyl and Alvogen's Midazolam Product, NDOC was required to provide Cardinal Health with proof of a medical license issued to NDOC's medical director. NDOC's purchase orders to Cardinal Health for Hikma's Fentanyl and Alvogen's Midazolam Product used the Nevada Chief Medical Officer's license to illegally obtain the products. In doing so, NDOC intended Cardinal Health to believe that the orders for the products were being placed at the request or for the benefit of the physician and the medications would be

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used for a legitimate medical purpose, consistent with Nevada's Controlled Substances Act and the Nevada State Board of Medical Examiners regulations.

NDOC acquired Hikma's Fentanyl and Alvogen's Midazolam Products from Cardinal Health when it was aware that both manufacturers had strongly objected to and prohibited the use of all of their products in executions. NDOC acquired Hikma's Fentanyl and Alvogen's Midazolam Product nonetheless through a source that was not authorized to sell to the NDOC for the non-approved use in an execution.

Following Defendants' receipt of Hikma's 2016 Letters, *see* **Ex. A** at Ex. 3, and following Alvogen's April Letters, Defendants sought to circumvent both manufacturers' policies by purchasing the Hikma Fentanyl and Alvogen's Midazolam Product through an unsuspecting intermediary and without disclosing to said intermediary that they planned to use the products for an execution. Defendants were thus able to illicitly obtain both Hikma's Fentanyl and Alvogen's Midazolam Product in a manner that Defendants would not have been able to accomplish had they disclosed that they planned to use the products for an execution.

Even after receiving Hikma's 2017 Letters and Alvogen's April Letters reiterating their objections to NDOC's use of any of their products for executions, Defendants thereafter announced their intention to use Hikma's Fentanyl and Alvogen's Midazolam Product in the lethal injection protocol for Scott Raymond Dozier—a non-medical purpose for which neither are allowed nor intended to be used. Defendants' proposed use for Hikma's Fentanyl and Alvogen's Midazolam Product is unequivocally contrary to the intended therapeutic or medical use for this product. While neither manufacturer takes any position on the death penalty itself, these products were manufactured to meet the therapeutic or medical needs of healthcare patients—not to be used in state-facilitated executions of convicted felons.

Upon confirming that Defendants intended to use Hikma's Fentanyl in the scheduled lethal injection of Scott Raymond Dozier, on July 11, 2018, Hikma hand-delivered its third notices to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Defendant Dzurenda ("2018 Letters"). *See* **Ex. A** at Ex. 6. Hikma reminded these recipients, including NDOC—once again—of Hikma's position on the misuse of its medicines in executions. *See id.*

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Hikma stated its belief that NDOC is in possession of Hikma's Fentanyl, and that it may be used in a pending execution, additionally stating,

> 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.

Id.

Hikma demanded that NDOC immediately return all of its Fentanyl, and other products, intended for use in executions for a full refund, for such use would represent a serious misuse of life-saving medicines. *Id.* Hikma specifically requested that Defendant Dzurenda and other NDOC officials not circumvent Hikma's carefully-prepared controls or potentially undermine these specifically drafted legal provisions in its agreements. *Id.* Defendants have not responded to Hikma's letter.

Likewise, Defendants have refused Alvogen's offer to return Alvogen's Midazolam Product for a full refund. Alvogen Compl. 20.

Just as Defendants did with respect to Alvogen's Midazolam Product, Defendants obtained Hikma's Fentanyl to use it in an unintended and unapproved manner, and Defendants have violated Hikma's rights and Nevada law as well. If Defendants are allowed to continue to circumvent Nevada law, and Hikma's recognized right to use its own business judgment to determine how its products may be sold and used, and use Hikma's product for the unintended and unapproved use of lethal injection, Defendants' actions will result in Hikma's immediate and irreparable harm, damage to Hikma's hard-earned business reputation, and financial damage to Hikma and its investors.

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III. HIKMA IS ENTITLED TO INTERVENTION AS A MATTER OF RIGHT

The procedural mechanism governing a prospective party's ability to intervene in a matter is Rule 24 of the Nevada Rules of Civil Procedure. Traditionally, Rule 24 "receives liberal construction in favor of applicants for intervention." *Arakaki v. Cayetano*, 324 F.3d 1078, 1083 (9th Cir. 2003), *as amended* (May 13, 2003).

Under NRCP 24(a), a prospective intervenor

> shall be permitted to intervene in an action . . . when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.

See also NRS 12.130. Intervention as a matter of right must be permitted if the applicant can establish the following four requirements: "(1) that it has a sufficient interest in the litigation's subject matter, (2) that it could suffer an impairment of its ability to protect that interest if it does not intervene, (3) that its interest is not adequately represented by existing parties, and (4) that its application is timely." *Am. Home Assur. Co. v. Eighth Judicial Dist. Ct.*, 122 Nev. 1229, 1238, 147 P.3d 1120, 1126 (2006). As discussed below, each of the four requirements are satisfied, demonstrating that Hikma is entitled to intervene as a matter of right.

A. Hikma Has a Sufficient Interest in the Litigation's Subject Matter

The first requirement in the analysis under Rule 24(a) is whether the applicant can "show a 'significantly protectable interest.'" *Am. Home Assur. Co.*, 122 Nev. at 1239, 147 P.3d at 1127 (citing *S. Ca. Edison Co. v. Lynch*, 307 F.3d 794, 803 (9th Cir. 2002)). The Ninth Circuit Court of Appeals has explained that a "significantly protectable interest" is "one that is protected under the law and bears a relationship to the plaintiff's claims." An applicant can satisfy this requirement by demonstrating that "the resolution of the plaintiff's claims actually will affect the applicant." *Donnelly v. Glickman*, 159 F.3d 405, 410 (9th Cir. 1998).

There can be no reasonable dispute that Hikma has a "significantly protectable interest" in the subject matter of this litigation under the first prong of the Rule 24(a) analysis. As an initial matter, Hikma's property rights in its products are "protected under the law." *See Am. Home Assur. Co.*, 122 Nev. at 1239, 147 P.3d at 1127. Nearly 100 years ago, the United States Supreme

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Court made it clear that a manufacturer of a product has the right to not sell their products to certain individuals or entities, and that there is a "long recognized right of a trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). This right, commonly referred to as the "*Colgate* doctrine," continues to be recognized and applied by the Court. *See Pac. Bell Tel. Co. v. Linkline Communications, Inc.*, 555 U.S. 438, 448 (2009). Hikma, like any other seller of products, has protected property rights in its products—including in Hikma's Fentanyl that was unlawfully obtained by and in the possession of Defendants for use in Scott Raymond Dozier's execution.

To complete the first prong of the Rule 24(a) analysis, Hikma's interest "bears a relationship to the plaintiff's claims." *See Am. Home Assur. Co.*, 122 Nev. at 1239, 147 P.3d at 1127. In the Alvogen Complaint, Alvogen seeks, *inter alia*, "preliminary/permanent injunctive relief precluding the use of any Alvogen drug, including Midazolam, in carrying out any capital punishment." Alvogen Compl. 25. Hikma seeks the very same relief, but seeks such relief for its own products, specifically including Hikma's Fentanyl. *See generally* **Ex. A**. Both Alvogen and Hikma's claims raise similar questions of law with parallel fact patterns. *Compare* Alvogen's Compl. *with* **Ex. A**. Both Alvogen and Hikma seek to prevent the use of their products, which Defendants unlawfully obtained to facilitate an unlawful use, capital punishment, consequently damaging Alvogen's and Hikma's reputations and goodwill.

Because Hikma's interest is (1) protected under law, and (2) bears a relationship to Alvogen's claims, Hikma has a significantly protectable interest in the subject matter of the existing litigation. Accordingly, Hikma is entitled to intervention of right to protect that interest.

B. Hikma's Ability to Protect Its Interest Will Be Impaired if It Is Not Permitted to Intervene

An applicant meets the second prong of the Rule 24(a) analysis upon showing that its "ability to protect its interest in the litigation's subject matter might be impaired by the disposition of the [existing] action." *Am. Home Assur. Co.*, 122 Nev. at 1240, 147 P.3d at 1128. This consideration is "focused upon the future effect pending litigation will have on that interest."

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Palmer v. Nelson, 160 F.R.D. 118, 122 (D. Neb. 1994). "'[I]mpairment' exists if the decision of a legal question would, as a practical matter, foreclose rights of the proposed intervenor in a subsequent proceeding . . . ." *Lake Inv'rs Dev. Grp., Inc. v. Egidi Dev. Grp.*, 715 F.2d 1256, 1260 (7th Cir. 1983).

The disposition of the instant action in Hikma's absence will impede Hikma's rights and its ability to adequately protect its interests. At best, while Alvogen and Hikma raise identical questions of law and allege nearly identical factual backgrounds, resolution of the claims in Alvogen's favor alone would not guarantee that Defendants would be barred from using Hikma's products. Alvogen and Hikma are not in privity with one another. Consequently, any resolution of Alvogen's claims will not prohibit Defendants from using Hikma's products, including Hikma's Fentanyl or midazolam product, for the unintended and unlawful purpose of facilitating execution of capital punishment. This would harm Hikma's reputation and goodwill. Alvogen only seeks injunctive relief as it relates to use of Alvogen's products. Thus, Hikma's products are not encompassed in Alvogen's prosecution of this matter.

At worst, resolution of Alvogen's claims in favor of Defendants could create a legal precedent that would permit Defendants to use Hikma's products with impunity, harming Hikma, all without Hikma being afforded an opportunity to be heard on the matter that is already being litigated before this Court. Were Hikma forced to file an independent action to obtain the relief it now seeks, a substantial risk of inconsistent and conflicting outcomes and decisions arises. Even if an independent action was later consolidated with this action, the parties to this action are likely to be engaging in the discovery process without Hikma, causing additional delay and causing duplication of time and efforts.

In summary, irrespective of how Alvogen's claims are resolved, proceeding without allowing Hikma to intervene will impair Hikma's ability to protect its interests. Good reasons exist to grant intervention in this regard.

C. Hikma's Interest Is Not Adequately Represented by the Existing Parties

An applicant may establish the third prong of the Rule 24(a) analysis by demonstrating that the existing litigants do not adequately represent the applicant's interests. *Am. Home Assur. Co.*,

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122 Nev. at 1241, 147 P.3d at 1128. However, the applicant's burden to establish this prong is "minimal." *Id.* Courts generally consider three factors in determining the adequacy of representation:

> (1) [a]re the interests of a present party in the suit sufficiently similar to that of the absentee such that the legal arguments of the latter will undoubtedly be made by the former; (2) is that present party capable and willing to make such arguments; and (3) if permitted to intervene, would the intervenor add some necessary element to the proceedings which would not be covered by the parties in the suit?

