EXHIBIT 6

Drug company threatens legal action to prevent drug from being used in Dozier's execution

foxreno.com/news/local/new-drug-in-nevada-execution-plan-linked-to-botched-executions-in-other-states

by Ben Margiott

Thursday, July 5th 2018

New drug in Nevada execution plan linked to botched executions in other states

RENO, Nev. (News 4 & Fox 11) — UPDATE According to an Alvogen spokesperson, the company is considering taking legal action to prevent their drug from being used in Wednesday's scheduled execution in Ely.

Alvogen makes one of the drugs used that will be used in Scott Dozier's execution.

Statement from spokesperson Halldór Kristmannsson:

> "Alvogen does not market, promote or condone the use of any of its approved prescription drug products, including midazolam, for use in state sponsored executions. To avoid any improper, off label use of our products, Alvogen does not accept direct orders from prison systems or departments of correction. Alvogen works with our distributors and wholesalers to restrict any resale, either directly or indirectly, of our midazolam product to any prison system or department of correction.
>
> With respect to the alleged intent of the State of Nevada Department of Corrections to use our midazolam product in an execution, we are exploring all potential avenues, including legal recourse, to prevent the improper use of our product in this particular execution."

Nevada is just two days away from executing its first inmate in over a decade, but questions still linger about the controversial three-drug lethal injection combination the Department of Corrections plans to use.

After NDOC's supply of the sedative Diazepam recently expired, the state obtained adequate dosages of the sedative Midazolam, which has been linked to multiple botched executions in other states.

The new sedative drug Midazolam was made by the pharmaceutical company Alvogen, and distributed by Cardinal Health, according to a sales invoice obtained by News 4.

According to the Lethal Injection Information Center, "Alvogen is working to ensure that its distributors and wholesalers do not resell, either directly or indirectly, [Alvogen products] to prison systems or departments of correction."

Midazolam has factored into botched executions in Ohio, Oklahoma, Arizona and Alabama, according to the nonprofit and nonpartisan Death Penalty Information Center.

The sedative was also used in an April 2017 Arkansas execution where witnesses described the inmate "coughing, convulsing, lurching and jerking."

Kelly Kissel, a longtime Associated Press news editor and the current metro editor at The Advocate, has witnessed over 10 executions, including the recent Arkansas one.

"Three or four minutes into the execution was when he started lurching forward. His forehead was pressing against the restraint that was around his forehead," Kissel said.

> "For lack of a better term, it was the most violent execution that I had seen."

According to DPIC, the use of Midazolam factored into an Alabama inmate "heaving and gasping for breath" for about 15 minutes.

Both Florida and Arizona recently abandoned the use of Midazolam in three-drug lethal injection combinations.

Questions remain about the other drugs in the lethal injection combination — the opioid Fentanyl and the paralytic Cisatracurium.

The paralytic element Cisatracurium was the focus of court challenges late last year, with critics arguing that the drug would mask signs of possible suffering, or lead to so-called air hunger.

Fentanyl is in both Nevada and Nebraska's execution protocols, but has never been used in an execution in the United States.

Nevada plans to execute convicted murderer Scott Dozier, now 47, on July 11th at 8:00 p.m. at the Ely State Prison.

Dozier has voluntarily waived all his appeals and maintains that he wants to be executed.

EXHIBIT 7

Nevada releases records on sedative to be used in execution

AP apnews.com/79a2e272ac954e5bae7c0e63218fa51a

LAS VEGAS (AP) — Nevada prison officials released records Friday afternoon about where and when a sedative was obtained for use next week in the state's first execution since 2006.

Records from the Nevada Department of Corrections show midazolam slated for use in Scott Raymond Dozier's lethal injection Wednesday was purchased in May from the state's regular pharmaceutical distributor, Cardinal Health, and manufactured by pharmaceutical company Alvogen.

The U.S. Supreme Court ruled in 2015 that midazolam can be used in lethal injections. But the drug has been blamed in recent years for problem executions in several other states.

Messages seeking comment from Alvogen on Friday afternoon were not immediately returned. The company, however, said on a webpage for the product that it opposes the drug's use in lethal injections.

The company says it has taken steps to try to avoid having midazolam be used in executions and does not accept orders from prison systems or corrections departments. The company says it is also working to ensure its distributors and wholesalers do not directly or indirectly resell the drug to prisons or corrections departments.

A message seeking comment from Cardinal Health was not immediately returned Friday.

The American Civil Liberties Union of Nevada points to Arizona's decision to stop using the drug after a 2014 lethal injection that took nearly two hours to kill Joseph Rudolph Wood. The organization has criticized the plan for Dozier's lethal injection as being less human than putting down a pet.

Nevada plans to use midazolam injections to be followed by high doses of the powerful synthetic opioid fentanyl and muscle-paralyzing drug cisatracurium. Fentanyl and cisatracurium have never before been used for executions.

Dozier has been on death row since 2007 after being convicted in murders in Phoenix and Las Vegas. The 47-year-old has waived appeals in his case and has said he wants to die and doesn't care if he suffers.

ACLU of Nevada spokesman Wesley Juhl said the organization was reviewing the Nevada records Friday afternoon and figuring out its next steps.

BUSINESS COURT CIVIL COVER SHEET

County, Nevada

Case No. A-18-777312-B
(Assigned by Clerk's Office)

Department 27

I. Party Information *(provide both home and mailing addresses if different)*

Plaintiff(s) (name/address/phone):

ALVOGEN, INC.

Attorney (name/address/phone):

Todd L. Bice, Esq., #4534, Pisanelli Bice PLLC
400 South 7th Street, Suite 300
Las Vegas, NV 89101
702-214-2100

Defendant(s) (name/address/phone):

STATE OF NEVADA;
NEVADA DEPARTMENT OF CORRECTION;
JAMES DZURENDA
IHSAN AZZAM, PH.D., M.D.

Attorney (name/address/phone):

II. Nature of Controversy *(Please check the applicable boxes for both the civil case type and business court case type)*

☐ Arbitration Requested

Civil Case Filing Types

Real Property

Landlord/Tenant
- ☐ Unlawful Detainer
- ☐ Other Landlord/Tenant

Title to Property
- ☐ Judicial Foreclosure
- ☐ Other Title to Property

Other Real Property
- ☐ Condemnation/Eminent Domain
- ☐ Other Real Property

Construction Defect & Contract

Construction Defect
- ☐ Chapter 40
- ☐ Other Construction Defect

Contract Case
- ☐ Uniform Commercial Code
- ☐ Building and Construction
- ☐ Insurance Carrier
- ☐ Commercial Instrument
- ☐ Collection of Accounts
- ☐ Employment Contract
- ☐ Other Contract

Torts

Negligence
- ☐ Auto
- ☐ Premises Liability
- ☐ Other Negligence

Malpractice
- ☐ Medical/Dental
- ☐ Legal
- ☐ Accounting
- ☐ Other Malpractice

Other Torts
- ☐ Product Liability
- ☐ Intentional Misconduct
- ☐ Employment Tort
- ☐ Insurance Tort
- ☒ Other Tort

Civil Writs
- ☐ Writ of Habeas Corpus
- ☐ Writ of Mandamus
- ☐ Writ of Quo Warrant
- ☐ Writ of Prohibition
- ☐ Other Civil Writ

Judicial Review/Appeal/Other Civil Filing

Judicial Review
- ☐ Foreclosure Mediation Case

Appeal Other
- ☐ Appeal from Lower Court

Other Civil Filing
- ☐ Foreign Judgment
- ☐ Other Civil Matters

Business Court Filing Types

CLARK COUNTY BUSINESS COURT
- ☐ NRS Chapters 78-89
- ☐ Commodities (NRS 91)
- ☐ Securities (NRS 90)
- ☐ Mergers (NRS 92A)
- ☐ Uniform Commercial Code (NRS 104)
- ☐ Purchase/Sale of Stock, Assets, or Real Estate
- ☐ Trademark or Trade Name (NRS 600)
- ☐ Enhanced Case Management
- ☒ Other Business Court Matters

WASHOE COUNTY BUSINESS COURT
- ☐ NRS Chapters 78-88
- ☐ Commodities (NRS 91)
- ☐ Securities (NRS 90)
- ☐ Investments (NRS 104 Art.8)
- ☐ Deceptive Trade Practices (NRS 598)
- ☐ Trademark/Trade Name (NRS 600)
- ☐ Trade Secrets (NRS 600A)
- ☐ Enhanced Case Management
- ☐ Other Business Court Matters

7-10-18
Date

Signature of initiating party or representative

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DISTRICT COURT

CLARK COUNTY, NEVADA

ALVOGEN, INC.,

Plaintiff,

v.

STATE OF NEVADA;

NEVADA DEPARTMENT OF CORRECTION;

Case No.: A-18-777

Dept. No.: XI

PLAINTIFF'S *EX PA*
FOR TEMPORARY R
ORDER AND MOTIO
PRELIMINARY INJU

Plaintiff Alvogen, Inc. ("Alvogen") hereby seeks an emergency temporary restraining order to enable the Court to hear evidence and argument at a preliminary injunction hearing regarding why Defendants should be enjoined from using midazolam hydrochloride distributed by Alvogen to carry out capital punishment, including in the execution of inmate Scott Raymond Dozier currently scheduled for July 11, 2018, at 8:00 p.m.

On April 20, 2018, Alvogen gave written notice to Defendants that its products were not to be directly or indirectly acquired or used for in executions. Shortly thereafter, Defendants surreptitiously and wrongfully obtained midazolam hydrochloride distributed by Alvogen through a third party for use in the upcoming Dozier execution. Defendants then took steps to avoid any public disclosure of the source of any of the drugs it intended to use in the Dozier execution. As they later admitted in court, Defendants hoped that secrecy would prevent the companies whose drugs they intended to use from objecting to that use. Defendants were finally forced to identify the proposed drugs and their source by court order entered on July 6th, and Alvogen first learned that Defendants had identified Alvogen as the source of one of the drugs early the next morning (Saturday, July 7th), when a member of the press contacted an Alvogen employee for comment.

Alvogen immediately took steps to investigate. Alvogen filed the instant action to protect its business reputation and goodwill from the injury that will inevitably result if Defendants are allowed to use the wrongfully-acquired Alvogen medicines in an execution. Alvogen has already been the subject of critical press reports in connection with Defendants' conduct, and if Defendants' conduct is not enjoined, Alvogen will suffer further irreparable harm.

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This Motion is based upon NCRP 65, E.D.C.R. 2.26, the accompanying Memorandum of Points and Authorities, the Harker Declaration (attached hereto as Exhibit 1), the Sweet Declaration (attached hereto as Exhibit 2), the supporting evidence attached hereto, and any oral arguments of counsel that the Court may choose to consider.

DATED this 10th day of July, 2018.

PISANELLI BICE PLLC

By: _____

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Todd L. Bice, Esq., Bar No. 4534
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DECLARATION OF TODD L. BICE, ESQ.

I, TODD L. BICE, ESQ., hereby declare as follows:

1. I am one of the attorneys for Alvogen, Inc. ("Alvogen") in the above-entitled action. I make this Declaration in support of the Plaintiff's *Ex Parte* Application for a Temporary Restraining Order and Motion for Preliminary Injunction; *Ex Parte* Motion for Order Shortening Time.

2. 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.

3. As set forth in the Motion and accompanying declarations, Plaintiff Alvogen is the ANDA holder and distributor of Midazolam. On July 6, 2018, the Defendants publicly revealed their intent was to carry out the execution of Scott Dozier through use of such Alvogen Midazolam.

4. I am informed and believe that Alvogen learned of the Defendants' intended use of its product from a press inquiry early the next morning, Saturday, July 7. I can attest that legal counsel for Alvogen has acted as quickly as possible thereafter to investigate the matter and prepare its Complaint and request for temporary restraining order to present it to this Court.

5. As set forth in the Motion and accompanying declarations, Alvogen maintains that the use of its drug for this purpose is in violation of Nevada law, particularly because the Defendants were on notice that they could not acquire Alvogen's Midazolam for use in capital punishment. Alvogen also attests that it will suffer serious irreparable harm through any misuse of its product, as it is in the business of creating and distributing life-preserving medications. As set forth in the declarations accompanying the motion, Alvogen has already received negative publicity and harm to its business reputation and good will as a result of the Defendants' actions. That harm will be exacerbated if the Defendants are allowed to proceed with its intended misuse of Alvogen's product.

6. I am informed and believe, including based upon the decision from Judge Wilson in the First Judicial District from last Friday, which I have reviewed, that the Defendants had

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endeavored to conceal from Alvogen how they had acquired the Midazolam, precisely because the Defendants feared that Alvogen would exercise its legal rights to object to this misuse. Accordingly, the time constraints and necessity from prompt action without opportunity for full notice and briefing is a direct consequence of the Defendants' actions.

7. Although Alvogen is entitled to ex parte relief, I certify that promptly upon filing of the Complaint, it has been sent for service upon each Defendant. I further certify that I caused the Complaint and this Motion to be served by email upon the Attorney General's Office, specifically upon Deputy Attorney General Jordan Smith – jsmith@ag.nv.gov – who I know is handling the Dozier matter for the Attorney General's office. I further provided by cell phone number to Mr. Smith and informed him that we were seeking a temporary restraining order in light of the Defendants' intention to use Alvogen's product in an execution scheduled for July 11, 2018, at 8:00 p.m.

8. I certify that this declaration is not made for any improper purpose.

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

Executed this 10th day of July, 2018.

TODD L. BICE, ESQ.