Blake v. Pallan, 554 F.2d 947, 954-55 (9th Cir. 1977).

As discussed *supra*, Alvogen cannot adequately represent Hikma's interests in this matter. Alvogen appropriately seeks relief to which it has standing to request; that is, an injunction prohibiting Defendants from using Alvogen's Midazolam Product. Thus, a judgment in favor of Alvogen will not extend to prevent Defendants from using Hikma's Fentanyl, or any other Hikma product. Allowing Hikma to intervene would consequently "add some necessary element to the proceedings which would not be covered by the parties in the suit." *See id.* at 955. This prong weighs decidedly in favor of allowing intervention as a matter of right.

D. Hikma's Application Is Timely

For the final consideration in the Rule 24(a) analysis, an applicant establishes the fourth prong by showing that the application to intervene is timely. NRCP 24(a). "Determining whether an application is timely under NRCP 24 involves examining 'the extent of prejudice to the rights of existing parties resulting from the delay' and then weighing that prejudice against any prejudice resulting to the applicant if intervention is denied." *Am. Home Assur. Co.*, 122 Nev. at 1244, 147 P.3d at 1130 (quoting *Dangberg Holdings Nevada, L.L.C. v. Douglas Cty.*, 115 Nev. 129, 141, 978 P.2d 311, 318 (1999)). "[T]he timeliness of an application may depend on when the applicant learned of its need to intervene to protect its interests." *Id.* Some courts parse this inquiry into a four-factor test, which considers "(1) the length of time the intervenor knew or should have known of his interest in the case; (2) the prejudice caused to the original parties by the delay; (3) the prejudice to the intervenor if the motion is denied; [and] (4) any other unusual circumstances." *Sokaogon Chippewa Cmty. v. Babbitt*, 214 F.3d 941, 949 (7th Cir. 2000).

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Under all factors, it cannot reasonably be disputed that Hikma's application is timely. Several facts exist to support the veracity of this proposition. First, Hikma only learned about the possibility that Defendants may be in possession of Hikma's products, triggering Hikma's interest in this specific case, on July 10, 2018.

Second, the original parties, Alvogen and Defendants, will suffer no prejudice caused by any delay. The delay of 14 days from Alvogen's initiation of this action is too minimal to have caused prejudice. As a result of this Court's TRO, the State of Nevada postponed the execution of Scott Raymond Dozier without affording any consideration to Hikma's potential intervention. Moreover, while the Court has allowed the parties to conduct discovery in preparation for the preliminary injunction hearing, the parties have yet to schedule or serve any discovery in this case. Given that discovery has yet to commence, and the legal and factual issues that Hikma will raise are identical and substantially similar, respectively, to those raised by Alvogen, no original party to this action will suffer prejudice if Hikma is permitted to intervene.

Third, Hikma will suffer prejudice if it is precluded from joining in this case. As addressed *supra*, without the intervention of Hikma, (1) if Alvogen prevails on its claims, the judgment will not encompass Hikma's products, and Defendants will continue to use Hikma's products in the lethal injection protocol to the detriment of Hikma's reputation and goodwill; and (2) if Defendants prevail, it could create precedent that would preclude Hikma from successfully challenging future illicit and unauthorized use of its products.

Finally, there are no "unusual circumstances" militating against permitting intervention as a matter of right. Hikma will seek the same relief as Alvogen, with the sole exception being that Hikma's products be protected. Hikma will raise the same questions of law arising under substantially similar fact patterns. In the interest of judicial efficiency, Hikma's claims should be heard simultaneously and in conjunction with Alvogen's claims in this case, where discovery can proceed in a streamlined fashion with all interested parties present to avoid duplication. Hikma's request to intervene is timely.

For the foregoing reasons, Hikma is entitled to intervention as a matter of right.

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III. ALTERNATIVELY, AN ORDER GRANTING HIKMA PERMISSION TO INTERVENE UNDER NRCP 24(b) IS APPROPRIATE

NRCP 24(b) sets forth the requirements for permissive intervention: "Upon timely application anyone may be permitted to intervene in an action . . . when an applicant's claim or defense and the main action have a question of law or fact in common." Where the claims of the plaintiff and the applicant are substantially the same, the commonality test for permissive intervention is easily met. *See, e.g., Epstein v. Weiss*, 50 F.R.D. 387, 395 (E.D. La. 1970). Moreover, "[i]n exercising its discretion the court shall consider whether the intervention will unduly delay or prejudice the adjudication of the rights of the original parties." *Id.* "The most important question to be resolved in the determination of the timeliness of an application for intervention is not the length of the delay by the intervenor but the extent of prejudice to the rights of existing parties resulting from the delay." *Lawler v. Ginochio*, 94 Nev. 623, 626, 584 P.2d 667, 669 (1978).

Hikma has alleged claims for relief that are substantially similar to Alvogen's alleged claims, therefore warranting permission to intervene. While these claims may have slight variances factually, they share identical questions of law and parallel factual backdrops. *Compare* Alvogen Compl. *with* **Ex. A.**

Moreover, as discussed above, Hikma's intervention will not result in undue delay or prejudice the adjudication of the rights of the original parties. Hikma now seeks to enter the litigation only 14 days after the initiation of this action, and 13 days after this Court issued the TRO and allowed the parties to commence discovery in preparation for the preliminary injunction hearing. At this initial stage of litigation, no original party will suffer prejudice if Hikma is permitted to intervene.

IV. CONCLUSION

This litigation involves Hikma's significantly protectable interest, which will be impaired without Hikma's intervention, and for which the Alvogen cannot adequately represent. Moreover, Hikma's request to intervene is timely. Accordingly, pursuant to NRCP 24(a), Hikma is entitled to intervention of right.

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Alternatively, Hikma's claims present common questions of law and fact as those raised in the Alvogen complaint and Hikma's request to intervene is timely and would not prejudice the original parties. Thus, if the Court finds Hikma is not entitled to intervention of right, it should exercise its discretion to grant Hikma permissive intervention under NRCP 24(b).

DATED this 24th day of July, 2018.

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By: /s/ *Josh M. Reid*

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CERTIFICATE OF SERVICE

Pursuant to Nevada Rule of Civil Procedure 5(b) and E.D.C.R. 8.05, I certify that I am an employee of Lewis Roca Rothgerber Christie LLP, and that on this day, I caused a true and correct copy of the foregoing **Hikma Pharmaceuticals USA Inc.'s Motion To Intervene On Order Shortening Time** to be served via the Court's File & Serve Electronic Filing System, on all interested parties in the above-referenced matter. The date and time of the electronic service is in place of the date and place of deposit in the mail.

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DATED this 26th day of July, 2018.

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EXHIBIT A

EXHIBIT A

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DISTRICT COURT

CLARK COUNTY, NEVADA

ALVOGEN, INC.,

Plaintiff,

vs.

STATE OF NEVADA;

NEVADA DEPARTMENT OF CORRECTION;

JAMES DZURENDA, Director of the Nevada Department of Correction, 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;

Defendants.

HIKMA PHARMACEUTICALS USA INC.,

Intervenor,

vs.

STATE OF NEVADA;

NEVADA DEPARTMENT OF CORRECTION;

Case No. A-18-777312-B

Dept. No. XI

HIKMA PHARMACEUTICALS USA INC.'S COMPLAINT IN INTERVENTION

JAMES DZURENDA, Director of the Nevada Department of Correction, 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;

Defendants.

COMES NOW Intervenor Hikma Pharmaceuticals USA Inc. ("Hikma"), through its counsel of Lewis Roca Rothgerber Christie LLP, and for its Complaint in Intervention alleges and complains against Defendants as follows:

PARTIES, JURISDICTION, AND VENUE

1. Intervenor Hikma, formerly known as West-Ward Pharmaceuticals Corp., is a Delaware corporation with its principal place of business located at 246 Industrial Way West, Eatontown, New Jersey. Hikma is a subsidiary of Hikma Pharmaceuticals PLC, a publicly-traded company on the London Stock Exchange.

2. Upon information and belief, Plaintiff Alvogen, Inc. ("Alvogen"), is a Delaware corporation with its principal place of business located at 10 Bloomfield Avenue, Pine Brook, New Jersey.

3. Defendant State of Nevada is the sovereign government of Nevada.

4. Defendant Nevada Department of Corrections ("NDOC"), led by its Director James Dzurenda ("Dzurenda"), is a Nevada state governmental entity, with offices in Nevada, including at 3995 West Russell Road, Las Vegas, Nevada, 89118.

5. Defendant Dr. Ihsan Azzam, Ph.D., M.D., serves as the Nevada State Chief Medical Officer at the Nevada Department of Health and Human Services, Division of Public and Behavioral Health, with offices in Nevada, including in Las Vegas.

6. Defendant John Doe I is an individual who was going to serve as the attending physician at the planned execution of inmate Scott Raymond Dozier. To the extent there are

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multiple individuals who serve as attending physicians at the future execution of Scott Raymond Dozier, or any other execution performed in the future by the State of Nevada, they are named herein as John Doe II, John Doe III, *et seq.*

7. This Court has jurisdiction over these Defendants as each of them is an entity or agent of the State of Nevada, conducting business in Nevada. Venue is proper in this Court pursuant to NRS 13.020, as material events giving rise to this action, including Defendants' unauthorized acquisition of the drug Fentanyl, occurred in Clark County, Nevada.

INTRODUCTION

8. Nearly one-hundred years ago, the United States Supreme Court made it very clear that a manufacturer of a product has the right to not sell its products to certain individuals or entities, and that there is a "long recognized right of a trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." *See United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). This right, commonly referred to as the "*Colgate* doctrine," continues to be recognized and applied by the Court. *See Pac. Bell Tele. Co. v. Linkline Communications, Inc.*, 555 U.S. 438, 448 (2009). Since its inception, Hikma has had a mission to treat illnesses and enhance lives by providing patients with access to high quality and affordable medicines. Upon learning that some states, including the State of Nevada, were considering new medicines to use in their lethal injection protocols, Hikma exercised its rights and took proactive action to prevent its medicines from being used in this use that is inconsistent with the U.S. Food and Drug Administration's ("FDA") approved therapeutic and medical uses for its products and counter to Hikma's values as an organization, the interests of its customers, and the financial interests of Hikma and its shareholders.

9. In 2016, Hikma exercised its right not to sell its products to the State of Nevada for use in lethal injection, and gave written notice to Defendants that Hikma objected in the strongest possible terms to the use of any of its products for lethal injection. Again in 2017, Hikma took proactive action to enforce its rights and provided another written notice to Defendants to restate its policy and position on the use of these drugs in which it stated that "[w]e object in the strongest possible terms to the use of any or our products for lethal injection." In addition, Hikma has taken

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additional proactive actions to prevent its products from being used for lethal injection, including placing certain controls on the sale of its products.

10. Hikma is not the only pharmaceutical company that has taken affirmative action to exercise its rights to not sell their products for use in lethal injection. More than 20 American and European pharmaceutical companies have taken action to prevent their products from being used for lethal injections. *See* **Ex. 1**. Similar to other pharmaceutical companies, Hikma has an important interest in protecting its business reputation and meeting its fiduciary duties to its shareholders. Experts have commented, for example, that a pharmaceutical company's involvement with lethal injection may open the company to liability, including the loss of large institutional investors and litigation from their shareholders. *See id.* As U.S. a subsidiary of an international pharmaceutical company publicly traded on the London Stock Exchange, Hikma has taken multiple proactive actions to protect its rights and values, and also to protect its business and investor and prospective investor relations.

11. In spite of Hikma's written demands and warnings not to have its products sold and used in conjunction with lethal injection, Defendants took action to illegitimately acquire Hikma's products and use them as part of their lethal injection protocol.

12. NDOC has acknowledged that they have made attempts to maintain the secrecy of and/or conceal their acquisition and possession of Hikma's fentanyl product ("Hikma's Fentanyl") because of a concern that information as to "where a state obtains execution drugs" may be used "to persuade the manufacturer and others to cease selling that drug for execution purposes." *Am. Civil Liberties Union of Nev. Found. v. State*, Case No. 18-OC-00163, Order Granting In-Part Emergency Pet. Issuing Writ of Mandamus, at 4 (Nev. Dist. Ct. July 6, 2018).

13. Now that Defendants have acquired Hikma's product to use it in conjunction with a lethal injection protocol (over the specific objections of Hikma) Defendants have violated Hikma's rights and Nevada law relating to controlled substances. If Defendants are allowed to continue to circumvent Nevada law, and Hikma's recognized right to use its own business judgment to determine how its products may be sold and used, and use Hikma's product for lethal injection,

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Defendants' actions will result in Hikma's immediate and irreparable harm, damage to Hikma's hard-earned business reputation, and financial damage to Hikma and its shareholders.

GENERAL ALLEGATIONS

I. HIKMA'S MANUFACTURE AND APPROVED DISTRIBUTION OF FENTANYL

14. The Hikma Group acquired West-Ward Pharmaceuticals Corp., now known as Hikma, more than 20 years ago. Since then, it has become a leading manufacturer and provider of quality oral, liquid, inhalant, and injectable branded and non-branded generic medicines in the United States. Hikma aims to improve lives by providing patients access to high-quality, affordable medicines. Hikma's medicines are used thousands of times a day around the world to treat illnesses and save lives. It has built a global reputation for the same.

15. Among its products in the United States, Hikma manufactures and distributes a product called Fentanyl Citrate Injection, USP C-II ("Hikma's Fentanyl"), which is in the narcotic (opiate) analgesics class of medications.

16. Upon information and belief, eight other manufactures produce fentanyl in the United States.

17. Fentanyl is a synthetic opioid that was originally developed in 1959 or 1960 as a powerful, intravenous anesthetic for surgery. Fentanyl has been approved by the FDA since 1972 (but in combination since 1968) for use in as an analgesic (pain relief) and anesthetic. It is used to treat sudden breakthrough pain that occurs despite continuous treatment with pain medication, and in people who suffer from severe, long-term pain, primarily in cancer patients but also in other chronic, intense pain scenarios presenting with non-cancerous maladies. It is also the most often used intraoperative analgesia.

18. Fentanyl has become extremely important in severe, chronic pain management in the practice of modern-day medicine due to its effectiveness, as well as its minimal or nonexistent effects to the cardiovascular system and plasma histamine (distinguishing it from other μ-opioid receptor agonists), its rapid onset of action and short duration of effects, and the ease and low cost in synthesizing and preparing for the marketplace.

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19. Fentanyl is a Schedule II controlled substance; therefore, it has a high potential for abuse, with use potentially leading to severe psychological or physical dependence.

20. To maintain Hikma's reputation for producing safe, high-quality products, Hikma is committed to going beyond mere compliance with the law and strives to uphold the highest ethical standards in everything it does.

21. In an attempt to ensure that its fentanyl product, among other products, is used responsibly, Hikma has placed controls on the purchase and use of its products. Such controls include internal policies and procedures, and contracts with its customers to restrict the supply of Hikma products for the distribution and use in lethal injection protocols.

22. Hikma 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.

23. Hikma states its policy against the use of any of its products in capital punishment on its website:

> 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.

Ex. 2 (http://www.hikma.com/about/our-policies/use-of-products-in-capital-punishment/ (last accessed July 24, 2018)). Hikma's website further publishes the various controls it has in place "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." *Id.* Hikma also restricted particular drugs that have a heightened potential of misuse

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for lethal injection protocols, publishing them on Hikma's restricted list. *See id.* These drugs include Hikma's Fentanyl and midazolam products. *Id.*

II. DEFENDANTS ADD FENTANYL TO THE STATE'S LETHAL INJECTION PROTOCOL, THE FIRST STATE TO DO SO

24. Upon information and belief, NDOC, like other death-penalty states, was well-aware of certain drug manufacturers' restrictions on the use of their drugs in executions. According to the Las Vegas Review-Journal, as reported on October 7, 2016, NDOC sent out 247 requests for proposals on September 2, 2016, to manufactures for the purchase of the drugs that it intended to use in legal injunctions after the stockpile of at least one of the drugs in its possession expired. (Nevada's last execution occurred in 2006.) Not one response was received. Because no pharmaceutical companies bid to supply the drugs for lethal injections, Nevada prison officials were on the record as stating that "the state will have to explore its options to carry out executions." *See* Alvogen Compl. for Emergency Injunctive Relief & Return of Illegally-Obtained Prop. at Ex. 1.

25. Other states in which the death penalty is implemented have also looked to locate alternative compounds for their legal injection protocols as a result of drug manufacturers' opposition to having their medicines used in executions. Upon information and belief, some states started to experiment with mixtures of drugs that were never intended for this purpose.

26. On December 20, 2016, Hikma sent letters to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Defendant Dzurenda, in which Hikma vehemently objected to any of its products being used for lethal injection ("2016 Letters"). Hikma stated, "We object in the strongest possible terms to the use of **any of our products** for lethal injection," including Hikma's Fentanyl, and again made clear that its objection should be applied to all of its products. **Ex. 3 (emphasis added)**. Hikma notified these recipients that such use was

> 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 our values as an organization.

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Id. Hikma stated that it was not aware of Defendants having possession of any of its products at that time, but noted that its objection was made because it had become aware that some states were considering new compounds to use in lethal injections.

27. 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.

Id.

28. By the end of September 2017, in addition to its general prohibitions, Hikma expressly placed its fentanyl and midazolam products on the restricted list.

29. In November 2017, in Scott Raymond Dozier's habeas corpus case (*Dozier v. State*, Case No. 05C21503, Notice of Redacted Version of the State of Nev.'s Execution Protocol (Dist. Ct. Nev. Nov. 11, 2017), the State filed a redacted version of NDOC's Executional Manual, dated November 7, 2017, wherein it confirmed that fentanyl was one of the three drugs consisting of Nevada's new lethal injection protocol.

30. This was the first time any state in the country included fentanyl as part of its lethal injection protocol. This fact means that the State's novel misuse of the drug in executions is experimental.

31. According to Josh Bloom, Senior Director of Chemical and Pharmaceutical Sciences of the American Council on Science and Health, the State's decision to use fentanyl in Scott Raymond Dozier's execution rendered him "flabbergasted,"

> You got something that's killing hundreds of people a day across the United States, and you got prisons who can't get death penalty drugs, so they're turning to the drug that's killing hundreds of people across the United States. . . . This sounds like an article from the Onion[, a news satire website].

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32. Upon information and belief, shortly before the NDOC's execution manual was published, the drug manufacturer Pfizer indicated that the fentanyl and diazepam that NDOC originally intended to use to execute Scott Raymond Dozier were Pfizer products. Pfizer objected to NDOC's use of its products for lethal injections, and demanded return of the products.

33. Upon information and belief, Nevada prisons spokeswoman Brooke Keast rejected any assertion that the State was obligated to return their product.

34. As another reminder to Defendants in light of the on-going controversy, on December 17, 2017, Hikma sent letters to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Defendant Dzurenda, in which Hikma again vehemently objected to any of its products being used for lethal injection ("2017 Letters"). *See* **Ex. 4**. Hikma restated that such use of any Hikma products is contrary to the FDA approved-use, in addition to being contradictory to the intended use of the products and Hikma's organizational values. *Id.*

35. Hikma echoed its 2016 Letters in stating that it has certain controls in place to prevent departments of corrections from using its products for lethal injection, "including the restriction of any direct sales to Departments of Corrections of restricted products, or sales to customers." *Id.*

36. Although Hikma was not aware of the State being in possession of Hikma products for such purpose and communicated the same, to be sure, Hikma echoed,

> [W]e are writing again to restate our policy and our position on the use of these drugs: We object in the strongest possible terms to the use of any of our products for lethal injection.
>
> We wrote to you on this same topic this time last year, and are reaching out to advise you that we have had to extend the restriction of products to include additional drugs, as states continue to experiment with new cocktails. There is a list of restricted products on our website which we keep current.
>
> To this point, we would like to make clear that our objection should be applied to any and all West-Ward and Hikma products, not just those on our restricted list.

Id.

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III. DEFENDANTS ILLEGALLY OBTAINED HIKMA'S FENTANYL PRODUCT FOR DEFENDANTS' INTENTIONAL AND UNAPPROVED USE IN SCOTT RAYMOND DOZIER'S EXECUTION

37. On or about July 10, 2018, Hikma was informed that the State had confirmed its intention to execute Scott Raymond Dozier on Wednesday, July 11, 2018, using fentanyl and midazolam in its three-drug protocol. At that time, it was unclear whether Defendants were in possession of Hikma's Fentanyl or midazolam products.