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ORDER SHORTENING TIME

Good cause appearing, it is hereby ordered that the foregoing **PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION; EX PARTE MOTION FOR ORDER SHORTENING TIME** shall be heard on shortened time on the 11 day of July, 2018, at the hour of 9 o'clock a.m in Department 11.

DATED: 10th July 2018

DISTRICT COURT JUDGE

Respectfully submitted:

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Defendants State of Nevada ("Nevada"), the Nevada Department of Corrections ("NDOC"), NDOC Director James Dzurenda ("Dzurenda"), and Chief Medical Officer of the State of Nevada Ihsan Azzam ("Azzam") (collectively, "Defendants") have announced their intention to execute inmate Scott Raymond Dozier on July 11, 2018, at 8:00 pm in Nevada's Ely State Prison. Alvogen takes no position on the appropriateness of the death penalty or its application to this inmate. Nonetheless, Alvogen has an absolute right to control the sale, distribution, and threatened misuse of its products.

As described in detail below, Alvogen has exercised its right to decline to sell or otherwise distribute its products to prisons and specifically for purposes of being used in executions. As a result of the controversies that have surrounded several prior botched executions by lethal injection, particularly those involving the product at issue here, Alvogen and virtually all other suppliers of such medicines have policies prohibiting their use in executions. Alvogen expressly notified these Defendants that it would not sell them the product at issue and objected to its use in executions. Defendants nonetheless ignored Alvogen's warning, acquired the product indirectly through subterfuge, took steps to keep Alvogen from learning about its purchase, and now propose to use Alvogen's product in an unauthorized execution.

Defendants' conduct violates numerous Nevada laws:

- Defendants' acquisition violates NRS § 453.331(1)(d), which prohibits any person from acquiring a controlled substance by misrepresentation, fraud, deception or subterfuge. Similarly, Defendants' acquisition also violates NAC § 630.230(d), which prohibits physicians from acquiring a controlled substance by misrepresentation, fraud, deception or subterfuge.
- Defendants' proposed use violates NRS § 453.381(1), which permits physicians to administer controlled substances only for legitimate medical purposes. Intentionally causing death is not a legitimate medical purpose.

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- Because both the acquisition and proposed us of the product is unlawful, Defendants' conduct also violates NRS § 453.391(1), which prohibits anyone from unlawfully obtaining a controlled substance.
- NRS § 41.700(1)(a)-(b) states any person who "knowingly and unlawfully services, sells or otherwise furnishes a controlled substance to another person" is liable for all damages caused as a result of the use of the controlled substance, including injury to Alvogen.

In addition to these statutory violations, Defendants' conduct violates Alvogen's property rights, according Alvogen actions in Replevin and for Conversion and under the Uniform Commercial Code for return of this property.

Alvogen also has a right to protect its professional and business reputation and goodwill from being injured by unauthorized uses of its medicines. As demonstrated herein, that reputation and goodwill has already been injured, and by this action Alvogen seeks to avoid any further irreparable harm.

II. RELEVANT FACTUAL BACKGROUND

Alvogen is a leading pharmaceutical company focused on developing, manufacturing and selling life-saving and life-enhancing products around the world. *See* Harker Decl. ¶ 4 (attached hereto as Exhibit 1). Committed to patients' safety, Alvogen endorses the use of its products in indications approved by the U.S. Food and Drug Administration ("FDA"). Harker Decl. ¶ 5. One of the pharmaceutical products Alvogen distributes is Midazolam Hydrochloride Injection, Solution (Abbreviated New Drug Application number 090850) (the "Alvogen Midazolam Product"). The Alvogen Midazolam Product is an injectable medication approved by the FDA for use in inducing general anesthesia and preoperative sedation/anxiolysis/amnesia, among other uses. Compl. ¶ 12; Harker Decl. ¶ 6 & Ex. A. Midazolam is on the World Health Organization's List of Essential Medicines, the most safe and effective medicines used in any health system for priority conditions. Compl. ¶ 12. It is also a Schedule IV controlled substance. *Id.*; NAC § 453.540(3).

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In addition to its uses by physicians, midazolam has been used by some state correctional facilities as a component of those states' and facilities' capital punishment regimens. Compl. ¶ 13. But the medicine was not created, or approved by the FDA, for use in executions. *Id.*; Harker Decl. Ex. A. Past attempts by other states to use the medicine in lethal injections have been extremely controversial, and have led to widespread concern that prisoners have suffered cruel and unusual treatment. Compl. ¶ 15. Several such attempts have been characterized as "botched" executions.

For example, midazolam was used in Oklahoma's high-profile execution of Clayton Lockett in April, 2014.[1] Compl. ¶ 15. Lockett apparently regained consciousness and started speaking midway through his execution, after Oklahoma prison officials began administering an untested three-drug cocktail using 100 mg of midazolam. *Id.* Prison officials reportedly cancelled the execution and discussed taking him to the hospital before he was pronounced dead of a heart attack 40 minutes after the execution began. *Id.* In July, 2014, Arizona attempted to execute Joseph R. Wood III with a combination of drugs that included midazolam.[2] Compl. ¶ 16. Observers reported that Wood repeatedly gasped for one hour and 40 minutes after the drugs were injected. The entire procedure, which should have taken approximately ten to fifteen minutes, took almost two hours. *Id.* On December 8, 2016, Alabama attempted to execute Ronald Bert Smith by lethal injection using midazolam.[3] Compl. ¶ 17. According to reports, the execution went awry soon after midazolam was administered. *Id.* His execution took 34 minutes. *Id.* During the 13 minutes after being administered midazolam, Smith appeared to be struggling for

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[1] M. Pearce, M. Hennessy-Fiske, and P. Dave, "Oklahoma halts double execution after one is botched," Los Angeles Times, April 29, 2014, *available at* http://www.latimes.com/nation/nationnow/la-na-nn-oklahoma-execution-20140429-story.html#axzz30NTC6FT5.

[2] Erik Eckholm, "Arizona Takes Nearly 2 Hours to Execute Inmate, New York Times, Jul. 23, 2014," *available at* https://www.nytimes.com/2014/07/24/us/arizona-takes-nearly-2-hours-to-execute-inmate.html.

[3] K. Faulk, "Alabama Death Row inmate Ronald Bert Smith heaved, coughed for 13 minutes during execution," AL.com, December 8, 2016, https://www.al.com/news/birmingham/index.ssf/2016/12/alabama_death_row_inmate_is_se.html#incart_std.

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breath and heaved, coughed and clenched his left fist, while his lips moved and one eye appeared to be slightly open. *Id.*

In light of these and other controversial instances of prolonged and botched executions, Alvogen has undertaken controls to prevent diversion of midazolam and prohibit its use in executions. Harker Decl. ¶ 7. On April 20, 2018, Alvogen sent letters to the Governors, Attorneys General, and Department of Corrections Directors in every state that has a death penalty, including Nevada. Compl. ¶ 23; Sweet Decl. ¶ 4 & Exs. A & B (attached hereto as Exhibit 2). In that letter, Alvogen stated "in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment." *Id.* Alvogen specifically identified its Midazolam Product as one that should not be used in executions, and noted that use of midazolam or other products in executions "clearly runs counter to the FDA-approved indication for these products." *Id.* The letter went on to explain:

> To ensure our products are not purchased for use in lethal injection executions, Alvogen does not accept orders from any state departments of corrections. Further, Alvogen has controls in place and directs its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions. These controls reflect our company's policy of ensuring the appropriate use of our medicines.

Id. In addition, Alvogen specifically demanded that any state that obtained products for execution return them immediately for a full refund. Compl. ¶ 24; Sweet Decl. Ex. A. Alvogen warned Defendants against attempting to obtain its Midalozam Product for executions surreptitiously, illicitly, and/or by subterfuge. Compl. ¶ 25; Sweet Decl. Ex. A.

One of Alvogen's April 20, 2018 letters were sent directly to the Nevada Department of Corrections' facility at Ely State Prison, where Nevada's newly-constructed death penalty chamber is located, as well as to Defendant Dzurenda. Compl. ¶ 26; Sweet Decl. 4 & Ex. B.

Alvogen has reinforced its policy prohibiting the use of its products in executions by including a notice to that effect on the page of its website describing the Alvogen Midazolam Product:

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> Alvogen endorses the use of its products in accordance with FDA-approved indications. To this end, Alvogen has undertaken controls to avoid diversion of this product for use in execution protocols. In furtherance of this effort, Alvogen does not accept direct orders from prison systems or departments of correction. In addition, Alvogen is working to ensure that its distributors and wholesalers do not resell, either directly or indirectly this product, to prison systems or departments of correction.

Compl. ¶ 28-29; Harker Decl. ¶ 8.

When Alvogen began distributing its Midazolam Product in the United States, Alvogen had conversations with its distributor Cardinal Health ("Cardinal") regarding Alvogen's desire that its products not be sold to corrections facilities for use in lethal injection protocols. From those conversations, Alvogen understood that Cardinal would not distribute midazolam to corrections facilities for use in lethal injections. Compl. ¶ 30; Harker Decl. ¶ 9. That understanding was confirmed when Alvogen conducted a quarterly review of sales data for the first quarter of 2018 and found that no Cardinal sales to correctional departments had occurred. *Id.* Alvogen and Cardinal subsequently entered into negotiations regarding the formal terms on which Cardinal would agree to restrict such sales. *Id.* As a result of those negotiations, Alvogen and Cardinal amended their Generic Wholesale Service Agreement effective May 28, 2018 to prohibit sales to correctional facilities in return for a service fee to be paid to Cardinal. Harker Decl. ¶ 10.

Despite these efforts, on July 7, 2018, Alvogen was contacted by members of the press and told that Nevada had announced its intent to conduct the execution of Scott Raymond Dozier on Wednesday, July 11, 2018 by use of a three-drug cocktail that included the Alvogen Midazolam Product. Compl. ¶ 31; Harker Decl. ¶ 11; Sweet Decl. ¶ 5. Alvogen subsequently learned from disclosures made in response to litigation by the Nevada branch of the American Civil Liberties Union that NDOC had acquired the midazolam it intends to use in the execution from Cardinal by way of purchase orders from May 2018 which were to be completed in June 2018. Compl. ¶ 31; Harker Decl. ¶ 13.

Defendants knew from the written communications they had received from Alvogen that that Alvogen prohibits the distribution, sale, and transfer its Midazolam Product use in execution

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protocols. Nonetheless, Alvogen believes that Defendants acquired the product secretly from an unsuspecting intermediary without disclosing to that intermediary the contents of the April 20 Alvogen letters or the fact that they planned to use the Alvogen Midazolam Product for a non-approved, non-therapeutic use. Compl. ¶ 33. Defendants were thus able to illicitly and through subterfuge obtain the Alvogen Midazolam Product in a manner that they would not have been able to accomplish had they disclosed to the intermediary the contents of Alvogen's letter or the fact that they planned to use the Alvogen Midazolam Product for a non-therapeutic use. *Id.*

III. ARGUMENT

Defendants have publicly declared their intent to use midazolam on Wednesday, July 11, 2018, to execute inmate Dozier in violation of Alvogen's stated policy and warnings. Alvogen is entitled to a temporary restraining order or preliminary injunction under Rule 65 of the Nevada Rules of Civil Procedure to preserve the status quo and because money damages will not adequately provide relief to protect Alvogen from the irreparable harm that will result if the Alvogen Midazolam Product is used in an execution.

The purpose of a temporary restraining order is to preserve the status quo and prevent irreparable harm until a hearing can be held. *See Granny Goose Foods, Inc. v. Bhd. of Teamsters,* 415 U.S. 423, 439 (1974), *cited by Reno Air Racing Ass'n, Inc. v. McCord,* 452 F.3d 1126, 1131 (9th Cir. 2006). In circumstances where immediate action is necessary, "as in the case of an application for an injunction to prevent irreparable injury which would result from delay, and where there is no plain, speedy and adequate remedy at law," a temporary restraining order without notice should be issued. *See Farnow v. Eighth Judicial Dist. Ct.*, 64 Nev. 109, 118, 178 P.2d 371, 375 (1947) ("*Ex parte* motions, that is, motions without notice, are of various kinds and are frequently and commonly permitted under the Nevada law and practice."); *see also* NRCP 65(b).

A. THE STANDARD FOR INJUNCTIVE RELIEF

Injunctive relief is available where (1) the moving party enjoys a reasonable likelihood of success on the merits, and (2) the non-moving party's conduct, if permitted to continue, will result in irreparable harm for which compensatory damages are an inadequate remedy. *Boulder Oaks*

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Cmty. Ass'n v. B & J Andrews Enters., LLC, 125 Nev. 397, 403, 215 P.3d 27, 31 (2009); *Dep't of Conservation & Natural Res., Div. of Water Res. v. Foley,* 121 Nev. 77, 80, 109 P.3d 760, 762 (2005). An injunction or TRO can issue to preserve the status quo and/or to restore the status quo when damage appears to have already been done. *See, e.g., No. One Rent-A-Car v. Ramada Inns, Inc.,* 94 Nev. 779, 780, 587 P.2d 1329, 1330 (1978) (preserve status quo); *Memory Gardens of Las Vegas, Inc. v. Pet Ponderosa Mem'l Gardens, Inc.,* 88 Nev. 1, 4,492 P.2d 123, 124-25 (1972) (restore status quo); *Leonard v. Stoebling,* 102 Nev. 543, 550-51, 728 P.2d 1358, 1363 (1986) (restore); *City of Reno v. Matley,* 79 Nev. 49, 61, 378 P.2d 256, 262 (1963) (restore); *see also Dodge Bros. v. Gen. Petrol. Corp. of Nev.,* 54 Nev. 245, 10 P.2d 341, 342 (1932) (stating that a "mandatory injunction" is one that requires a defendant to do a particular act). Here, the injunction prayed for by Alvogen will preserve the status quo.