38. On July 10, 2018, Hikma was notified of Alvogen's initiation of the instant lawsuit, and Alvogen's request for a preliminary injunction. Through these filings, Alvogen confirmed that Defendants were intending to use Alvogen's Midazolam Product in the execution, not Hikma's.

39. This Court heard argument on Alvogen's *ex parte* application for a Temporary Restraining Order at 9 a.m. on July 11, 2018. This Court issued the Temporary Restraining Order the same day, prohibiting and enjoining Defendants from using Alvogen's Midazolam Product in capital punishment until further order of the Court.

40. After the hearing on Alvogen's *ex parte* application, Hikma obtained copies of documents produced as a result of a court order in litigation initiated by the American Civil Liberties Union of Nevada. *See Am. Civil Liberties Union of Nev. Found. v. State*, Case No. 18 OC 00163 1B, Order Granting In-Part Emergency Pet. Issuing Writ of Mandamus (Nev. Dist. Ct. July 6, 2018). The court order compelled NDOC to disclose the lethal injection procedures it planned to implement in Scott Raymond Dozier's execution. The documents 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 Hikma's Fentanyl, NDC/UPC 0061-6027-25. *See* **Ex. 5**. These invoices further showed that NDOC placed multiple small orders of the drugs over a number of months, with some orders following the last by only one day.

41. The invoice for Hikma's Fentanyl was from one of Hikma's wholesale distributors, Cardinal Health, placed on September 28, 2017, for shipment the next day, and addressed to be billed and shipped to the Nevada Department of Correction Center Pharmacy, located at the NDOC's administrative building in Las Vegas—not to the Ely State Prison, which is where

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Nevada's executions take place and located over 200 miles away from its Las Vegas building. *See id.*

42. Under the product description, Cardinal Health referenced message 121: "This product is required by the FDA to be dispensed with a medication guide. . . ." *Id.*

43. In order to purchase Hikma's Fentanyl, NDOC was required to provide Cardinal Health with proof of a medical license issued to NDOC's medical director.

44. Under Nevada's Uniform Controlled Substances Act, codified at NRS Chapter 453, "a physician . . . may prescribe or administer controlled substances only for a legitimate medical purpose and in the usual course of his or her professional practice." NRS 453.381(1) (emphasis added). A physician is not allowed to use a non-physician to evade that prohibition.

45. Upon information and belief, NDOC's purchase order to Cardinal Health for Hikma's Fentanyl used the Nevada Chief Medical Officer's license to obtain Hikma's Fentanyl. In doing so, NDOC intended Cardinal Health to believe that the order was placed at the request or for the benefit of the physician and would be used for a legitimate medical purpose, consistent with Nevada's Controlled Substances Act, and the Nevada State Board of Medical Examiners' regulations.

46. NDOC acquired Hikma's Fentanyl from Cardinal Health when it was aware that Hikma strongly objected to and prohibited the use of all of its products in executions, as being contrary to FDA-approved therapeutic and medical uses, and Hikma's intention of manufacturing products for the health and well-being of patients in need, and values as a company. *See* **Ex. 2.**

47. NDOC was further aware of the approved and disapproved uses of fentanyl in Cardinal Health's invoice message informing NDOC that fentanyl "is required by the FDA to be dispensed with a medication guide." *See* **Ex. 5.**

48. NDOC acquired Hikma's Fentanyl nonetheless through a source that was not authorized to sell to the NDOC for the non-approved use in an execution.

49. Following Defendants' receipt of Hikma's 2016 Letters, *see* **Ex. 3**, Defendants thereafter sought to circumvent Hikma's policy by purchasing the Hikma Fentanyl through an unsuspecting intermediary and without disclosing to said intermediary that they planned to use the

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Hikma's Fentanyl product for an execution. Defendants were thus able to obtain the Hikma Fentanyl in a manner that they would not have been able to accomplish had they disclosed that they planned to use the Hikma Fentanyl for an execution.

50. Even after receiving Hikma's 2017 Letters reiterating its objection to NDOC's use of any of its products for executions, *see* **Ex. 4**, Defendants thereafter announced their intention to use Hikma's Fentanyl in the lethal injection protocol for Scott Raymond Dozier—a purpose for which it is neither allowed nor intended to be used. While Hikma takes no position on the death penalty sentence imposed upon Scott Raymond Dozier, Hikma's products were manufactured to promote the health and well-being of patients in need—not in state-facilitated executions.

51. Upon confirming that Defendants intended to use Hikma's Fentanyl in the scheduled lethal injection of Scott Raymond Dozier on July 11, 2018, Hikma hand-delivered its third notices to Nevada's Attorney General Adam Laxalt, Governor Brian Sandoval, and Defendant Dzurenda ("2018 Letters"). *See* **Ex. 6**. Hikma reminded these recipients, including NDOC—once again—of Hikma's position on the misuse of its medicines in executions. *See id.*

52. Hikma stated its belief that NDOC is in possession of Hikma's Fentanyl, and that it may be used in a pending execution, additionally stating,

> 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.

Id.

53. Hikma demanded that NDOC immediately return all of Hikma's Fentanyl, and other products, intended for use in executions, in exchange for a full refund for such use would represent a serious misuse of life-saving medicines. *Id.* Hikma specifically requested that

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Defendant Dzurenda and other NDOC officials not circumvent Hikma's carefully-prepared controls or potentially undermine these specifically drafted legal provisions in its agreements. *Id.*

54. Defendants have not responded to Hikma's letter.

IV. DEFENDANTS CONTINUED MISUSE OF HIKMA'S FENTANYL IN EXECUTIONS, INCLUDING THAT OF SCOTT RAYMOND DOZIER, WILL CAUSE HIKMA TO SUFFER IMMEDIATE AND IRREPARABLE INJURY

55. Since NDOC's declaration of its new and untested lethal injection protocol to be used in the execution of Scott Raymond Dozier, including the novel use of fentanyl in the execution, a media frenzy has exploded. NDOC's decision to use fentanyl has been widely criticized.

56. The severe criticism communicated by the American public, medical and legal professionals, and scholars alike, leads to Hikma as the manufacturer of the first-time use of this already controversial drug in this even more divisive execution. As more fully set forth herein, Defendants' actions have caused, and will continue to cause, unless preliminarily and permanently enjoined, substantial and irreparable injury to Hikma including, but not limited to, reputational injury arising out of (i) association with the manufacture of drugs used for executions, (ii) the corresponding damage to business and investor and prospective investor relationships, (iii) damage to goodwill, and (iv) other irreparable harm to be proven at trial.

FIRST CLAIM FOR RELIEF
(Unlawful Obtainment of a Controlled Substance)

57. Hikma incorporates the preceding paragraphs as though fully set forth herein.

58. Upon information and belief, Defendants sought to circumvent Hikma's controls by issuing purchase orders for Hikma's Fentanyl for completion in September 2017 with an unsuspecting distributor. Thus, on or about September 28, 2017, the NDOC Pharmacy submitted a purchase order for Hikma's Fentanyl to Cardinal Health, a wholesaler for Hikma's Fentanyl, for use in the execution of Scott Raymond Dozier scheduled for July 11, 2018. Fentanyl is a Schedule II controlled substance. The purchase orders were scheduled to be completed the next day.

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59. Upon information and belief, including the procedures outlined in the NDOC Execution Manual, Defendant Azzam, the Nevada Chief Medical Officer, a licensed physician, acquired and/or directed the acquisition of Hikma's Fentanyl by or for Defendants and in active concert with the other Defendants.

60. Under Nevada law, "a person shall not . . . unlawfully take, obtain or attempt to take or obtain a controlled substance from a manufacturer, wholesaler, pharmacist, physician, . . . or any other person authorized to administer, dispense or possess controlled substances." NRS 453.391(1). Defendants each qualify as a "person" for purposes of the foregoing. *See* NRS 453.113.

61. As described above in Paragraphs, Defendants knew that Hikma "object[s] in the strongest possible terms to the use of any of [its] products for lethal injection," including Hikma's Fentanyl, and again made clear that its objection should be applied to all of its products. **Ex. 3.** Indeed, on December 20, 2016, Hikma sent the 2016 Letters to Defendants informing them that such use was

> 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 our values as an organization.

Id. Defendants also knew that Hikma was forced to implement additional controls to prevent uses of its products in lethal injections. *Id.* As described above in Paragraph 12, the NDOC's own statements in other litigation related to Scott Raymond Dozier's execution further show that the NDOC was aware of and actively fought disclosure of certain execution-related information because such information had been used to persuade manufacturers to cease selling their products for executions.

62. Upon information and belief, following their receipt of the 2016 Letters, Defendants, at the direction of and/or with the approval of Defendant Azzam, thereafter sought to circumvent Hikma's policy by purchasing Hikma's Fentanyl through an unsuspecting intermediary and without disclosing to said intermediary the contents of the 2016 Letters and/or the fact that they sought to obtain Hikma's Fentanyl for non-therapeutic purposes (*i.e.*, an

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execution). Defendants were thus able to illicitly obtain Hikma's Fentanyl in a manner that they would not have been able to accomplish had they disclosed the contents of said letter and/or their intended non-therapeutic use of Hikma's Fentanyl to the intermediary.

63. Upon information and belief, Defendants sought to circumvent Hikma's controls by issuing purchase orders for Hikma's Fentanyl for completion in September 2017 with an unsuspecting distributor. Upon information and belief, Defendants, including Defendant Azzam, acted in concert with one another to acquire Hikma's Fentanyl from Cardinal Health. At the time of their actions, Defendants knew and had been placed on notice that Hikma, along with all other FDA-approved sources, had prohibited the distribution, sale, and transfer of such drugs for use in execution protocols. Upon information and belief, Defendants acted in concert with one another—and with at least one physician in violation of Nevada law—to acquire Hikma's Fentanyl through a source that was not authorized to sell to NDOC for the non-approved use in an execution.

64. To further the implication that Hikma's Fentanyl was for a legitimate medical purpose, Defendants specified that Hikma's Fentanyl should be shipped to NDOC's Central Pharmacy at the NDOC's administrative building in Las Vegas, rather than directly to the Ely State Prison, where Nevada's newly-constructed execution chamber is located. By way of the foregoing, Defendants thus tacitly and erroneously misrepresented that Hikma's Fentanyl would be used for legitimate medical purposes.

65. Defendants undertook these actions with full knowledge that Hikma does not permit sales of any of its products, including Hikma's Fentanyl, to state correctional facilities nor to any entity for purposes of capital punishment.

66. Based upon the foregoing, and upon information and belief, NDOC's purchase from Cardinal Health leveraged the NDOC Chief Medical Officer's license to illicitly obtain Hikma's Fentanyl. In so doing, NDOC intended Cardinal Health to believe that the order was placed at the request of, or for the benefit of, the physician and would be used for a legitimate medical purpose, consistent with Nevada's Controlled Substances Act and Nevada State Board of Medical Examiners regulations.

LEWIS ROCA ROTHGERBER CHRISTIE
3993 Howard Hughes Pkwy, Suite 600
Las Vegas, NV 89169-5996

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR
United Kingdom
Tel: +44 20 7399 2760
Fax: +44 20 7399 2761

20 December 2016

The Honorable Brian Sandoval
Governor
State of Nevada
Capitol Building
Carson City, NV 89701
USA

Dear Governor Sandoval,

Hikma aims to improve lives by providing patients with access to high quality, affordable medicines. Our medicines are used millions of times a day to treat illness and save lives. This has been our mission for more than 40 years and one that is shared by our US subsidiary, West-Ward.

We are extremely dismayed to learn that, despite our best efforts to ensure our medicines are used only for their intended medicinal purposes, some states continue to attempt to procure our products for use in lethal injection. Not only is this an off-label use and 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 also it is completely counter to our values as an organization.

You are likely aware that to prevent Phenobarbital Sodium, Midazolam Hydrochloride and Hydromorphone Hydrochloride being used by Departments of Corrections for lethal injection, we have put certain controls in place. While we are not aware that Nevada is in possession of any of these products intended for this purpose, we are writing to restate our policy and our position on the use of these drugs: We object in the strongest possible terms to the use of any of our products for lethal injection.

In addition, we have become aware that some states are considering a new list of compounds to use in lethal injection. We would like to make clear that our objection should be applied to all West-Ward products, not just Phenobarbital Sodium, Midazolam Hydrochloride and Hydromorphone Hydrochloride.

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 medical 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 tne positions that we have set forth in this letter and be our partner in furthering our values and policy.

Sincerely,

Brooke S Clarke
VP Corporate Affairs

20 December 2016

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR
United Kingdom
Tel: +44 20 7399 2760
Fax: +44 20 7399 2761

Mr. James Dzurenda
Director
Department of Corrections
5500 Snyder Ave
P.O. Box 7011
Carson City, Nevada 89701
USA

Dear Mr. Dzurenda,

Hikma aims to improve lives by providing patients with access to high quality, affordable medicines. Our medicines are used millions of times a day to treat illness and save lives. This has been our mission for more than 40 years and one that is shared by our US subsidiary, West-Ward.

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Sincerely,

Brooke S Clarke
VP Corporate Affairs

EXHIBIT 4

EXHIBIT 4

HIKMA
QUALITY

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR
United Kingdom
Tel: +44 20 7399 2760
Fax: +44 20 7399 2761

12 December 2017

The Honorable Adam Paul Laxalt
Attorney General
State of Nevada
Old Supreme Ct. Bldg., 100 N. Carson St.
Carson City, NV 89701
USA

Dear Mr. Laxalt,

Hikma aims to improve lives by providing patients with access to high quality, affordable medicines. Our medicines are used millions of times a day to treat illness and save lives. This has been our mission for more than 40 years and one that is shared by our US subsidiary, West-Ward.

We are extremely dismayed to learn that, despite our best efforts to ensure our medicines are used only for their intended medicinal purposes, some states continue to attempt to procure our products from distributors and other intermediaries for use in lethal injection. Not only is this an off-label use and 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 also it is completely counter to our values as an organization.

You are likely aware that to prevent our products being used by Departments of Corrections for lethal injection, we have put certain controls in place including the restriction of any direct sales to Departments of Corrections of restricted products, or sales to customers

While we are not aware that Nevada is in possession of any of these products intended for this purpose, we are writing again to restate our policy and our position on the use of these drugs: We object in the strongest possible terms to the use of any of our products for lethal injection.

We wrote to you on this same topic this time last year, and are reaching out to advise you that we have had to extend the restriction of products to include additional drugs, as states continue to experiment with new cocktails. There is a list of restricted products on our website which we keep current.

To this point, we would like to make clear that our objection should be applied to any and all West-Ward and Hikma products, not just those on our restricted list.

In the event we were forced to implement additional controls to prevent diversion and misuse, it may have the unintended consequence of potentially preventing certain patients from receiving these medicines despite having a genuine medical need. This outcome would not be beneficial for anyone, particularly the good people of your state. High quality, generic medicines play a vital role in improving health. As such, we hope you will be our partner in furthering our values and upholding our policy.

Brooke S Clarke
VP Corporate Affairs

HIKMA
QUALITY

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR
United Kingdom
Tel: +44 20 7399 2760
Fax: +44 20 7399 2761

12 December 2017

The Honorable Brian Sandoval
Office of Governor Brian Sandoval
Capitol Building
Carson City, NV 89701
USA

Dear Mr. Sandoval,

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Brooke S Clarke
VP Corporate Affairs

HIKMA
QUALITY

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR
United Kingdom
Tel: +44 20 7399 2760
Fax: +44 20 7399 2761

12 December 2017

Mr. James Dzurenda
Director
Nevada Dept of Corrections
5500 Snyder Ave,
P.O. Box 7011
Carson City, Nevada, 89701
USA

Dear Mr. Dzurenda,

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Brooke S Clarke
VP Corporate Affairs

EXHIBIT 5

EXHIBIT 5

S (623) 478-8500

CARDINAL HEALTH
600 N 83RD AVE
TOLLESON, AZ 85353

 ROUTE/STOP 307 / 010

RO

CardinalHealth

DEA RW-0263056 FED ID 68-0158739

CUST. NO.	DATE	ORIGINAL INVOICE
163264	9/29/17	3232190

REG NO.	CUST. DEA NO.	ORDER NO.	CUSTOMER P.O. NUMBER
CA0000	1AS2995922	5265965	17XCO0039
	ORDER DATE	CONF. NO.	
	9/28/17	03582	

BILL TO
NV DEPT OF CORRECTION CTR PHCY
CENTRAL PHCY
3955 W RUSSELL RD-CASA GRANDE
LAS VEGAS, NV 89118

SHIP TO
NV DEPT OF CORRECTION CTR PHCY
CENTRAL PHCY
3955 W RUSSELL RD-CASA GRANDE
LAS VEGAS, NV 89118
FORM 222: 17XCO0039

ITEM NUMBER	NDC/UPC	QTY ORDERED	QTY SHIPPED	C/N/I	DESCRIPTION	SIZE	FORM	CLASS	RETAIL PRICE			UNIT PRICE	EXTENSION	NOTE CODE
4726162	00641-6027-25 TOTE# 3	1	1	CT	FENTANYL CIT50MCG/ML 25X2ML C2	25	SF	2				15.23	1523	CT
	see message(s): 121													
5094883	17478-0030-25 TOTE# 3	2	2	CT	FENTANYL CIT50MCG/ML 25X2ML C2	25	AM	2				34.14	6828	CT
	see message(s): 121													
			3		PIECES SHIPPED							SUBTOT	8351	
			3		TOTAL PIECES SHIPPED									
					---------- S U M M A R Y ----------									
					Total RX				83.51					
					NET AMOUNT				83.51					

INVOICE SHIP DATE: 9/28/2017

For SDS Visit: http://www.mycardinalsdspd.com

PLEASE REMIT YOUR PAYMENTS TO FOLLOWING ADDRESS:
CARDINAL HEALTH 110, LLC
C/O BANK OF AMERICA
PO BOX 56412
LOS ANGELES, CA 90074-6412

Messages

121 This product is required by the FDA to be dispensed with a medication guide. To obtain a medication guide for this product, please visit http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

FOR DELIVERY 9/29/17
10/29/17
DUE DATE
8351

Note Codes:		
T	Taxable	
CO	Contract Item Override	
SP	Special Pricing	
CT	Contract	
SN	Special Net	
OV	Price Override	
CS	Source Contract	

Omit Codes:		
C Dropship	4 Not stocked	7 Drug Recall
2 DC Out	5 Min Disc	8 New item stock unavail
3 Mfr Out	6 DC Disc	9 Restricted item
		S Regulatory Review

List Chemical Designations:
E - Ephedrine
P - Phenylpropanolamine
S - Pseudoephedrine
L - Other List Chemical

307 / 010

Customer is a final dispenser purchasing for own use and will not redistribute prescription pharmaceuticals into the secondary market.

The prices shown on this invoice are net of discounts provided at the time of purchase. Some of the products listed on this invoice may be subject to additional discounts or rebates. Please refer to your contract for any specific additional discounts or rebates that may apply to these purchases. You may have an obligation pursuant to 42 USC §1320a-7b to report discounts and rebates to Medicare, Medicaid or other governmental health care programs.

Effective January 1, 2015, DSCSA Transaction Data for qualified prescription drugs can be accessed via your usual ordering platform, such as Order Express or Med eCommerce, or at cardinalhealth.com/trace.

EXHIBIT 6

EXHIBIT 6

Lewis Roca
ROTHGERBER CHRISTIE

Lewis Roca Rothgerber Christie LLP
One East Liberty Street
Suite 300
Reno, NV 89501

775 823 2900 main
775 823 2929 fax
lrrc.com

Kristen L. Martini
Admitted in California and Nevada
775.321.3446 direct
775.823.2929 fax
kmartini@lrrc.com

July 11, 2018

VIA HAND DELIVERY

Mr. James Dzurenda
Director, Nevada Department of Corrections
Stewart Facility
5500 Snyder Avenue, Bldg. 17
Carson City, Nevada 89701

RE: Hikma Pharmaceuticals PLC Products--Prohibited Use in Executions in the State of Nevada

Dear Director Dzurenda:

We represent Hikma Pharmaceuticals PLC regarding the above-referenced matter. Enclosed please find a letter from our client advising you of its position with regard to the same.

Very truly yours,

Kristen L. Martini
Lewis Roca Rothgerber Christie LLP

KLM
Enclosure

hikma.