To the extent that the Court goes beyond a TRO to evaluate the propriety of preliminary injunctive relief, the decision to "grant or deny a preliminary injunction is within the district court's sound discretion." *Labor Comm'r of State of Nev. v. Littlefield,* 123 Nev. 35, 38, 153 P.3d 26, 28 (2007). In exercising this discretion, this Court must weigh the relative interests of the parties—the damage to the non-moving party if the injunction issues versus the damage to the moving party should the injunction not issue. *Home Fin. Co. v. Balcom,* 61 Nev. 301, 127 P.2d 389 (1942).

As demonstrated in the sections below, Alvogen has more than a reasonable likelihood of success on the merits, will suffer irreparable harm without the issuance of a temporary restraining order or preliminary injunction, and the relative interests of the parties support entry of the requested injunction.

B. ALVOGEN HAS MORE THAN A REASONABLE LIKELIHOOD OF SUCCESS ON ITS MERITS

Alvogen has a strong likelihood of success on the merits of its claims against Defendants. The test for determining the likelihood of success is whether a party demonstrates a "reasonable probability of success on the merits." *Dixon v. Thatcher,* 103 Nev. 414, 415, 742 P.2d 1029, 1031 (1987) (per curiam) (emphasis added) (reversing a denial of an injunction after finding that the

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400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

plaintiffs presented "sufficient indicia" to make a prima facie showing before a trier of fact); *see also Dangberg Holdings Nev., L.L.C. v. Douglas Cty. & Bd. of Cty. Comm'rs*, 115 Nev. 129, 143, 978 P.2d 311, 319 (1999) (upholding injunction because the plaintiff "demonstrated a reasonable probability of success" on the claim). For the reasons described below, that test is satisfied here.

1. Acquisition Of A Controlled Substance By Misrepresentation, Fraud, Deception Or Subterfuge

Defendants are in the possession of approximately 90 vials of Alvogen's Midazolam Product. Nevada law makes it unlawful for "a person to knowingly and intentionally . . . [a]cquire or obtain or attempt to acquire or obtain possession of a controlled substance . . . by misrepresentation, fraud, forgery, deception, subterfuge or alteration." NRS § 453.331(1)(d). Defendants each qualify as a "person" for the foregoing, and midazolam is a Schedule IV controlled substance. *See* Compl. ¶ 12; NAC § 453.540(3). As demonstrated below, Defendants obtained possession through deception and subterfuge intended to evade Alvogen's policies against selling its products for use in executions.

Defendants were well aware that they were not authorized to purchase midazolam from Alvogen. By May of 2016, it was well known and widely reported that manufacturers and suppliers of FDA-approved products were universally declining to sell medicines to be used in executions. Compl. ¶ 20. On September 20, 2016, the NDOC sent out 247 requests for proposals to suppliers of drugs to use in its lethal injection protocol, but not a single supplier was willing to supply. Compl. ¶ 19. On April 20, 2018, Alvogen sent a letter directly to the Governor of Nevada and Defendants NDOC and Dzurenda notifying them that they were not authorized to purchase Alvogen medicines for executions either directly or through a distributor. Compl. ¶¶ 23-26; Sweet Decl. ¶ 4. In that letter, Alvogen told Defendants "in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment" and that Alvogen was actively taking steps "to ensure that [its] products are not purchased for use in lethal injection executions." Sweet Decl. ¶ 4, Ex. A.

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400 South 7th Street, Suite 300
Las Vegas, Nevada 89101

Nonetheless, Defendants circumvented Alvogen's controls and express instructions by issuing purchase orders for the Alvogen Midazolam Product for completion in June 2018 using subterfuge. That subterfuge is apparent from the following:

- Defendants' efforts to acquire the Alvogen Midazolam Product occurred a few weeks after they were provided actual and/or constructive notice by way of the April 20, 2018 letters that Alvogen objected to the use of its product for purposes of execution and refused to supply said product to Defendants (either directly or indirectly), *compare* Sweet Decl. at ¶ 4 & Ex. A (letters dated April 20, 2018) with Ex. 1 (Purchase Orders dated from May 2018);
- The purchase orders identify the shipment location as the Central Pharmacy for the NDOC in Las Vegas (*see* Ex. 3), rather than the Ely facility that has been identified as the site of the proposed execution (Ex. 4, Press Release, NDOC Requests Stay of Execution, November 9, 2017);
- In so doing, NDOC created the impression 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 the Nevada controlled substances statute and Nevada State Board of Medical Examiners regulations (Compl. at ¶ 38);
- Plaintiff reasonably believes and contends that Defendants acquired the Alvogen Midazolam Product without disclosing to the unsuspecting distributor the contents of the April Alvogen Letters and/or the fact that they sought to obtain the Alvogen Midazolam Product for non-therapeutic purposes (*i.e.*, an execution), *see* Compl. ¶¶ 49, 60, and that Defendants could not have acquired the Alvogen Midazolam Product had they disclosed those salient facts (*id.*);
- The reasonableness of Plaintiff's contention and belief is underscored by its published written policy on the matter (Ex. 5, Website notice regarding the Alvogen Midazolam Product), its warning to Defendants that they could not and should not attempt to obtain the Alvogen Midazolam Product because "Alvogen has controls in place and directs its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions," (Sweet Decl. ¶ 4 & Ex. A), its communications with Cardinal in the Fall of 2017 which led Alvogen to understand that Cardinal would not sell to prisons for such purposes

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400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

(Harker Decl. ¶ 9), and its verification that no such sales had taken place since launch upon examining sales data through the First Quarter of 2018 (*id.*); and

- Defendants have acknowledged that they took efforts to maintain the secrecy of and/or conceal the fact of their acquisition of Alvogen midazolam 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." *Order* at 4, *ACLU Nev. Found. v. State*, No. 18-OC-00163 (Nev. Carson City 1st Dist. 2018).

The foregoing conduct plainly qualifies as "subterfuge" within the meaning of the statute. *See United Airlines, Inc. v. McMann*, 434 U.S. 192, 203 (1977) ("In ordinary parlance, and in dictionary definitions as well, a subterfuge is a scheme, plan, stratagem, or artifice of evasion."); *State v. Logan*, 59 Nev. 24, 83 P.2d 1035, 1039 (1938) (upholding defendant's conviction for "willfully, unlawfully and feloniously attempt[ing] to obtain a narcotic drug, to-wit morphine, by fraud, deceit, misrepresentation and subterfuge" where defendant took a blank prescription form from a doctor's office and filled it out himself, forged the doctor's signature, and presented it to be filled at a pharmacy); CAMBRIDGE DICTIONARY https://dictionary.cambridge.org/us/dictionary/english/subterfuge ("Subterfuge: an action taken to hide something from someone").

Finally, Plaintiffs reasonably contend that there is a private right of action implied within NRS § 453.331. The test for implying such a cause of action was articulated by the Nevada Supreme Court:

> Whether a private cause of action can be implied is a question of legislative intent. To ascertain the Legislature's intent in the absence of plain, clear language, we examine the entire statutory scheme, reason, and public policy. In so doing, we are guided by three factors originally set forth by the U.S. Supreme Court: (1) whether the plaintiffs are "'of the class for whos[e] special benefit the statute was enacted'"; (2) whether the legislative history indicates any intention to create or to deny a private remedy; and (3) whether implying such a remedy is "'consistent with the underlying purposes of the legislative [sch]eme.'"

Baldonado v. Wynn Las Vegas, LLC, 124 Nev. 951, 958, 194 P.3d 96, 100-01 (2008) (citations and footnotes omitted). As noted, the statute makes it "unlawful for a person knowingly" to

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LAS VEGAS, NEVADA 89101

"[a]cquire or obtain or attempt to acquire or obtain possession of a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge or alteration," and prescribes that conduct to be a felony. NRS § 453.331. With regard to the first factor, while the statute certainly benefits the citizenry as a whole, it particularly benefits suppliers like Alvogen – manufacturers, suppliers, and distributors are members of the special class of persons who would particularly benefit from subsection (d) because they are the entities who would be the victims of such conduct. With regard to the second factor, at present, Alvogen is not aware of any legislative history that speaks to that particular inquiry. And with regard to the third factor, there is little doubt that implying such a remedy is consistent with the underlying purposes of the legislative scheme, as injunctive relief against the further use of improperly acquired controlled substances minimizes the chances for misuse. Such a private right of action is also consistent with the "public interest" dictates identified elsewhere in the statute, which include, *inter alia*, "[m]aintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research or industrial channels," as well as "[c]ompliance with state and local law." NRS § 453.231.[4]

2. Acquisition By A Physician Of A Controlled Substance By Subterfuge

Nevada law prohibits a physician from "[a]cquir[ing] any controlled substances from any pharmacy or other source by misrepresentation, fraud, deception or subterfuge." NAC § 630.230(d). Here, Plaintiffs understand that Defendant Azzam, the Nevada Chief Medical Officer, a licensed physician, acquired and/or directed the acquisition of the Alvogen Midazolam Product by or for Defendants and in active concert with the other Defendants. Compl. ¶ 61. The available press reports support Alvogen's claim, as Defendants have announced that "[t]he current State of Nevada Chief Medical Officer concurred that the drugs in the NDOC execution protocol (Midazolam, Fentanyl and Cisatracurium) are appropriate and effective for the use intended." (Ex. 6; July 6, 2018 Press Release).

[4] Even were there no implied right of action available, Defendants' conduct in violation of NRS § 453.331 demonstrates that their conduct is "unlawful" for purposes of Alvogen's claim for violation of NRS § 41.700(1)(a).

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400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

The facts, as discussed above, show that the acquisition occurred by way of subterfuge. (*See supra* at 13). Dr. Azzam's improper acquisition of Alvogen's product thus plainly violates Nevada law in this respect as well. The law creates no exception for government actors. *See Jaworski v. R. I. Board of Regents*, 530 F. Supp. 60, 65 (D.R.I. 1981) ("It is elementary that government must follow the law just as private citizens must."); *Equal Employment Opportunity Commission v. CRST Van Expedited, Inc.*, 2009 WL 2524402, *19 (Aug. 13, 2009, N.D. Iowa) ("The government, like its citizens, must follow the law.").

Plaintiffs reasonably contend that there is a private right of action implied within NAC § 630.230(d). Under the first factor of the three-part *Baldonado* inquiry set forth above, manufacturers like Alvogen are members of the special class of persons who would particularly benefit from NAC § 630.230(d) because the provision seeks to ensure that controlled substances are distributed and used lawfully. The provision ensures that physicians only obtain controlled substances for intended, lawful purposes, providing full disclosure in their relationships with "other source[s]" like manufacturers. As such, the risk of misuse of controlled substances is diminished and so is any liability for the manufacturer that often attaches to misuse. Still further, the provision seeks to protect Alvogen's property from a taking by deceitful means. Under the second factor, Alvogen, at present, is unaware of regulatory or legislative history that addresses this issue. And as to the third factor, implying a private right of action serves the legislative scheme's purpose by protecting authorized sources of controlled substances against unlawful taking and providing a remedy for such taking after it occurs.[5]

3. UNLAWFUL OBTAINMENT OF A CONTROLLED SUBSTANCE

Under Nevada law, "a person shall not . . . [u]nlawfully take, obtain or attempt to take or obtain a controlled substance or a prescription for a controlled substance from a manufacture, 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.

[5] Even were there no implied right of action available, Defendants' conduct in violation of NAC § 630.230(d) demonstrates that their conduct is "unlawful" for purposes of Alvogen's claim for violation of NRS § 41.700(1)(a).

PISANELLI BICE PLLC
400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

Defendants obtained the Alvogen Midazolam Product in an unlawful manner because, *inter alia*, it was obtained from Alvogen and/or Cardinal Health – both of whom are "authorized to . . . dispense or possess controlled substances" – by way of misrepresentation, deception, evasion, and/or subterfuge, in violation of NRS § 453.331(1)(d); NAC § 630.230(d). Further, Defendants obtained the Alvogen Midazolam Product in an unlawful manner for the reasons explained below, as Defendants' acquisition of the Alvogen Midazolam Product 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. *See* disc. *infra* at 17-19.

Plaintiff reasonably contends that there is a private right of action implied within NRS § 453.391(1).[6] As to the first *Baldonado* factor, "manufacturer[s]" and "wholesaler[s]" like Alvogen are members of the class of persons who would particularly benefit from NAC § 453.391(1) because the statute seeks to ensure that their products are obtained lawfully. The statute is clearly intended to protect such authorized persons—explicitly including manufacturers and wholesalers—against unlawful takings. Under the second factor, Alvogen, at present, is unaware of legislative history that addresses this issue. And with respect to the third factor, implying such a right is consistent with the purpose of the legislative scheme to protect parties involved with the dispensation and administration of controlled substances against unlawful taking and provide a remedy for such taking after it occurs. An injunctive remedy allows Alvogen to recover its own property that was unlawfully taken. Such a right also furthers the public interest aims of the statute to protect the public against the diversion of controlled substances.

4. ADMINISTRATION OF A CONTROLLED SUBSTANCE FOR AN ILLEGITIMATE PURPOSE

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.

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[6] Even were there no implied right of action available, Defendants' conduct in violation of NRS § 453.391(1) demonstrates that their conduct is "unlawful" for purposes of Alvogen's claim for violation of NRS § 41.700(1)(a).