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR

T (0) 20 7399 2760

July 11th, 2018

The Honorable Brian Sandoval
Governor, State of Nevada

Mr. Adam Paul Laxalt
Attorney General, State of Nevada

Mr. James Dzurenda
Director, Nevada Department of Corrections

Nevada State Capital Building
101 N Carson St # 1,
Carson City, NV 89701

via Fax

Dear Governor Sandoval, Mr. Laxalt and Mr. Dzurenda,

Further to our correspondence to you in 2016 and 2017, I am writing to you to remind you again of Hikma's position on the misuse of our medicines in executions. We object in the strongest possible terms to the use of any of our products for the purpose of capital punishment. Hikma aims to improve lives by providing patients with access to high quality, affordable medicines. Our medicines are used millions of times a day to treat illness and save lives. This has been our mission for more than 40 years.

We understand that the State of Nevada Department of Corrections is in possession of fentanyl made by our company, Hikma, and that it may be used in a pending execution.

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 Correction 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.

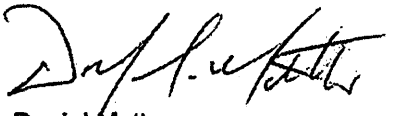
We request that Nevada immediately return to us any Hikma or West-Ward fentanyl intended for use in executions, and any other of our products which have been obtained for this purpose, in exchange for a full refund, unless the State of Nevada is prepared to provide to us an original, raised seal copy of an affidavit signed by the Governor or Attorney General, certifying under penalty of perjury that the product(s) will only be used for patient care, not capital punishment. The use of these products in executions would represent a serious misuse of life saving medicines.

(more)

We also request that the Director and other relevant Nevada Department of Corrections officials not circumvent our carefully prepared controls or potentially undermine these specifically drafted legal provisions in our agreements. In the event we were forced to implement additional controls to prevent diversion and misuse, it may have the unintended consequence of potentially preventing certain patients from receiving these medicines despite having a genuine medical need. This outcome would not be beneficial for anyone, particularly the good people of Nevada. High quality, generic medicines play a vital role in improving health. As such, we hope you will be our partner in furthering our values and upholding our policy.

I look forward to receiving your response.

Sincerely,



Daniel Motto
Executive Vice President
Hikma/West-Ward Pharmaceuticals

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Kristen L. Martini
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kmartini@lrrc.com

July 11, 2018

VIA HAND DELIVERY

The Honorable Adam Paul Laxalt
Attorney General, State of Nevada
5420 Kietzke Lane, Suite 202
Reno, Nevada 89511

RE: Hikma Pharmaceuticals PLC Products--Prohibited Use in Executions in the State of Nevada

Dear Attorney General Laxalt:

We represent Hikma Pharmaceuticals PLC regarding the above-referenced matter. Enclosed please find a letter from our client advising you of its position with regard to the same.

Very truly yours,

Kristen L. Martini
Lewis Roca Rothgerber Christie LLP

KLM
Enclosure

hikma.

Hikma Pharmaceuticals PLC
1 New Burlington Place
London W1S 2HR

T (0) 20 7399 2760

July 11th, 2018

The Honorable Brian Sandoval
Governor, State of Nevada

Mr. Adam Paul Laxalt
Attorney General, State of Nevada

Mr. James Dzurenda
Director, Nevada Department of Corrections

Nevada State Capital Building
101 N Carson St # 1,
Carson City, NV 89701

via Fax

Dear Governor Sandoval, Mr. Laxalt and Mr. Dzurenda,

Further to our correspondence to you in 2016 and 2017, I am writing to you to remind you again of Hikma's position on the misuse of our medicines in executions. We object in the strongest possible terms to the use of any of our products for the purpose of capital punishment. Hikma aims to improve lives by providing patients with access to high quality, affordable medicines. Our medicines are used millions of times a day to treat illness and save lives. This has been our mission for more than 40 years.

We understand that the State of Nevada Department of Corrections is in possession of fentanyl made by our company, Hikma, and that it may be used in a pending execution.

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 Correction 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.

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July 11, 2018

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Governor, State of Nevada
State Capitol Building
101 N. Carson Street
Carson City, NV 89701

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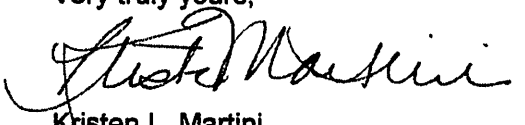

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July 11th, 2018

The Honorable Brian Sandoval
Governor, State of Nevada

Mr. Adam Paul Laxalt
Attorney General, State of Nevada

Mr. James Dzurenda
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Nevada State Capital Building
101 N Carson St # 1,
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via Fax

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I look forward to receiving your response.

Sincerely,

Daniel Motto
Executive Vice President
Hikma/West-Ward Pharmaceuticals

67. Further, Defendants obtained Hikma's Fentanyl in an unlawful manner for the reasons explained in Hikma's Fourth and Fifth Claims for Relief, as Defendants' acquisition of Hikma's Fentanyl is in derogation of, and violates, Hikma's property rights.

68. Further, Defendants obtained Hikma's Fentanyl in an unlawful manner for the reasons explained in Hikma's Second and Third Claims for Relief, as Defendants' acquisition of Hikma's Fentanyl was undertaken for purposes of unlawfully administering it for a non-therapeutic use (an execution) as well as for unlawfully furnishing it to non-physician administrators.

69. Because of Defendants' wrongdoing, Hikma has suffered and continues to suffer injuries, including, but not limited to reputational injury arising out of (i) association with the manufacture of drugs used for executions, (ii) the corresponding damage to business and investor and prospective investor relationships, (iii) damage to goodwill, and (iv) other irreparable harm to be proven at trial.

SECOND CLAIM FOR RELIEF
(Administration of a Controlled Substance for an Illegitimate Purpose)

70. Hikma incorporates the preceding paragraphs as though fully set forth herein.

71. Under Nevada law, "a physician . . . may prescribe or administer controlled substances only for a legitimate medical purpose and in the usual course of his or her professional practice." NRS 453.381(1). A physician may not use a non-physician to evade that prohibition.

72. Under the NDOC's Execution Manual, "an attending physician or other properly trained and qualified medical professional" will be present at the execution to assess the inmate's need for pre-execution sedatives, observe the preparation of the lethal drugs, advise on the venipuncture for the delivery of the lethal drugs, monitor the inmate's consciousness during the execution, and respond in the event the execution is ordered to be stopped. *See* Nevada Department of Corrections, *Execution Manual § 110.02—Execution of Condemned Inmate* (Effective Date: June 11, 2018).

73. As the "Attending Physician," the doctor who attends the execution is ultimately responsible for the care and treatment of the patient, including the administration of any drugs to

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that patient. *See, e.g.*, Center for Medicare and Medicaid Services, *Glossary* (last accessed July 19, 2018), https://www.cms.gov/apps/glossary/default.asp?Letter=ALL (defining the attending physician as the licensed physician "who has primary responsibility for the patient's medical care and treatment"); Educational Commission for Foreign Medical Students, Health Care Team (last accessed July 19, 2018), https://www.ecfmg.org/echo/team-doctors-attending-physician.html (stating that the attending physician is "ultimately responsible for all patient care" and "has legal and ethical responsibility for directing care of the patient").

74. Execution by lethal injection is not a "legitimate medical purpose." *See, e.g.*, American Medical Association, Code of Medical Ethics Opinion 9.7.3 (stating that "as a member of a profession dedicated to preserving life when there is hope in doing so, a physician must not participate in a legally authorized execution").

75. Defendants threatened and continue to threaten to have a physician administer and/or direct and supervise the administration of Hikma's Fentanyl for a purpose that is neither therapeutic nor in furtherance of the "healing arts" (as they are called under Nevada law), but rather to facilitate a patient's death. The administration of Hikma's Fentanyl for a lethal injection constitutes the administration of a controlled substance for a purpose (ending a life) that does not qualify as a legitimate medical purpose.

76. Accordingly, to the extent permitted to implement Defendants' proposed execution protocol, John Doe I will violate Nevada law by directing the administration of Hikma's Fentanyl, a controlled substance, for a purpose that is outside of the therapeutic purposes set forth in the Hikma labeling and for a use (ending a life) that does not qualify as a legitimate medical purpose.

77. To the extent that Defendants intend to employ non-physicians to administer Hikma's Fentanyl, John Doe I would again be acting in violation of Nevada law, as the attending physician is ultimately responsible for the administration of anesthetic agents like Hikma's Fentanyl. *See* NAC 630.830 (prohibiting a delegating practitioner from delegating or allowing a medical assistant "to administer an anesthetic agent which renders a patient unconscious or semiconscious").

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78. Unless enjoined, Defendants' threatened and imminent wrongdoing will cause Hikma to suffer injuries, including, but not limited to reputational injury arising out of (i) association with the manufacture of drugs used for executions, (ii) the corresponding damage to business and investor and prospective investor relationships, (iii) damage to goodwill, and (iv) other irreparable harm to be proven at trial.

THIRD CLAIM FOR RELIEF
(Unlawful Furnishing of a Controlled Substance)

79. Hikma incorporates the preceding paragraphs as though fully set forth herein.

80. Under Nevada law, a person who "knowingly and unlawfully services, sells or otherwise furnishes a controlled substance to another person" is liable for wrongdoing or damage caused as a result of the use of the controlled substance. NRS 41.700(1)(a)-(b).

81. Defendants' furnishing of Hikma's Fentanyl to John Doe I and/or non-physician administrators is unlawful because, *inter alia*, it was obtained from Hikma and/or Cardinal Health for an illegitimate medical purpose in violation of NRS 453.381(1).

82. Further, Defendants' furnishing of Hikma's Fentanyl to John Doe I and/or non-physician administrators is unlawful for the reasons set forth in Hikma's Fourth and Fifth Claims for Relief, as Defendants' acquisition of Hikma's Fentanyl is in derogation of, and violates, Hikma's property rights.

83. Further, Defendants' furnishing of Hikma's Fentanyl to John Doe I and/or non-physician administrators is unlawful because Defendants' acquisition of Hikma's Fentanyl was undertaken for purposes of unlawfully administering it for a non-therapeutic use (an execution) as well as for unlawfully furnishing it to non-physician administrators.

84. Under Nevada law, a person who "[k]nowingly allows another person to use a controlled substance in an unlawful manner on premises or in a conveyance belonging to the person allowing the use or over which the person has control," is liable for any wrongdoing or damage caused as a result of the use of the controlled substance. NRS 41.700(1)(b).

85. Defendants intend to imminently allow another person—John Doe I and/or non-physician administrators—to use a controlled substance (Hikma's Fentanyl) on their premises.