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400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

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* Ex. 5 (Nev. Dep't. of Corr., *Execution Manual Sec. 110.02 – Execution of Condemned Inmate* eff. June 11, 2018); Ex. 6 (Press Release, July 6, 2018) ("As part of the execution protocol, an attending physician, who is a practicing physician in the State of Nevada, will attend the execution.").

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 that patient. *See, e.g.*, Ctr. for Medicare & Medicaid Servs., *Glossary* https://www.cms.gov/apps/glossary/default.asp?Letter=ALL (last visited July 8, 2018) (defining the attending physician as the licensed physician "who has primary responsibility for the patient's medical care and treatment"); Educ. Comm'n for Foreign Medic. Students, Health Care Team https://www.ecfmg.org/echo/team-doctors-attending-physician.html (last visited July 8, 2018) (stating that the attending physician is "ultimately responsible for all patient care" and "has legal and ethical responsibility for directing care of the patient."). Given the nature of the attending physician role and the drug at issue, the attending physician may not delegate those responsibilities. *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").

Execution by lethal injection using the Alvogen Midazolam Product is not a "legitimate medical purpose" given the lone uses for which it is approved. *See, e.g.*, Ex. 6 (AMA Code of Med. Ethics Op. 9.7.3, stating, "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"); Harker Decl. ¶ 6 (listing approved uses).

Accordingly, to the extent permitted to implement Defendants' proposed execution protocol, John Doe I will violate Nevada law by directing the administration of the Alvogen

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400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

Midazolam Product, a controlled substance, for a purpose that is outside of the therapeutic purposes set forth in the Alvogen labeling and for a use (ending a life) that does not qualify as a legitimate medical purpose.

Plaintiff also maintains that there is a private right of action under NRS § 453.381(1).[7] As to the first *Baldonado* factor, manufacturers like Alvogen are members of the class of persons who would specially benefit from § 453.381(1) because the statute seeks to ensure that their products are only used for intended, safe, and therapeutic purposes. The requirement that physicians only administer controlled substances for a legitimate medical purpose can be reasonably construed to protect three classes of persons—manufacturers (and other similarly situated parties, such as distributors), health care payers, and patients—the purpose of the requirement being to protect manufacturers, distributors, and payers from the risk of fraud and liability and to protect patients from harm. Under the second factor, Alvogen, at present, is unaware of legislative history that addresses this issue. And under the third factor, a private right action is consistent with the protective goal of the statutory scheme and would allow affected parties to proactively avoid the harm that would come from the use of controlled substances outside of legitimate medical purposes and to remedy such harm after it occurs.

5. LIABILITY FOR DAMAGES CAUSED BY USE OF CONTROLLED SUBSTANCE

Under Nevada law, a person who "[k]nowingly and unlawfully services, sells or otherwise furnishes a controlled substance to another person" is "liable in a civil action for any damages caused as a result of the person using the controlled substance." NRS § 41.700(1)(a). In addition, 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 in a civil action for any damages caused as a result of the person using the controlled substance." NRS 41.700(1)(b).

Defendants' conduct violates the foregoing for multiple reasons. Initially, Defendants have announced that they intend to furnish the Alvogen Midazolam Product to John Doe I and/or

[7] Even were there no implied right of action available, Defendants' conduct in violation of NRS § 453.381(1) demonstrates that their conduct is "unlawful" for purposes of Alvogen's claim for violation of NRS § 41.700(1)(a).

PISANELLI BICE PLLC
400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

non-physician administrators for purposes of the scheduled execution. *See* Ex. 6 (Press Release, July 6, 2018 at 1) ("As part of the execution protocol, an attending physician, who is a practicing physician in the State of Nevada, will attend the execution."); Ex. 7 (Execution Manual) at § 103.3 ("The Drug Administrators will be two individuals who, based on their years of experience and proven performance within the corrections industry, are uniquely trusted to perform the sensitive and critical tasks of properly preparing the lethal drugs for the execution, and injecting the lethal drugs into the condemned inmate per the these instructions when so ordered."). The foregoing means that the controlled substance will be "unlawfully . . . furnish[ed]" on myriad grounds:

- Defendants intend to imminently furnish the controlled midazolam substance, which was obtained unlawfully from Alvogen and/or Cardinal Health by way of subterfuge, in violation of NRS § 453.331(1)(d) and NAC § 630.230(d), *see* disc. *supra* at 12-15.
- Defendants have announced that they will imminently furnish the controlled midazolam product to John Doe I, the attending physician, for purposes of unlawfully administering it for a non-therapeutic use (an execution), for which it is not approved and therefore which is unlawful under NRS § 453.381(1), *see* disc. *supra* at 17-19.
- Defendants' furnishing is unlawful as Defendants' acquisition of the product was in derogation of, and violates, Alvogen's property rights, *see* disc. *infra* at 20-24.

Defendants also threaten to imminently violate subpart (b), which makes them liable for "[k]nowingly allow[ing] 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." NRS § 41.700(1)(b). There is no doubt that Defendants control the Ely facility. *See* Ex. 4 (Press Release, NDOC Requests Stay of Execution, Nov. 9, 2017). Defendants intend to imminently allow another person – John Doe I and/or non-physician administrators – to use a controlled substance (the Alvogen Midazolam Product) on their premises. *See id.; see also* (Ex. 7) (Execution Manual) at *passim*. Defendants' proposed conduct is unlawful for the reasons set forth *supra*. *See* disc. *supra* at 12-19. Defendants' imminently threatened wrongdoing will be in violation of Nevada law for this independent reason.

PISANELLI BICE PLLC
400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

6. THE DOCTRINE OF REPLEVIN MANDATES THE RETURN OF ALVOGEN'S PROPERTY

Defendants are wrongfully in the possession of Alvogen's property, the Alvogen Midazolam product. The doctrine of replevin allows for Alvogen's recovery of its own property. Replevin involves four elements. (1) Plaintiff's ownership of the property; (2) a right to immediate possession; (3) defendant's wrongful taking of the property; and (4) a demand for its return. *Johnson v. Johnson*, 27 P.2d 532, 533 (1933).

Alvogen meets all four elements and is therefore entitled to the return of its property. Alvogen owns the property and has a right to its immediate possession because at the time Defendants attempted to purchase it, they were aware from the April 2018 letter that they could not purchase the Midazolam product and that Alvogen's distributors were not authorized to sell them the Midazolam product. *See* Sweet Decl. ¶ 4 and Exs. A & B. Thus, Defendants could not in good faith acquire title to the Alvogen Midazolam Product.[8]

For the reasons discussed above, NDOC wrongfully took possession of the Alvogen Midazolam Product by using an intermediary to circumvent Alvogen's controls on the product's sale and tacitly misrepresenting that it would be used for a legitimate medical purpose. Harker Decl. ¶¶ 9-14; Sweet Decl. ¶ 5. Alvogen demanded the return of such products in its April 2018 letter. *See* Sweet Decl. ¶ 4 and Exs. A & B. Indeed, Alvogen even offered to provide a full refund for the wrongfully acquired products. *Id.* Yet, Defendants have refused that demand and remain in possession of the illegitimately acquired Midazolam Product. As such, Alvogen is entitled to the return of its property.

[8] Defendants actual or constructive knowledge that Alvogen's distributor was not authorized to sell the Alvogen Midazolam Product and that Alvogen refused to sell to Defendants – as well of their subterfuge detailed *supra* – prevents them from qualifying as either a "good faith purchaser for value" under NRS 104.2403(1) or a "buyer in ordinary course of business" under NRS § 104.2403(2). *See Tempur-Pedic Int'l., Inc v. Waste To Charity, Inc.*, No. 07-2015, 2007 WL 535041, at *1-2 (W.D. Ark. Feb. 16, 2007) (granting a preliminary injunction on the basis that a company that purchased products from an intermediary under circumstances suggesting that the intermediary lacked authority to sell them was not a "good faith purchaser" capable of receiving title); *see also* disc. *supra* at pp. 9-10, 12-15 (detailing Alvogen's clear statements that Alvogen's distributors were not authorized to sell midazolam to prisons).

PISANELLI BICE PLLC
400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

Alvogen has a property right in both its Midazolam product 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, [a]nd, 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). Alvogen 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*, Alvogen specifically wrote to the Nevada Department of Corrections (through the Warden at the prison at which the Execution is to take place) and the Nevada Attorney General to specifically warn them that they were customers with whom Alvogen refused to deal – both directly and indirectly – with regard to the acquisition of its Midazolam Product. *See* disc. *supra* at 6-8.

The closest authority of which Alvogen is aware supports a TRO based on replevin. In *McKesson Medical-Surgical Inc. v. State*, a medication distributor sued the Arkansas Department of Corrections for circumventing controls the distributor had in place to prevent the purchase of drugs for use in lethal injection. Pls.' Compl. ¶¶ 13-15; Ex. 9 (*McKesson Medical-Surgical Inc. v. State*, No. 60CV-17-1960 (Ark. Cir. Ct. Apr. 20, 2017)). The court found that McKesson had established a reasonable probability of success on its claim for replevin and, therefore, granted a preliminary injunction. Ex. 9 (*McKesson Medical-Surgical Inc. v. State*, No. 60CV-17-1960 (Ark. Cir. Ct. Apr. 20, 2017) (order granting preliminary injunction ¶¶ 6, 8). Alvogen is entitled to a similar injunction in this case.

7. DEFENDANTS HAVE CONVERTED THE ALVOGEN MIDAZOLAM PRODUCT

Alvogen is also entitled to the return of its property under the doctrine of conversion. Conversion is "a distinct act of dominion wrongfully exerted over another's personal property in denial of, or inconsistent with his title or rights therein or in derogation, exclusion, or defiance of such title or rights." *M.C. Multi-Family Dev., L.L.C. v. Crestdale Assocs., Ltd.*, 124 Nev. 901, 910, 193 P.3d 536, 542 (2008). Further, "conversion is an act of general intent, which does not

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LAS VEGAS, NEVADA 89101

require wrongful intent and is not excused by care, good faith, or lack of knowledge." *Id.* at 910-11, 193 P.3d at 542-43.

Defendants committed a wrongful act of dominion over Alvogen's property when they evaded Alvogen's stated policy of not selling midazolam to prisons by purchasing the product through an unsuspecting intermediary. *See* disc. *supra* at 6-8. Defendants were thus able to illicitly and through subterfuge obtain the Alvogen Midazolam Product in a manner that they would not have been able to accomplish had they disclosed the contents of the April 2018 letter and/or their intended non-therapeutic use of the Alvogen Midazolam Product to the intermediary. *See id.* Defendants' actions are inconsistent with Alvogen's rights in its own property.[9] Thus, Defendants must return Alvogen's wrongfully converted property.

Further, as discussed above, Alvogen has the right to its "own independent discretion as to parties with whom he will deal, [a]nd, of course, [to] announce in advance the circumstances under which he will refuse to sell." *Colgate.*, 250 U.S. at 307. Defendants' decision to circumvent Alvogen's controls and purchase the product against Alvogen's express policies and distributor agreements is a violation of that right that stands to cause significant reputational harm to Alvogen.

8. False Pretenses

Defendants also should be ordered to return Alvogen's property because they obtained it under false pretenses. False pretenses claims require four elements: "(1) intent to defraud, (2) a false representation, (3) justifiable reliance on that representation, and (4) that the victim was defrauded." *Leavitt v. Elizarde*, No. 2:14-cv-01043-JAD-NJK, 2016 WL 270074 at *5 (D. Nev. Jan. 21, 2016) (citing *Bright v. Sheriff, Washoe Cty*, 90 Nev. 168, 170, 521 P.2d 371, 372 (1974)).

Defendants' conduct fulfills all four elements. Alvogen contends and reasonably believes that Defendants intentionally defrauded Alvogen's distributor by concealing the April 2018 letter from the distributor and ordering the Alvogen Midazolam Product. Harker Decl. ¶¶ 9-14; Sweet Decl. ¶ 5; disc. *supra* at 13-14. In doing so, Defendants omitted relevant information and

[9] As discussed above, Defendants were aware that they were not entitled to purchase the Alvogen Midazolam Product and thus could not take title to it in good faith. *See* disc. *supra* at p. 21.

PISANELLI BICE PLLC
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Las Vegas, Nevada 89101

implicitly made the false representation that they had legitimate therapeutic rationale to purchase the Alvogen Midazolam Product. *See id.* Defendants thus obtained Alvogen's property under false pretenses and, as a consequence, threaten significant reputational harm to Alvogen.

C. SOVEREIGN IMMUNITY DOES NOT SHIELD THE STATE'S BAD FAITH CONDUCT

The State of Nevada has "waive[d] its immunity from liability and action" for itself and "all political subdivisions." NRS § 41.031. As such, Defendants are subject to "the same rules of law as are applied to civil actions against natural persons and corporations" and may not raise sovereign immunity as a defense to these claims. *Id.*

Additionally, this case does not fall under any exception to Nevada's sovereign immunity waiver. The most commonly raised, potentially relevant exception is that the wrongful act occurred in "the exercise or performance or the failure to exercise or perform a discretionary function or duty." NRS § 41.032(2). This exception requires two elements: the "decision must (1) involve an element of individual judgment or choice and (2) be based on considerations of social, economic, or political policy." *Martinez v. Maruszczak*, 123 Nev. 433, 446-47, 168 P.3d 720, 729 (2007). The decision to illegitimately subvert Alvogen's controls in order to purchase the Alvogen Midazolam Product does not meet this test because it was not based on a policy decision. Indeed, the Nevada Supreme Court has already held in *Martinez* that individualized medical decisions by doctors do not meet the policy consideration portion of the immunity test. *Id.* at 447, 168 P.3d at 729. Moreover, discretionary-act immunity cannot preclude liability for "intentional torts or bad-faith misconduct" because these bad faith acts are inherently "unrelated to any plausible policy objective."[10] *Franchise Tax Brd. of State of Cal. v. Hyatt*, 133 Nev., Adv. Op. 102, 407 P.3d 717, 733 (2017). Thus, even if the decision did fall within the discretionary-act exemption, sovereign immunity still would not shield Defendants' bad-faith decision to circumvent Alvogen's controls and illegitimately purchase the Alvogen Midazolam Product.

[10] The *McKesson* court similarly found that the Arkansas Department of Correction's refusal to return medication wrongfully purchased for use in lethal injection was an act of bad faith that abrogated sovereign immunity under a similar provision of Arkansas law. *McKesson Med.-Surgical Inc. v. State.*, No. 60CV-17-1960 (Ark. Cir. Ct. Apr. 20, 2017) (order granting preliminary injunction ¶¶ 2-4).

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D. ALVOGEN WILL SUFFER IRREPARABLE HARM IF DEFENDANTS ARE NOT ENJOINED FROM USING THE ALVOGEN MIDAZOLAM PRODUCT FOR DOZIER'S EXECUTION

Alvogen will suffer grave irreparable harm for being associated with Defendants' planned execution of inmate Dozier using the Alvogen Midazolam Product that it refuses to sell (directly or indirectly) for such purposes. Defendants' intended use of Alvogen's midazolam product is contrary to Alvogen's express policies and controlled distribution agreements, and would interfere with the operation of Alvogen's legitimate business by creating public confusion regarding Alvogen's permitted use of the product. First, Alvogen would suffer severe reputational harm were it to be associated with an execution that could be characterized by members of the public as cruel and unusual. Harker Decl. ¶ 18. Second, the prohibited use of Alvogen's product would also negatively impact Alvogen's business relationships, resulting in loss of customers and end-user good will built up over the years. *See id.* In addition, the use of the Alvogen Midazolam Product risks creating the erroneous misperception in the minds of the public, customers, employees, and prospective investors that Alvogen is acting hypocritically in light of its public stance that its therapeutic products are designed to enhance human health. *See id.*

In contravention of Alvogen's express policy and controlled distribution agreements, as well as its multiple enforcement efforts, Defendants intend to misuse the Alvogen Midazolam Product in the upcoming execution of Dozier. Alvogen has a significant commercial interest in ensuring that its contracts are implemented correctly. Such reputational and business harms are immeasurable and cannot be adequately remedied later through a monetary judgment against Defendants. *See Sobol v. Capital Mgmt. Consultants, Inc.*, 102 Nev. 444, 446, 726 P.2d 335, 337 (1986) (finding "acts committed without just cause which unreasonably interfere with a business or destroy its credit or profits, may do an irreparable injury and thus authorize issuance of an injunction"); *see also Finkel v. Cashman Prof., Inc.*, 128 Nev. 68, 73, 270 P.3d 1259, 1263 (2012); *Hosp. Int'l Grp. v. Gratitude Grp., LLC*, 387 P.3d 208 (Nev. 2016) (unpublished) ("loss of its initial investment, incalculable future losses, and damage to the goodwill and reputation of the entities"). In *Sobol*, which addressed a business's attempt to operate with a similar name as its

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competitor, the Nevada Supreme Court affirmed the district court's finding that the misuse of company name injured the competitor by "clearly interfer[ing] with the operation of a legitimate business by creating public confusion, infringing on goodwill, and damaging reputation in the eyes of creditors"). *Sobol,* 102 Nev. at 446, 726 P.2d at 337.

Here too, Defendants' use of the Alvogen Midazolam Product would interfere with the operation of its legitimate business by creating public confusion, infringing on goodwill, and damaging its reputation among business partners and in the public at large. The use of midazolam in executions has been extremely controversial, in part because of the role it played in Oklahoma's high-profile botched execution of Clayton Lockett in April 2014, in Arizona's botched execution of Joseph R. Wood III in July 2014, and in Alabama's botched execution of Ronald Bert in December 2016. Compl. ¶¶ 15-17. As a result of these and other instances of prolonged and botched executions involving the use of midazolam, since Alvogen began distributing midazolam, Alvogen has always had a policy of prohibiting midazolam from being diverted for use in execution protocols. Alvogen has made this policy clear in letters it has sent to the Governors, Attorneys General, and Department of Corrections Directors in every state that has a death penalty, in its controlled distribution agreements, and on its website. Sweet Decl. ¶ 4.

Courts have found irreparable injury in other cases involving fraudulent misuse of contracted-for products that harms a company's reputation. In *Tempur-Pedic Int'l, Inc. v. Waste To Charity, Inc.*, Tempur-Pedic donated mattresses to a charity under a contract that stipulated those mattresses would be distributed to victims of Hurricane Katrina. No. 07-2015, 2007 WL 535041, at *1-2 (W.D. Ark. Feb. 16, 2007). Tempur-Pedic later learned that the charity was selling those donated mattresses to unauthorized retailers who in turn were selling them for below-market rates. *Id.* at *4-5. The court found irreparable injury because "these below market sales cheapen the marketing and brand image that Tempur-Pedic has spent years of effort and millions of dollars to cultivate." *Id.* at *10. In one trademark case, Coca-Cola sought to enjoin another business from using the term "Cocaine-Cola," and the court found irreparable harm because "[t]o associate such a noxious substance as cocaine with plaintiff's wholesome beverage as symbolized by its 'Coca-Cola' trademark and format would clearly have a tendency to impugn

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that product and injure plaintiff's business reputation, as plaintiff contends." *Coca-Cola Co. v. Gemini Rising, Inc.*, 346 F. Supp. 1183, 1189 (E.D.N.Y. 1972). Similarly here, Defendants' misuse of Alvogen's product would be devastating to Alvogen's reputation. Alvogen has spent over 130 years developing its reputation for products that save and enhance lives. Its association with an execution—in particular one that carries the serious risk of being characterized as cruel and unusual—is contrary to Alvogen's mission, philosophy, and policies. *See McKesson Medical-Surgical Inc. v. State.*, No. 60CV-17-1960 (Ark. Cir. Ct. Apr. 20, 2017) (finding that in the absence of a preliminary injunction, a pharmaceutical distributor would suffer irreparable harm—were the State of Arkansas to misuse its product in connection with capital punishment proceedings—which cannot be adequately compensated by money damages or redressed by a court of law).

Alvogen has already faced negative media attention, indicating that damage to Alvogen's reputation, goodwill, and business prospects is imminent. *See* Harker Decl. ¶ 17 and Exs. D & E.

Because this execution is set to proceed immediately, the threatened harms cannot be remedied later. In contrast, Defendants will suffer no harm whatsoever. There is no urgency warranting the immediate ad wrongful use of the Alvogen Midazolam Product by July 11, 2018. Indeed, Defendants have held this inmate for over a decade, and the State of Nevada has not executed an inmate since 2006. Defendants can always pursue their desire to execute Dozier later, and by means other than by way of the improper use of the Alvogen Midazolam Product.

Allowing Defendants to use Alvogen's midazolam product in Dozier's execution will irreparably harm Alvogen beyond what monetary remedies will be able to calculate and provide. Consequently, this Court should enter a temporary restraining order so Alvogen can continue to bring life-enhancing and life-saving products to the doctors and patients who need them.

E. THE BALANCE OF INTERESTS SUPPORTS INJUNCTIVE RELIEF

The balance of interests in this case could not be clearer. If allowed to use Alvogen's midazolam product in the upcoming execution, Defendants will severely harm Alvogen. The harm to Alvogen will be severe because Alvogen has pursued policies and distributor agreements to expressly prohibit the use of its midazolam product in capital punishment proceedings. In light

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of the fact that midazolam has been linked to botched executions, Alvogen will suffer reputational damage and loss of goodwill and will be subject to the risk of future litigation. Alvogen has already received attention in press reports highly critical of the use of its product in the execution of inmate Dozier, scheduled for Wednesday, July 11, 2018. Compl. ¶ 43, Exs. 6, 7. For Defendants, a temporary and/or preliminary injunction will not damage them. To the contrary, the temporary and/or preliminary injunction will serve to allow Defendants to comply with Nevada law as well as Alvogen's express policies and controlled distribution agreements, which they have no right to breach, while preventing them from improperly handling a capital punishment proceeding.

IV. CONCLUSION

Based on the foregoing, Alvogen respectfully requests that a temporary restraining order or preliminary injunction be issued immediately requiring Defendants to discontinue all plans to use the Alvogen Midazolam Product in any executions and to return to Alvogen the 90 vials it wrongfully obtained.

DATED this 10th day of July 2018.

PISANELLI-BICE PLLC

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EXHIBIT 1

DECLARATION OF RICHARD HARKER IN SUPPORT OF PLAINTIFF'S *EX PARTE* APPLICATION FOR TEMPORARY RESTRAINING ORDER AND MOTION FOR PRELIMINARY INJUNCTION; *EX PARTE* MOTION FOR ORDER SHORTENING TIME

I, RICHARD HARKER, declare as follows:

1. I am Alvogen's Vice President of Sales, Marketing, and Commercial Operations for the US Injectables business unit, and am competent to testify to the matters stated herein based upon personal knowledge, except for those matters stated upon information and belief, and to those matters, I believe them to be true.

2. If called as a witness, I would testify competently thereto.

3. I make this Declaration in support of Alvogen, Inc.'s ("Alvogen") *Ex Parte* Application for Temporary Restraining Order and Motion for Preliminary Injunction; *Ex Parte* Motion for Order Shortening Time.

4. Alvogen is a leading pharmaceutical company focused on developing, manufacturing and selling life-saving and life-enhancing products around the world.

5. Committed to patients' safety, Alvogen endorses the use of its products in accordance with FDA-approved indications. Alvogen's products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

6. In August 2017, Alvogen began selling generic midazolam, which is an injectable medication indicated for the following:

> intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia; intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures either alone or in combination with other CNS depressants; intravenously for induction of general anesthesia, before administration of other anesthetic agents; and for continuous intravenous infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

A true and correct copy of the labeling for the Alvogen midazolam hydrochloride product is attached hereto as Exhibit A.

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7. Due to controversy over the use of midazolam in lethal injections, Alvogen has undertaken controls to avoid diversion of midazolam and prohibit its use in executions.

8. Alvogen has also sought to reinforce this policy by including the following notice on its website's description of midazolam:

> Alvogen endorses the use of its products in accordance with FDA-approved indications. To this end, Alvogen has undertaken controls to avoid diversion of this product for use in execution protocols. In furtherance of this effort, Alvogen does not accept direct orders from prison systems or departments of correction. In addition, Alvogen is working to ensure that its distributors and wholesalers do not resell, either directly or indirectly this product, to prison systems or departments of correction.

Attached as Exhibit B to this Declaration is a true and correct copy of the website.

9. When Alvogen began selling midazolam, I was under the impression from communications with our distributor, Cardinal Health ("Cardinal"), that Cardinal was not selling Midazolam to the correctional facility customer base. Consistent with my impression, when we looked at sales data in Q1 2018, we did not observe any purchases by correctional facilities in the months following our launch. Alvogen and Cardinal subsequently entered into negotiations regarding the formal terms on which Cardinal would restrict such sales.

10. Thereafter, Alvogen and Cardinal amended their Generic Wholesale Service Agreement to include sales under Alvogen's Controlled Distribution Program Schedule, effective May 28, 2018 ("Controlled Distribution Agreement"). That agreement provides, "Cardinal Health agrees to restrict the distribution and sale of certain Products in accordance with the terms and in exchange for the Service Fees described in the Controlled Distribution Program Schedule attached to this agreement." The Controlled Distribution Program Schedule provides that certain customers are ineligible to purchase products subject to the Controlled Distribution Program, including Midazolam and Rocuronium Bromide. Consistent with its website, Alvogen communicated to Cardinal that correctional facilities are ineligible customers. Attached as Exhibit C to this Declaration is a true and correct copy of the Controlled Distribution Agreement.

11. On July 7, 2018, I learned that Alvogen was contacted by at least one member of the press, who conveyed that Nevada had announced its intent to conduct the execution of Scott

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Raymond Dozier on Wednesday, July 11, 2018 by use of a three-drug cocktail, including midazolam distributed by Alvogen.

12. NDOC never disclosed to Alvogen that NDOC intended to use its product in connection with executions.

13. Upon review of Cardinal's sales on July 7, 2018, Alvogen discovered that the Nevada Department of Correction Center Pharmacy had issued purchase orders from Cardinal 50mg/10ml of Midazolam on May 9 and May 11, 2018, respectively, and 25mg/5ml of Midazolam on May 29, 2018. The purchase orders indicate that the purchases were to be completed by way of payment in June 2018.

14. Given the foregoing, my understanding is that each of the acquisitions by NDOC occurred after the effective May 28, 2018 Controlled Distribution Agreement date.

15. Should Defendants use Alvogen's midazolam product in the execution of Mr. Dozier, Alvogen will suffer immediate and irreparable harm.

16. Defendants' intended use of Alvogen's midazolam product is contrary to Alvogen's express policies, and would interfere with the operation of Alvogen's legitimate business by creating public confusion regarding Alvogen's permitted use of the product.