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Defendants' proposed conduct is unlawful for the reasons set forth *supra*. Defendants' imminently threatened wrongdoing will be in violation of Nevada law for this independent reason.

86. Unless enjoined, Defendants' threatened and imminent wrongdoing will cause Hikma to suffer injuries, including, but not limited to reputational injury arising out of (i) association with the manufacture of drugs used for executions, (ii) the corresponding damage to business and investor and prospective investor relationships, (iii) damage to goodwill, and (iv) other irreparable harm to be proven at trial.

FOURTH CLAIM FOR RELIEF
(Replevin)

87. Hikma incorporates the preceding paragraphs as though fully set forth herein.

88. Upon information and belief, Defendants sought to circumvent Hikma's controls by issuing purchase orders for Hikma's Fentanyl for completion in September 2017 with an unsuspecting distributor, Cardinal Health. Based on those purchase orders to be completed in September 2017, Cardinal Health shipped to Defendants a total of 25 2ml vials of 50mcg/ml Hikma's Fentanyl.

89. As set forth above, Defendants knew or should have known that the distributor was not permitted, allowed, or authorized to sell Hikma's Fentanyl or other Hikma products to NDOC and the remaining Defendants, let alone for the purpose of an execution. Indeed, Hikma had written to Defendants in December 2016—prior to their illicit acquisition of Hikma's Fentanyl—to warn them that Hikma "object[s] in the strongest possible terms to the use of any of [its] products for lethal injection," including Hikma's Fentanyl, and that certain controls were in place to prevent such usage. Hikma's website further published 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

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Departments of Corrections/correctional facilities, or to secondary distributors or retail pharmacies."

90. Upon information and belief, NDOC wrongfully took possession of Hikma's Fentanyl by tacitly misrepresenting that it would be used for a legitimate medical purpose.

91. As set forth in its 2016 Letters to Defendants, in light of its clear and unambiguous communications and restrictions regarding the sale of Hikma's Fentanyl, Hikma is the rightful owner of its Fentanyl and has a present and immediate right of possession to said property.

92. Given the unambiguous contents of Hikma's 2016 Letters and its public statements regarding its corporate policies, Defendants were on actual and/or constructive notice that they could not purchase any product, including Hikma's Fentanyl, directly from Hikma absent an original, raised seal copy of an affidavit signed by the Attorney General, certifying under penalty of perjury that the products will not be used for capital punishment. Defendants were also on actual and/or constructive notice that Hikma's distributors were not authorized to transfer any Hikma product, including Hikma's Fentanyl, to Defendants for purposes of utilizing it in an execution. Thus, Defendants had actual and/or constructive notice that they could not in good faith acquire title to Hikma's Fentanyl. Hence, Hikma's Fentanyl is neither the property of NDOC nor the State of Nevada.

93. Defendants received additional actual or constrictive notice when Hikma again notified Defendants through Hikma's 2017 and 2018 Letters, that none of Hikma's products could be used for lethal objection, and that it had controls in place to prevent departments of corrections from using Hikma products for capital punishment or sales to customers. Defendants were aware that their possession of Hikma's Fentanyl was unlawful.

94. Hikma has a specific interest in Hikma's Fentanyl vials that are in the possession of NDOC because NDOC intends to use Hikma's property for the administration of capital punishment, in violation of Hikma's policies and agreements between Hikma and its distributor(s).

95. In its 2018 Letter, Hikma specifically demanded that Defendants immediately return to Hikma its Fentanyl intended for use in executions, and any other products which have

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been obtained for that purpose in exchange for a full refund. Hikma also requested that Defendants not circumvent Hikma's controls, intentions, and legal provisions and agreements.

96. In spite of said demand, Defendants have refused to return Hikma's Fentanyl that they illicitly and improperly obtained.

97. Hikma's Fentanyl is approved by the FDA solely for the therapeutic uses as an analgesic (pain relief) and anesthetic.

98. Defendants have announced plans to utilize Hikma's Fentanyl for a purpose for which it is neither indicated nor intended to be used—*to wit*, in Defendants' lethal injection protocol. While Hikma takes no position on the death penalty sentence imposed upon Scott Raymond Dozier, Hikma's products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

99. Hikma has a property right in both its Fentanyl and its right to deal—or refuse to deal—with particular prospective customers with respect to said drug. The Supreme Court of the United States long ago recognized the "right of [a] trader or manufacturer engaged in an entirely private business freely to exercise his own independent discretion as to parties with whom he will deal, and, of course, [to] announce in advance the circumstances under which he will refuse to sell." *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). Hikma has exercised those rights both generally in its statements to the public and to prison officials and specifically in communications with Defendants. Thus, as set forth supra, Hikma specifically wrote to NDOC (through Defendant Dzurenda) and the Nevada Attorney General to specifically warn them that they were customers with whom Hikma refused to deal—both directly and indirectly—with regard to the acquisition of Hikma's Fentanyl.

100. Defendants' actions are wrongful vis-à-vis Hikma because, *inter alia*, they are inconsistent with Hikma's property rights, they do not constitute the appropriate and therapeutic use for Hikma's Fentanyl for a legitimate medical purpose, they are contrary to the therapeutic uses for which the drug can be utilized, and they risk grave harm to Hikma's reputation and goodwill.

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101. Because of Defendants' wrongdoing, Hikma has suffered and continues to suffer injuries, including, but not limited to reputational injury arising out of (1) association with the manufacture of drugs used for executions, (ii) the corresponding damage to business and investor relationships, (iii) damage to goodwill, and (iv) other irreparable harm to be proven at trial.

FIFTH CLAIM FOR RELIEF
(Conversion)

102. Hikma incorporates the preceding paragraphs as though fully set forth herein.

103. NDOC has undertaken a distinct act of dominion wrongfully exerted over Hikma's personal property, Hikma's Fentanyl, in denial of, or inconsistent with his title or rights therein, or in derogation, exclusion, or defiance of such title or rights.

104. NDOC has dominion over Hikma's Fentanyl because NDOC is currently in possession of Hikma's Fentanyl.

105. Given the unambiguous contents of Hikma's 2016 Letters and its public statements regarding its corporate policies, Defendants were on actual and/or constructive notice that they could not purchase Hikma's Fentanyl directly from Hikma and that Hikma's distributors were not authorized to transfer Hikma's Fentanyl to Defendants for purposes of utilizing it in an execution. Thus, Defendants had actual and/or constructive notice that they could not in good faith acquire title to Hikma's Fentanyl.

106. Hikma has true right or title to Hikma's Fentanyl because, *inter alia*, they were sold without authorization, in direct contravention of Hikma's stated policy of not selling its Fentanyl, or any of its products, directly to departments of corrections and other entities, and not allowing its distributors to sell Hikma's Fentanyl to customers for use in lethal injections, and in violation of Hikma's fundamental property right to refuse to sell to Defendants (either directly or indirectly), and because Defendants illicitly obtained possession of said product.

107. NDOC's dominion is wrongfully exerted because NDOC was aware of Hikma's policy of not selling any of its products to Departments of Corrections for use in carrying out lethal injections. Indeed, Hikma's 2016 Letters sent to NDOC informed them that Hikma "object[s] in the strongest possible terms to the use of any of [its] products for lethal injection,"

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including Hikma's Fentanyl, and again made clear that its objection should be applied to all of its products. As described in Paragraph 12 above, NDOC's own statements in other litigation related to this execution further show that NDOC was aware of and actively fought disclosure of certain execution-related information because such information had been used to persuade manufacturers to cease selling their products for executions.

108. NDOC's dominion is wrongfully exerted for the additional reasons set forth *supra*, in Hikma's Second and Third Claims for Relief.

109. Upon information and belief, following their receipt of Hikma's 2016 Letters, Defendants thereafter sought to circumvent Hikma's policy by purchasing Hikma's Fentanyl through an unsuspecting intermediary and without disclosing to said intermediary the contents of the 2016 Letters and/or the fact that they sought to obtain Hikma's Fentanyl for purposes of a non-therapeutic use (*i.e.*, an execution). Defendants were thus able to obtain Hikma's Fentanyl in a manner that they would not have been able to accomplish had they disclosed the contents of said letter and/or their intended non-therapeutic use of Hikma's Fentanyl to the intermediary.

110. Defendants received additional actual or constrictive notice of Hikma's policies when Hikma again notified Defendants through Hikma's 2017 and 2018 Letters, that none of Hikma's products could be used for lethal objection, and that it had controls in place to prevent departments of corrections from using Hikma products for capital punishment or sales to customers. Defendants were aware that their possession of Hikma's Fentanyl was unlawful. In its 2018 Letter, Hikma specifically demanded that Defendants immediately return to Hikma its Fentanyl intended for use in executions, and any other products which have been obtained for that purpose in exchange for a full refund. Hikma also requested that Defendants not circumvent Hikma's controls, intentions, and legal provisions and agreements.

111. In spite of said demand, Defendants have refused to return Hikma's Fentanyl that they improperly obtained.

112. Defendants have announced plans to utilize Hikma's Fentanyl for a purpose for which it is neither indicated nor intended to be used—*to wit*, in Defendants' lethal injection protocol. While Hikma takes no position on the death penalty sentence imposed upon Scott

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114. Defendants' actions are wrongful vis-à-vis Hikma because, *inter alia*, they are inconsistent with Hikma's property rights, they do not constitute the appropriate and therapeutic use for Hikma's Fentanyl for a legitimate medical purpose, they are contrary to the therapeutic uses for which the drug can be utilized, and they risk grave harm to Hikma's reputation and goodwill.

115. Because of Defendants' wrongdoing, Hikma has suffered and continues to suffer injuries, including, but not limited to reputational injury arising out of (i) association with the manufacture of drugs used for executions, (ii) the corresponding damage to business and investor relationships, (iii) damage to goodwill, and (iv) other irreparable harm to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Intervenor Hikma prays for relief as follows:

1. For a preliminary and permanent injunction precluding the use of any Hikma drug, including Hikma's Fentanyl and midazolam, in carrying out any capital punishment and further

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ordering NDOC to return immediately all of Hikma's Fentanyl to Hikma, as well as requiring an impoundment of all of Hikma's Fentanyl possessed by Defendants pending a hearing on its status;

2. For declaratory relief as requested herein;

3. For an award of attorneys' fees and costs of suit as allowed by law; and

4. For such other and further relief as this Court deems appropriate under the circumstances.

DATED this ___ day of July, 2018.

LEWIS ROCA ROTHGERBER CHRISTIE LLP

By: /s/_____
E. LEIF REID, ESQ., SBN 5750
JOSH M. REID, ESQ., SBN 7497
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EXHIBIT 1

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The New York Times

Pfizer Blocks the Use of Its Drugs in Executions

By Erik Eckholm

May 13, 2016

The pharmaceutical giant Pfizer announced on Friday that it had imposed sweeping controls on the distribution of its products to ensure that none are used in lethal injections, a step that closes off the last remaining open-market source of drugs used in executions.

More than 20 American and European drug companies have already adopted such restrictions, citing either moral or business reasons. Nonetheless, the decision from one of the world's leading pharmaceutical manufacturers is seen as a milestone.

"With Pfizer's announcement, all F.D.A.-approved manufacturers of any potential execution drug have now blocked their sale for this purpose," said Maya Foa, who tracks drug companies for Reprieve, a London-based human rights advocacy group. "Executing states must now go underground if they want to get hold of medicines for use in lethal injection."

The obstacles to lethal injection have grown in the last five years as manufacturers, seeking to avoid association with executions, have barred the sale of their products to corrections agencies. Experiments with new drugs, a series of botched executions and covert efforts to obtain lethal chemicals have mired many states in court challenges.

The mounting difficulty in obtaining lethal drugs has already caused states to furtively scramble for supplies.

Some states have used straw buyers or tried to import drugs from abroad that are not approved by the Food and Drug Administration, only to see them seized by federal agents. Some have covertly bought supplies from loosely regulated compounding pharmacies while others, including Arizona, Oklahoma and Ohio, have delayed executions for months or longer because of drug shortages or legal issues tied to injection procedures.

A few states have adopted the electric chair, firing squad or gas chamber as an alternative if lethal drugs are not available. Since Utah chooses to have a death penalty, "we have to have a means of carrying it out," said State Representative Paul Ray as he argued last year for authorization of the firing squad.

Lawyers for condemned inmates have challenged the efforts of corrections officials to conceal how the drugs are obtained, saying this makes it impossible to know if they meet quality standards or might cause undue suffering.

"States are shrouding in secrecy aspects of what should be the most transparent government activity," said Ty Alper, associate director of the death penalty clinic at the University of California, Berkeley, School of Law.

Before Missouri put a prisoner to death on Wednesday, for example, it refused to say in court whether the lethal barbiturate it used, pentobarbital, was produced by a compounding pharmacy or a licensed manufacturer. Akorn, the only approved company making that drug, has tried to prevent its use in executions.

Pfizer's decision follows its acquisition last year of Hospira, a company that has made seven drugs used in executions including barbiturates, sedatives and agents that can cause paralysis or heart failure. Hospira had long tried to prevent diversion of its products to state prisons but had not succeeded; its products were used in a prolonged, apparently agonizing execution in Ohio in 2014, and are stockpiled by Arkansas, according to documents obtained by reporters.

Because these drugs are also distributed for normal medical use, there is no way to determine what share of the agents used in recent executions were produced by Hospira, or more recently, Pfizer.

Campaigns against the death penalty, and Europe's strong prohibitions on the export of execution drugs, have raised the stakes for pharmaceutical companies. But many, including Pfizer, say medical principles and business concerns have guided their policies.

"Pfizer makes its products to enhance and save the lives of the patients we serve," the company said in Friday's statement, and "strongly objects to the use of its products as lethal injections for capital punishment."

Pfizer said it would restrict the sale to selected wholesalers of seven products that could be used in executions. The distributors must certify that they will not resell the drugs to corrections departments and will be closely monitored.

David B. Muhlhausen, an expert on criminal justice at the Heritage Foundation, accused Pfizer and other drug companies of "caving in to special interest groups." He said that while the companies have a right to choose how their products are used, their efforts to curb sales for executions "are not actually in the public interest" because research shows, he believes, that the death penalty has a deterrent effect on crime.

Pressure on the drug companies has not only come from human rights groups. Trustees of the New York State pension fund, which is a major shareholder in Pfizer and many other producers, have used the threat of shareholder resolutions to push two other companies to impose controls and praised Pfizer for its new policy.

"A company in the business of healing people is putting its reputation at risk when it supplies drugs for executions," Thomas P. DiNapoli, the state comptroller, said in an email. "The company is also risking association with botched executions, which opens it to legal and financial damage."

Less than a decade ago, lethal injection was generally portrayed as a simple, humane way to put condemned prisoners to death. Virtually all executions used the same three-drug combination: sodium thiopental, a barbiturate, to render the inmate unconscious, followed by a paralytic and a heart-stopping drug.

In 2009, technical production problems, not the efforts of death-penalty opponents, forced the only federally approved factory that made sodium thiopental to close. That, plus more stringent export controls in Europe, set off a cascade of events that have bedeviled state corrections agencies ever since.

Many states have experimented with new drug combinations, sometimes with disastrous results, such as the prolonged execution of Joseph R. Wood III in Arizona in 2014, using the sedative midazolam. The state's executions are delayed as court challenges continue.

Under a new glaring spotlight, deficiencies in execution procedures and medical management have also been exposed. After winning a Supreme Court case last year for the right to execute Richard E. Glossip and others using midazolam, Oklahoma had to impose a stay only hours before Mr. Glossip's scheduled execution in September. Officials discovered they had obtained the wrong drug, and imposed a moratorium as a grand jury conducts an investigation.

A majority of the 32 states with the death penalty have imposed secrecy around their drug sources, saying that suppliers would face severe reprisals or even violence from death penalty opponents. In a court hearing this week, a Texas official argued that disclosing the identity of its pentobarbital source "creates a substantial threat of physical harm."

But others, noting the evidence that states are making covert drug purchases, see a different motive. "The secrecy is not designed to protect the manufacturers, it is designed to keep the manufacturers in the dark about misuse of their products," said Robert Dunham, executive director of the Death Penalty Information Center, a research group in Washington.

Georgia, Missouri and Texas have obtained pentobarbital from compounding pharmacies, which operate without normal F.D.A. oversight and are intended to help patients meet needs for otherwise unavailable medications.

But other states say they have been unable to find such suppliers.

Texas, too, is apparently hedging its bets. Last fall, shipments of sodium thiopental, ordered by Texas and Arizona from an unapproved source in India, were seized in airports by federal officials.

For a host of legal and political reasons as well as the scarcity of injection drugs, the number of executions has declined, to just 28 in 2015, compared with a recent peak of 98 in 1999, according to the Death Penalty Information Center.

A version of this article appears in print on May 13, 2016, on Page A1 of the New York edition with the headline: Pfizer Prohibits Use of Its Drugs for Executions

EXHIBIT 2

EXHIBIT 2

Use of products in capital punishment

Hikma aims to improve lives by providing patients with access to high quality, affordable medicines. Our medicines are used thousands of times a day around the world to treat illness and save lives.

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.

While none of our products should ever be used for the purpose of capital punishment, in the table below, we have identified certain products that carry heightened risk of misuse for lethal injection protocols. Accordingly, to prevent these products from being used for the purpose of capital punishment, we 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. Further, we 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.

We vigorously monitor the distribution of these products and support industry serialization efforts that will help enhance these controls while continuing to promote our values and mission.

Further, transparency is one of our core values, and as such we object to attempts by any entity, person or state to obscure or hide the source of products for lethal injection. It is imperative that we are not impeded from protecting patient health and the integrity of our products and our supply chain.

Name / Description
HYDROMORPHONE 2MG/ML VIAL X 25
HYDROMORPHONE 40MG/20ML VIAL X 1
MIDAZOLAM 10MG/10ML VIAL X 10
MIDAZOLAM 10MG/2ML VIAL X 10
MIDAZOLAM 10MG/2ML VIAL X 25

MIDAZOLAM 2MG/2ML VIAL X 10

MIDAZOLAM 2MG/2ML VIAL X 25

MIDAZOLAM 50MG/10ML VIAL X 10

MIDAZOLAM 5MG/5ML VIAL X10

MIDAZOLAM 5MG/ML VIAL X 25

PHENOBARBITAL 130MG/ML VIAL X 25

PHENOBARBITAL 65MG/ML VIAL X 25

ETOMIDATE 20 MG/10 ML VIAL X 10

ETOMIDATE 40 MG/20 ML VIAL X 10

Fentanyl Citrate Injection, USP C-II (AMPULS) 100 mcg / 2 mL

Fentanyl Citrate Injection, USP C-II (AMPULS) 250 mcg / 5 mL

Fentanyl Citrate Injection, USP C-II (AMPULS) 1000 mcg / 20 mL

Fentanyl Citrate Injection, USP C-II (VIALS) 100 mcg / 2 mL

Fentanyl Citrate Injection, USP C-II (VIALS) 250 mcg / 5 mL

Fentanyl Citrate Injection, USP C-II (VIALS) 1000 mcg / 20 mL

Fentanyl Citrate Injection, USP C-II (VIALS) 2500 mcg / 50 mL

EXHIBIT 3

EXHIBIT 3

HIKMA
QUALITY

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20 December 2016

The Honorable Adam Laxalt
Attorney General
State of Nevada
Old Supreme Ct. Bldg.
100 N. Carson St.
Carson City, NV 89701
USA

Dear Mr. Laxalt,

Hikma aims to improve lives by providing patients with access to high quality, affordable medicines. Our medicines are used millions of times a day to treat illness and save lives. This has been our mission for more than 40 years and one that is shared by our US subsidiary, West-Ward.

We are extremely dismayed to learn that, despite our best efforts to ensure our medicines are used only for their intended medicinal purposes, some states continue to attempt to procure our products for use in lethal injection. Not only is this an off-label use and 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 also it is completely counter to our values as an organization.

You are likely aware that to prevent Phenobarbital Sodium, Midazolam Hydrochloride and Hydromorphone Hydrochloride being used by Departments of Corrections for lethal injection, we have put certain controls in place. While we are not aware that Nevada is in possession of any of these products intended for this purpose, we are writing to restate our policy and our position on the use of these drugs: We object in the strongest possible terms to the use of any of our products for lethal injection.

In addition, we have become aware that some states are considering a new list of compounds to use in lethal injection. We would like to make clear that our objection should be applied to all West-Ward products, not just Phenobarbital Sodium, Midazolam Hydrochloride and Hydromorphone Hydrochloride.

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 medical 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.

Sincerely,

Brooke S Clarke
VP Corporate Affairs