17. Alvogen has already received extremely critical press in association with the planned use of its product in Mr. Dozier's execution, and linking midazolam to multiple botched executions in other states. Attached as Exhibit D to this Declaration is a true and correct copy of the July 5, 2018 Fox News article, "Drug company threatens legal action to prevent drug from being used in Dozier's execution." Attached as Exhibit E to this Declaration is a true and correct copy of the July 7, 2018 Associated Press article, "Nevada releases records on sedative to be used in execution."

18. Defendants' use of the Alvogen Midazolam Product at Mr. Dozier's execution would cause severe reputational harm were Alvogen to be associated with an execution that could be characterized by members of the public as cruel and unusual. In my view, the use of Alvogen Midazolam Product at Mr. Dozier's execution would also result in loss of customer and end-user good will built up over the years.

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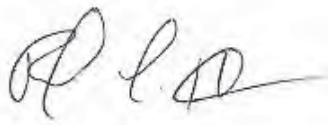
19. Such reputational and business harm to Alvogen would be immeasurable. Calculating money damages to redress the loss of business and customer relationships that would produce an indeterminate amount of business in years to come cannot be quantified in terms of a specific amount of lost sales.

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

Executed on July 9, 2018.



RICHARD HARKER

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EXHIBIT A

DAILYMED

LABEL: MIDAZOLAM- midazolam hydrochloride injection, solution

VIEW PACKAGE PHOTOS

NDC Code(s): 47781-589-17, 47781-589-20, 47781-589-22, 47781-589-91
Packager: Alvogen Inc.

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: CIV
Marketing Status: Abbreviated New Drug Application

DRUG LABEL INFORMATION

Updated May 31, 2017

If you are a consumer or patient please visit this version.

VIEW ALL SECTIONS

BOXED WARNING (WHAT IS THIS?)

Personnel and Equipment for Monitoring and Resuscitation Adults and Pediatrics: Intravenous midazolam hydrochloride has been associated with respiratory depression and ...

WARNINGS

Personnel and Equipment for Monitoring and Resuscitation

Adults and Pediatrics: Intravenous midazolam hydrochloride has been associated with respiratory depression and respiratory arrest, especially when used for sedation in noncritical care settings. In some cases, where this was not recognized promptly and treated effectively, death or hypoxic encephalopathy has resulted. Intravenous midazolam hydrochloride should be used only in hospital or ambulatory care settings, including physicians' and dental offices, that provide for continuous monitoring of respiratory and cardiac function, e.g., pulse oximetry. Immediate availability of resuscitative drugs and age- and

APP0190

size-appropriate equipment for bag/valve/mask ventilation and intubation, and personnel trained in their use and skilled in airway management should be assured (see WARNINGS). For deeply sedated pediatric patients, a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.

Risks From Concomitant Use With Opioids

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Monitor patients for respiratory depression and sedation (see WARNINGS and PRECAUTIONS, DRUG INTERACTIONS).

Individualization of Dosage

Midazolam hydrochloride must never be used without individualization of dosage. The initial intravenous dose for sedation in adult patients may be as little as 1 mg, but should not exceed 2.5 mg in a normal healthy adult. Lower doses are necessary for older (over 60 years) or debilitated patients and in patients receiving concomitant narcotics or other central nervous system (CNS) depressants. The initial dose and all subsequent doses should always be titrated slowly; administer over at least 2 minutes and allow an additional 2 or more minutes to fully evaluate the sedative effect. The use of the 1 mg/mL formulation or dilution of the 1 mg/mL or 5 mg/mL formulation is recommended to facilitate slower injection. Doses of sedative medications in pediatric patients must be calculated on a mg/kg basis, and initial doses and all subsequent doses should always be titrated slowly. The initial pediatric dose of midazolam for sedation/anxiolysis/amnesia is age, procedure, and route dependent (see DOSAGE AND ADMINISTRATION for complete dosing information).

Neonates: Midazolam should not be administered by rapid injection in the neonatal population. Severe hypotension and seizures have been reported following rapid IV administration, particularly with concomitant use of fentanyl (see DOSAGE AND ADMINISTRATION for complete information).

CLOSE

SPL UNCLASSIFIED SECTION

NOT FOR USE IN NEONATES

CONTAINS BENZYL ALCOHOL

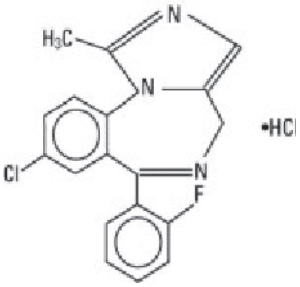
Rx only

CLOSE

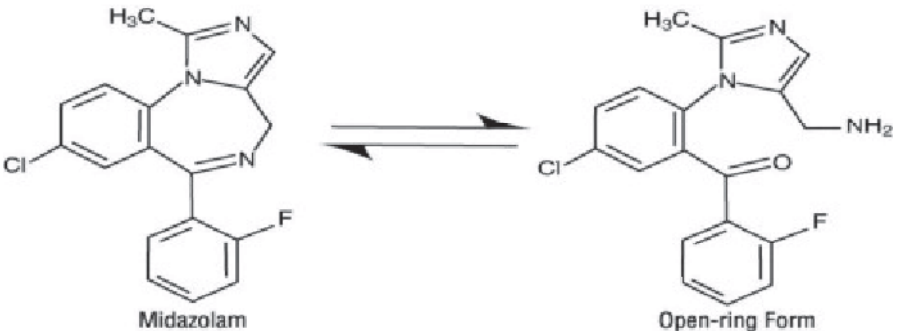
DESCRIPTION

Midazolam hydrochloride is a water-soluble benzodiazepine available as a sterile, nonpyrogenic parenteral dosage form for intravenous or intramuscular injection. Each mL contains midazolam hydrochloride equivalent to 5 mg midazolam compounded with 0.8% sodium chloride and 0.01% edetate disodium, with 1% benzyl alcohol as preservative; the pH is adjusted to 2.9 to 3.5 with hydrochloric acid and, if necessary, sodium hydroxide.

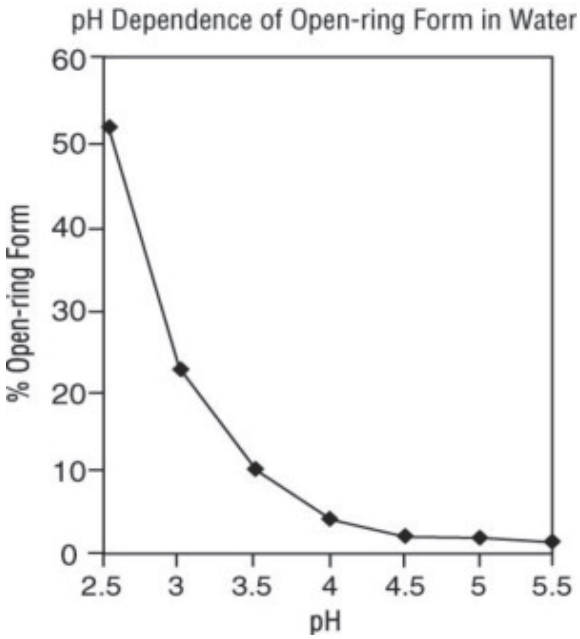
Midazolam is a white or yellowish crystalline powder, insoluble in water. The hydrochloride salt of midazolam, which is formed *in situ*, is soluble in aqueous solutions. Chemically, midazolam HCl is 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-imidazo[1,5-a][1,4]benzodiazepine hydrochloride. Midazolam hydrochloride has the empirical formula C18H13ClFN3•HCl, a calculated molecular weight of 362.25 and the following structural formula:



Under the acidic conditions required to solubilize midazolam in the product, midazolam is present as an equilibrium mixture (shown below) of the closed ring form shown above and an open-ring structure formed by the acid-catalyzed ring opening of the 4,5-double bond of the diazepine ring. The amount of open-ring form is dependent upon the pH of the solution. At the specified pH of the product, the solution may contain up to about 25% of the open-ring compound. At the physiologic conditions under which the product is absorbed (pH of 5 to 8) into the systemic circulation, any open-ring form present reverts to the physiologically active, lipophilic, closed-ring form (midazolam) and is absorbed as such.



The following chart plots the percentage of midazolam present as the open-ring form as a function of pH in aqueous solutions. As indicated in the graph, the amount of open-ring compound present in solution is sensitive to changes in pH over the pH range specified for the product: 3.0 to 3.6 for the 5 mg/mL concentration. Above pH 5, at least 99% of the mixture is present in the closed-ring form.



CLOSE

CLINICAL PHARMACOLOGY

Midazolam is a short-acting benzodiazepine central nervous system (CNS) depressant.

Pharmacodynamics

The effects of midazolam hydrochloride on the CNS are dependent on the dose administered, the route of administration, and the presence or absence of other medications. Onset time of sedative effects after IM administration in adults is 15 minutes, with peak sedation occurring 30 to 60 minutes following injection. In one adult study, when tested the following day, 73% of the patients who received midazolam hydrochloride intramuscularly had no recall of memory cards shown 30 minutes following drug administration; 40% had no recall of the memory cards shown 60 minutes following drug administration. Onset time of sedative effects in the pediatric population begins within 5 minutes and peaks at 15 to 30 minutes depending upon the dose administered. In pediatric patients, up to 85% had no recall of pictures shown after receiving intramuscular midazolam compared with 5% of the placebo controls.

Sedation in adult and pediatric patients is achieved within 3 to 5 minutes after intravenous (IV) injection; the time of onset is affected by total dose administered and the concurrent administration of narcotic premedication. Seventy-one percent of the adult patients in endoscopy studies had no recall of introduction of the endoscope; 82% of the patients had no recall of withdrawal of the endoscope. In one study of pediatric patients undergoing lumbar puncture or bone marrow aspiration, 88% of patients had impaired recall vs 9% of the placebo controls. In another pediatric oncology study, 91% of midazolam treated patients were amnestic compared with 35% of patients who had received fentanyl alone.

When midazolam hydrochloride is given IV as an anesthetic induction agent, induction of anesthesia occurs in approximately 1.5 minutes when narcotic premedication has been administered and in 2 to 2.5 minutes without narcotic premedication or other sedative premedication. Some impairment in a test of memory was noted in 90% of the patients studied. A dose response study of pediatric patients premedicated with 1 mg/kg intramuscular (IM) meperidine found that only 4 out of 6 pediatric patients who received 600 mcg/kg IV midazolam lost consciousness, with eye closing at 108 to 140 seconds. This

group was compared with pediatric patients who were given thiopental 5 mg/kg IV; 6 out of 6 closed their eyes at 20 ± 3.2 seconds. Midazolam did not dependably induce anesthesia at this dose despite concomitant opioid administration in pediatric patients.

Midazolam, used as directed, does not delay awakening from general anesthesia in adults. Gross tests of recovery after awakening (orientation, ability to stand and walk, suitability for discharge from the recovery room, return to baseline Trieger competency) usually indicate recovery within 2 hours but recovery may take up to 6 hours in some cases. When compared with patients who received thiopental, patients who received midazolam generally recovered at a slightly slower rate. Recovery from anesthesia or sedation for procedures in pediatric patients depends on the dose of midazolam administered, coadministration of other medications causing CNS depression and duration of the procedure.

In patients without intracranial lesions, induction of general anesthesia with IV midazolam hydrochloride is associated with a moderate decrease in cerebrospinal fluid pressure (lumbar puncture measurements), similar to that observed following IV thiopental. Preliminary data in neurosurgical patients with normal intracranial pressure but decreased compliance (subarachnoid screw measurements) show comparable elevations of intracranial pressure with midazolam and with thiopental during intubation. No similar studies have been reported in pediatric patients.

The usual recommended intramuscular premedicating doses of midazolam hydrochloride do not depress the ventilatory response to carbon dioxide stimulation to a clinically significant extent in adults. Intravenous induction doses of midazolam hydrochloride depress the ventilatory response to carbon dioxide stimulation for 15 minutes or more beyond the duration of ventilatory depression following administration of thiopental in adults. Impairment of ventilatory response to carbon dioxide is more marked in adult patients with chronic obstructive pulmonary disease (COPD). Sedation with IV midazolam does not adversely affect the mechanics of respiration (resistance, static recoil, most lung volume measurements); total lung capacity and peak expiratory flow decrease significantly but static compliance and maximum expiratory flow at 50% of awake total lung capacity (Vmax) increase. In one study of pediatric patients under general anesthesia, intramuscular midazolam (100 mcg/kg or 200 mcg/kg) was shown to depress the response to carbon dioxide in a dose-related manner.

In cardiac hemodynamic studies in adults, IV induction of general anesthesia with midazolam hydrochloride was associated with a slight to moderate decrease in mean arterial pressure, cardiac output, stroke volume and systemic vascular resistance. Slow heart rates (less than 65/minute), particularly in patients taking propranolol for angina, tended to rise slightly; faster heart rates (e.g., 85/minute) tended to slow slightly. In pediatric patients, a comparison of IV midazolam hydrochloride (500 mcg/kg) with propofol (2.5 mg/kg) revealed a mean 15% decrease in systolic blood pressure in patients who had received IV midazolam vs a mean 25% decrease in systolic blood pressure following propofol.

Pharmacokinetics

Midazolam's activity is primarily due to the parent drug. Elimination of the parent drug takes place via hepatic metabolism of midazolam to hydroxylated metabolites that are conjugated and excreted in the urine. Six single-dose pharmacokinetic studies involving healthy adults yield pharmacokinetic parameters for midazolam in the following ranges: volume of distribution (Vd), 1.0 to 3.1 L/kg; elimination half-life, 1.8 to 6.4 hours (mean approximately 3 hours); total clearance (Cl), 0.25 to 0.54 L/hr/kg. In a parallel group study, there was no difference in the clearance, in subjects administered 0.15 mg/kg (n=4) and 0.30 mg/kg

(n=4) IV doses indicating linear kinetics. The clearance was successively reduced by approximately 30% at doses of 0.45 mg/kg (n=4) and 0.6 mg/kg (n=5) indicating non-linear kinetics in this dose range.

Absorption

The absolute bioavailability of the intramuscular route was greater than 90% in a crossover study in which healthy subjects (n=17) were administered a 7.5 mg IV or IM dose. The mean peak concentration (Cmax) and time to peak (Tmax) following the IM dose was 90 ng/mL (20% CV) and 0.5 hour (50% CV). Cmax for the 1-hydroxy metabolite following the IM dose was 8 ng/mL (Tmax=1.0 hour).

Following IM administration, Cmax for midazolam and its 1-hydroxy metabolite were approximately one-half of those achieved after intravenous injection.

Distribution

The volume of distribution (Vd) determined from six single-dose pharmacokinetic studies involving healthy adults ranged from 1.0 to 3.1 L/kg. Female gender, old age, and obesity are associated with increased values of midazolam Vd. In humans, midazolam has been shown to cross the placenta and enter into fetal circulation and has been detected in human milk and CSF (see SPECIAL POPULATIONS).

In adults and pediatric patients older than 1 year, midazolam is approximately 97% bound to plasma protein, principally albumin and that for 1-hydroxy metabolite is about 89%.

Metabolism

In vitro studies with human liver microsomes indicate that the biotransformation of midazolam is mediated by cytochrome P450-3A4. This cytochrome also appears to be present in gastrointestinal tract mucosa as well as liver. Sixty to seventy percent of the biotransformation products is 1-hydroxy-midazolam (also termed alpha-hydroxy-midazolam) while 4-hydroxy-midazolam constitutes 5% or less. Small amounts of a dihydroxy derivative have also been detected but not quantified. The principal urinary excretion products are glucuronide conjugates of the hydroxylated derivatives.

Drugs that inhibit the activity of cytochrome P450-3A4 may inhibit midazolam clearance and elevate steady-state midazolam concentrations.

Studies of the intravenous administration of 1-hydroxy-midazolam in humans suggest that 1-hydroxy-midazolam is at least as potent as the parent compound and may contribute to the net pharmacologic activity of midazolam. *In vitro* studies have demonstrated that the affinities of 1- and 4-hydroxy-midazolam for the benzodiazepine receptor are approximately 20% and 7%, respectively, relative to midazolam.

Excretion

Clearance of midazolam is reduced in association with old age, congestive heart failure, liver disease (cirrhosis) or conditions which diminish cardiac output and hepatic blood flow.

The principal urinary excretion product is 1-hydroxy-midazolam in the form of a glucuronide conjugate; smaller amounts of the glucuronide conjugates of 4-hydroxy- and dihydroxy-midazolam are detected as well. The amount of midazolam excreted unchanged in the urine after a single IV dose is less than 0.5% (n=5). Following a single IV infusion in 5 healthy volunteers, 45% to 57% of the dose was excreted in the urine as 1-hydroxymethyl midazolam conjugate.

Pharmacokinetics-Continuous Infusion

The pharmacokinetic profile of midazolam following continuous infusion, based on 282 adult subjects, has been shown to be similar to that following single-dose administration for subjects of comparable age, gender, body habitus and health status. However, midazolam can accumulate in peripheral tissues with continuous infusion. The effects of accumulation are greater after long-term infusions than after short-term infusions. The effects of accumulation can be reduced by maintaining the lowest midazolam infusion rate that produces satisfactory sedation.

Infrequent hypotensive episodes have occurred during continuous infusion; however, neither the time to onset nor the duration of the episode appeared to be related to plasma concentrations of midazolam or alpha-hydroxy-midazolam. Further, there does not appear to be an increased chance of occurrence of a hypotensive episode with increased loading doses.

Patients with renal impairment may have longer elimination half-lives for midazolam (see SPECIAL POPULATIONS, RENAL IMPAIRMENT).

Special Populations

Changes in the pharmacokinetic profile of midazolam due to drug interactions, physiological variables, etc., may result in changes in the plasma concentration-time profile and pharmacological response to midazolam in these patients. For example, patients with acute renal failure appear to have a longer elimination half-life for midazolam and may experience delayed recovery (see SPECIAL POPULATIONS, RENAL IMPAIRMENT). In other groups, the relationship between prolonged half-life and duration of effect has not been established.

Pediatrics and Neonates

In pediatric patients aged 1 year and older, the pharmacokinetic properties following a single dose of midazolam reported in 10 separate studies of midazolam are similar to those in adults. Weight-normalized clearance is similar or higher (0.19 to 0.80 L/hr/kg) than in adults and the terminal elimination half-life (0.78 to 3.3 hours) is similar to or shorter than in adults. The pharmacokinetic properties during and following continuous intravenous infusion in pediatric patients in the operating room as an adjunct to general anesthesia and in the intensive care environment are similar to those in adults.

In seriously ill neonates, however, the terminal elimination half-life of midazolam is substantially prolonged (6.5 to 12.0 hours) and the clearance reduced (0.07 to 0.12 L/hr/kg) compared to healthy adults or other groups of pediatric patients. It cannot be determined if these differences are due to age, immature organ function or metabolic pathways, underlying illness or debility.

Obese

In a study comparing normals (n=20) and obese patients (n=20) the mean half-life was greater in the obese group (5.9 vs 2.3 hours). This was due to an increase of approximately 50% in the Vd corrected for total body weight. The clearance was not significantly different between groups.

Geriatric

In three parallel group studies, the pharmacokinetics of midazolam administered IV or IM were compared in young (mean age 29, n=52) and healthy elderly subjects (mean age 73, n=53). Plasma half-life was approximately two-fold higher in the elderly. The mean Vd based on total body weight increased

consistently between 15% to 100% in the elderly. The mean Cl decreased approximately 25% in the elderly in two studies and was similar to that of the younger patients in the other.

Congestive Heart Failure

In patients suffering from congestive heart failure, there appeared to be a two-fold increase in the elimination half-life, a 25% decrease in the plasma clearance and a 40% increase in the volume of distribution of midazolam.

Hepatic Impairment

Midazolam pharmacokinetics were studied after an IV single dose (0.075 mg/kg) was administered to 7 patients with biopsy proven alcoholic cirrhosis and 8 control patients. The mean half-life of midazolam increased 2.5-fold in the alcoholic patients. Clearance was reduced by 50% and the Vd increased by 20%. In another study in 21 male patients with cirrhosis, without ascites and with normal kidney function as determined by creatinine clearance, no changes in the pharmacokinetics of midazolam or 1-hydroxy-midazolam were observed when compared to healthy individuals.

Renal Impairment

Patients with renal impairment may have longer elimination half-lives for midazolam and its metabolites which may result in slower recovery.

Midazolam and 1-hydroxy-midazolam pharmacokinetics in 6 ICU patients who developed acute renal failure (ARF) were compared with a normal renal function control group. Midazolam was administered as an infusion (5 to 15 mg/hr). Midazolam clearance was reduced (1.9 vs 2.8 mL/min/kg) and the half-life was prolonged (7.6 vs 13 hours) in the ARF patients. The renal clearance of the 1-hydroxy-midazolam glucuronide was prolonged in the ARF group (4 vs 136 mL/min) and the half-life was prolonged (12 vs >25 hours). Plasma levels accumulated in all ARF patients to about ten times that of the parent drug. The relationship between accumulating metabolite levels and prolonged sedation is unclear.

In a study of chronic renal failure patients (n=15) receiving a single IV dose, there was a two-fold increase in the clearance and volume of distribution but the half-life remained unchanged. Metabolite levels were not studied.

Plasma Concentration-Effect Relationship

Concentration-effect relationships (after an IV dose) have been demonstrated for a variety of pharmacodynamic measures (e.g., reaction time, eye movement, sedation) and are associated with extensive intersubject variability. Logistic regression analysis of sedation scores and steady-state plasma concentration indicated that at plasma concentrations greater than 100 ng/mL there was at least a 50% probability that patients would be sedated, but respond to verbal commands (sedation score = 3). At 200 ng/mL there was at least a 50% probability that patients would be asleep, but respond to glabellar tap (sedation score = 4).

Drug Interactions

For information concerning pharmacokinetic drug interactions with midazolam (see PRECAUTIONS).

CLOSE

INDICATIONS AND USAGE

Midazolam Injection, USP is indicated:

intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia;

intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures either alone or in combination with other CNS depressants;

intravenously for induction of general anesthesia, before administration of other anesthetic agents. With the use of narcotic premedication, induction of anesthesia can be attained within a relatively narrow dose range and in a short period of time. Intravenous midazolam can also be used as a component of intravenous supplementation of nitrous oxide and oxygen (balanced anesthesia);

continuous intravenous infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

CLOSE

CONTRAINDICATIONS

Injectable midazolam hydrochloride is contraindicated in patients with a known hypersensitivity to the drug. Benzodiazepines are contraindicated in patients with acute narrow-angle glaucoma. Benzodiazepines may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. Measurements of intraocular pressure in patients without eye disease show a moderate lowering following induction with midazolam hydrochloride; patients with glaucoma have not been studied.

Midazolam hydrochloride is not intended for intrathecal or epidural administration due to the presence of the preservative benzyl alcohol in the dosage form. Midazolam hydrochloride is contraindicated for use in premature infants because the formulation contains benzyl alcohol (see WARNINGS and PRECAUTIONS, PEDIATRIC USE).

CLOSE

WARNINGS

Personnel and Equipment for Monitoring and Resuscitation

Prior to the intravenous administration of midazolam hydrochloride in any dose, the immediate availability of oxygen, resuscitative drugs, age- and size-appropriate equipment for bag/valve/mask ventilation and intubation, and skilled personnel for the maintenance of a patent airway and support of ventilation should be ensured. Patients should be continuously monitored for early signs of hypoventilation, airway obstruction, or apnea with means readily available (e.g., pulse oximetry). Hypoventilation, airway obstruction, and apnea can lead to hypoxia and/or cardiac arrest unless effective countermeasures are taken immediately. The immediate availability of specific reversal agents (flumazenil) is highly recommended. Vital signs should continue to be monitored during the recovery period. Because intravenous midazolam can depress respiration (see CLINICAL PHARMACOLOGY), especially when used concomitantly with opioid agonists and other sedatives (see DOSAGE AND ADMINISTRATION), it should be used for sedation/anxiolysis/amnesia only in the presence of personnel skilled in early detection of hypoventilation, maintaining a patent airway, and supporting ventilation. When used for

sedation/anxiolysis/amnesia, midazolam should always be titrated slowly in adult or pediatric patients. Adverse hemodynamic events have been reported in pediatric patients with cardiovascular instability; rapid intravenous administration should also be avoided in this population (see DOSAGE AND ADMINISTRATION for complete information).

Risks From Concomitant Use With Opioids

Concomitant use of benzodiazepines, including midazolam, and opioids may result in profound sedation, respiratory depression, coma, and death. If a decision is made to use midazolam concomitantly with opioids, monitor patients closely for respiratory depression and sedation (see PRECAUTIONS, DRUG INTERACTIONS).

Risk of Respiratory Adverse Events

Serious cardiorespiratory adverse events have occurred after administration of midazolam. These have included respiratory depression, airway obstruction, oxygen desaturation, apnea, respiratory arrest and/or cardiac arrest, sometimes resulting in death or permanent neurologic injury. There have also been rare reports of hypotensive episodes requiring treatment during or after diagnostic or surgical manipulations particularly in adult or pediatric patients with hemodynamic instability. Hypotension occurred more frequently in the sedation studies in patients premedicated with a narcotic.

Individualization of Dosage

Midazolam hydrochloride must never be used without individualization of dosage particularly when used with other medications capable of producing central nervous system depression (see DOSAGE AND ADMINISTRATION for complete information).

Other Adverse Events

Reactions such as agitation, involuntary movements (including tonic/clonic movements and muscle tremor), hyperactivity and combativeness have been reported in both adult and pediatric patients. These reactions may be due to inadequate or excessive dosing or improper administration of midazolam hydrochloride; however, consideration should be given to the possibility of cerebral hypoxia or true paradoxical reactions. Should such reactions occur, the response to each dose of midazolam hydrochloride and all other drugs, including local anesthetics, should be evaluated before proceeding. Reversal of such responses with flumazenil has been reported in pediatric patients.

Concomitant Use of Central Nervous System Depressants

Concomitant use of barbiturates, alcohol or other central nervous system depressants may increase the risk of hypoventilation, airway obstruction, desaturation, or apnea and may contribute to profound and/or prolonged drug effect. Narcotic premedication also depresses the ventilatory response to carbon dioxide stimulation.

Debilitation and Comorbid Considerations

Higher risk adult and pediatric surgical patients, elderly patients and debilitated adult and pediatric patients require lower dosages, whether or not concomitant sedating medications have been administered. Adult or pediatric patients with COPD are unusually sensitive to the respiratory depressant effect of midazolam hydrochloride. Pediatric and adult patients undergoing procedures involving the upper airway such as upper endoscopy or dental care, are particularly vulnerable to episodes of desaturation and hypoventilation due to partial airway obstruction. Adult and pediatric patients with chronic renal failure and patients with congestive heart failure eliminate midazolam more slowly (see CLINICAL PHARMACOLOGY). Because elderly patients frequently have inefficient function of one or more

organ systems and because dosage requirements have been shown to decrease with age, reduced initial dosage of midazolam hydrochloride is recommended, and the possibility of profound and/or prolonged effect should be considered.

Injectable midazolam should not be administered to adult or pediatric patients in shock or coma, or in acute alcohol intoxication with depression of vital signs. Particular care should be exercised in the use of intravenous midazolam in adult or pediatric patients with uncompensated acute illnesses, such as severe fluid or electrolyte disturbances.

Risk of Intra-Arterial Injection

There have been limited reports of intra-arterial injection of midazolam hydrochloride. Adverse events have included local reactions, as well as isolated reports of seizure activity in which no clear causal relationship was established. Precautions against unintended intra-arterial injection should be taken. Extravasation should also be avoided.

The safety and efficacy of midazolam following non-intravenous and non-intramuscular routes of administration have not been established. Midazolam hydrochloride should only be administered intramuscularly or intravenously.

Return to Full Cognitive Function

Midazolam is associated with a high incidence of partial or complete impairment of recall for the next several hours. The decision as to when patients who have received injectable midazolam, particularly on an outpatient basis, may again engage in activities requiring complete mental alertness, operate hazardous machinery or drive a motor vehicle must be individualized. Gross tests of recovery from the effects of midazolam (see CLINICAL PHARMACOLOGY) cannot be relied upon to predict reaction time under stress. It is recommended that no patient operate hazardous machinery or a motor vehicle until the effects of the drug, such as drowsiness, have subsided or until 1 full day after anesthesia and surgery, whichever is longer. For pediatric patients, particular care should be taken to assure safe ambulation.

Usage in Pregnancy

An increased risk of congenital malformations associated with the use of benzodiazepine drugs (diazepam and chlordiazepoxide) has been suggested in several studies. If this drug is used during pregnancy, the patient should be apprised of the potential hazard to the fetus.

Withdrawal symptoms of the barbiturate type have occurred after the discontinuation of benzodiazepines (see DRUG ABUSE AND DEPENDENCE).

Usage in Preterm Infants and Neonates

Rapid injection should be avoided in the neonatal population. Midazolam hydrochloride administered rapidly as an intravenous injection (less than 2 minutes) has been associated with severe hypotension in neonates, particularly when the patient has also received fentanyl. Likewise, severe hypotension has been observed in neonates receiving a continuous infusion of midazolam who then receive a rapid intravenous injection of fentanyl. Seizures have been reported in several neonates following rapid intravenous administration.

The neonate also has reduced and/or immature organ function and is also vulnerable to profound and/or prolonged respiratory effects of midazolam.

Exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates, and an increased incidence of kernicterus, particularly in small preterm infants. There have been rare reports of deaths, primarily in preterm infants, associated with exposure to excessive amounts of benzyl alcohol. The amount of benzyl alcohol from medications is usually considered negligible compared to that received in flush solutions containing benzyl alcohol. Administration of high dosages of medications (including midazolam hydrochloride) containing this preservative must take into account the total amount of benzyl alcohol administered. The recommended dosage range of midazolam hydrochloride for preterm and term infants includes amounts of benzyl alcohol well below that associated with toxicity; however, the amount of benzyl alcohol at which toxicity may occur is not known. If the patient requires more than the recommended dosages or other medications containing this preservative, the practitioner must consider the daily metabolic load of benzyl alcohol from these combined sources (see WARNINGS and PRECAUTIONS, PEDIATRIC USE).

Pediatric Neurotoxicity

Published animal studies demonstrate that the administration of anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of these findings is not clear. However, based on the available data, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but may extend out to approximately three years of age in humans (see PRECAUTIONS, PREGNANCY and PEDIATRIC USE, and ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY).

Some published studies in children suggest that similar deficits may occur after repeated or prolonged exposures to anesthetic agents early in life and may result in adverse cognitive or behavioral effects. These studies have substantial limitations, and it is not clear if the observed effects are due to the anesthetic/sedation drug administration or other factors such as the surgery or underlying illness.

Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

CLOSE

PRECAUTIONS

General

Intravenous doses of midazolam hydrochloride should be decreased for elderly and for debilitated patients (see WARNINGS and DOSAGE AND ADMINISTRATION). These patients will also probably take longer to recover completely after midazolam administration for the induction of anesthesia.

Midazolam does not protect against the increase in intracranial pressure or against the heart rate rise and/or blood pressure rise associated with endotracheal intubation under light general anesthesia.

The efficacy and safety of midazolam in clinical use are functions of the dose administered, the clinical status of the individual patient, and the use of concomitant medications capable of depressing the CNS. Anticipated effects range from mild sedation to deep levels of sedation virtually equivalent to a state of general anesthesia where the patient may require external support of vital functions. Care must be taken

to individualize and carefully titrate the dose of midazolam hydrochloride to the patient's underlying medical/surgical conditions, administer to the desired effect being certain to wait an adequate time for peak CNS effects of both midazolam hydrochloride and concomitant medications, and have the personnel and size-appropriate equipment and facilities available for monitoring and intervention (see BOXED WARNING, WARNINGS and DOSAGE AND ADMINISTRATION). Practitioners administering midazolam hydrochloride must have the skills necessary to manage reasonably foreseeable adverse effects, particularly skills in airway management. For information regarding withdrawal (see DRUG ABUSE AND DEPENDENCE).

Information for Patients

To assure safe and effective use of benzodiazepines, the following information and instructions should be communicated to the patient when appropriate:

Inform your physician about any alcohol consumption and medicine you are now taking, especially blood pressure medication and antibiotics, including drugs you buy without a prescription. Alcohol has an increased effect when consumed with benzodiazepines; therefore, caution should be exercised regarding simultaneous ingestion of alcohol during benzodiazepine treatment.

Inform your physician if you are pregnant or are planning to become pregnant.

Inform your physician if you are nursing.

Patients should be informed of the pharmacological effects of midazolam, such as sedation and amnesia, which in some patients may be profound. The decision as to when patients who have received injectable midazolam hydrochloride, particularly on an outpatient basis, may again engage in activities requiring complete mental alertness, operate hazardous machinery or drive a motor vehicle must be individualized.

Patients receiving continuous infusion of midazolam in critical care settings over an extended period of time, may experience symptoms of withdrawal following abrupt discontinuation.

Effect of anesthetic and sedation drugs on early brain development
Studies conducted in young animals and children suggest repeated or prolonged use of general anesthetic or sedation drugs in children younger than 3 years may have negative effects on their developing brains. Discuss with parents and caregivers the benefits, risks, and timing and duration of surgery or procedures requiring anesthetic and sedation drugs.

Drug Interactions

Effect of Concomitant Use of Benzodiazepines and Opioids

The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration. Benzodiazepines interact at GABAA sites and opioids interact primarily at mu receptors. When benzodiazepines and opioids are

combined, the potential for benzodiazepines to significantly worsen opioid-related respiratory depression exists. Monitor patients closely for respiratory depression and sedation.

Other CNS Depressants

The sedative effect of intravenous midazolam is accentuated by any concomitantly administered medication which depresses the central nervous system, particularly opioids (e.g., morphine, meperidine and fentanyl) and also secobarbital and droperidol. Consequently, the dosage of midazolam should be adjusted according to the type and amount of concomitant medications administered and the desired clinical response (see DOSAGE AND ADMINISTRATION).

Other Drug Interactions

Caution is advised when midazolam is administered concomitantly with drugs that are known to inhibit the P450-3A4 enzyme system such as cimetidine (not ranitidine), erythromycin, diltiazem, verapamil, ketoconazole and itraconazole. These drug interactions may result in prolonged sedation due to a decrease in plasma clearance of midazolam.

The effect of single oral doses of 800 mg cimetidine and 300 mg ranitidine on steady-state concentrations of oral midazolam was examined in a randomized crossover study (n=8). Cimetidine increased the mean midazolam steady-state concentration from 57 to 71 ng/mL. Ranitidine increased the mean steady-state concentration to 62 ng/mL. No change in choice reaction time or sedation index was detected after dosing with the H2 receptor antagonists.

In a placebo-controlled study, erythromycin administered as a 500 mg dose, three times a day, for 1 week (n=6), reduced the clearance of midazolam following a single 0.5 mg/kg IV dose. The half-life was approximately doubled.

Caution is advised when midazolam is administered to patients receiving erythromycin since this may result in a decrease in the plasma clearance of midazolam.

The effects of diltiazem (60 mg three times a day) and verapamil (80 mg three times a day) on the pharmacokinetics and pharmacodynamics of oral midazolam were investigated in a three-way crossover study (n=9).

The half-life of midazolam increased from 5 to 7 hours when midazolam was taken in conjunction with verapamil or diltiazem. No interaction was observed in healthy subjects between midazolam and nifedipine.

In a placebo-controlled study where saquinavir or placebo was administered orally as a 1200 mg dose, three times a day, for 5 days (n=12), a 56% reduction in the clearance of midazolam following a single 0.05 mg/kg IV dose was observed. The half–life was approximately doubled.

A moderate reduction in induction dosage requirements of thiopental (about 15%) has been noted following use of intramuscular midazolam hydrochloride for premedication in adults.

The intravenous administration of midazolam hydrochloride decreases the minimum alveolar concentration (MAC) of halothane required for general anesthesia. This decrease correlates with the dose of midazolam hydrochloride administered; no similar studies have been carried out in pediatric patients but there is no scientific reason to expect that pediatric patients would respond differently than adults.

Although the possibility of minor interactive effects has not been fully studied, midazolam and pancuronium have been used together in patients without noting clinically significant changes in dosage, onset or duration in adults. Midazolam hydrochloride does not protect against the characteristic circulatory changes noted after administration of succinylcholine or pancuronium and does not protect against the increased intracranial pressure noted following administration of succinylcholine. Midazolam does not cause a clinically significant change in dosage, onset or duration of a single intubating dose of succinylcholine; no similar studies have been carried out in pediatric patients but there is no scientific reason to expect that pediatric patients would respond differently than adults.

No significant adverse interactions with commonly used premedications or drugs used during anesthesia and surgery (including atropine, scopolamine, glycopyrrolate, diazepam, hydroxyzine, d-tubocurarine, succinylcholine and other nondepolarizing muscle relaxants) or topical local anesthetics (including lidocaine, dyclonine HCl and Cetacaine) have been observed in adults or pediatric patients. In neonates, however, severe hypotension has been reported with concomitant administration of fentanyl. This effect has been observed in neonates on an infusion of midazolam who received a rapid injection of fentanyl and in patients on an infusion of fentanyl who have received a rapid injection of midazolam.

Drug/Laboratory Test Interactions

Midazolam has not been shown to interfere with results obtained in clinical laboratory tests.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Midazolam maleate was administered with diet in mice and rats for 2 years at dosages of 1, 9 and 80 mg/kg/day. In female mice in the highest dose group there was a marked increase in the incidence of hepatic tumors. In high-dose male rats there was a small but statistically significant increase in benign thyroid follicular cell tumors. Dosages of 9 mg/kg/day of midazolam maleate (4 times a human induction dose of 0.35 mg/kg based on body surface area comparison) do not increase the incidence of tumors. The pathogenesis of induction of these tumors is not known. These tumors were found after chronic administration, whereas human use will ordinarily be of single or several doses.

Mutagenesis

Midazolam did not have mutagenic activity in ***Salmonella typhimurium*** (5 bacterial strains), Chinese hamster lung cells (V79), human lymphocytes or in the micronucleus test in mice.

Impairment of Fertility

Male rats were treated orally with 1, 4, or 16 mg/kg midazolam beginning 62 days prior to mating with female rats treated with the same doses for 14 days prior to mating to Gestation Day 13 or Lactation Day 21. The high dose produced an equivalent exposure (AUC) as 4 mg/kg intravenous midazolam (1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparison). There were no adverse effects on either male or female fertility noted.

Pregnancy

Teratogenic Effects: Pregnancy Category D (see WARNINGS).

Published studies in pregnant primates demonstrate that the administration of anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity during the period of peak brain

development increases neuronal apoptosis in the developing brain of the offspring when used for longer than 3 hours. There are no data on pregnancy exposures in primates corresponding to periods prior to the third trimester in humans (see DATA).

Data

Animal Data

Pregnant rats were treated with midazolam using intravenous doses of 0.2, 1, and 4 mg/kg/day (0.09, 0.46, and 1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparisons) during the period of organogenesis (Gestation Day 7 through 15). Midazolam did not cause adverse effects to the fetus at doses of up to 1.85 times the human induction dose. All doses produced slight to moderate ataxia. The high dose produced a 5% decrease in maternal body weight gain compared to control.

Pregnant rabbits were treated with midazolam using intravenous doses of 0.2, 0.6, and 2 mg/kg/day (0.09, 0.46, and 1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparisons) during the period of organogenesis (Gestation Day 7 to 18). Midazolam did not cause adverse effects to the fetus at doses of up to 1.85 times the human induction dose. The high dose was associated with findings of ataxia and sedation but no evidence of maternal toxicity.

Pregnant rats were administered midazolam using intravenous doses of 0.2, 1, and 4 mg/kg/day (0.09, 0.46, and 1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparisons) during late gestation and through lactation (Gestation Day 15 through Lactation Day 21). All doses produced ataxia. The high dose produced a slight decrease in maternal body weight gain compared to control. There were no clear adverse effects noted in the offspring. The study included no functional assessments of the pups, such as learning and memory testing or reproductive capacity.

In a published study in primates, administration of an anesthetic dose of ketamine for 24 hours on Gestation Day 122 increased neuronal apoptosis in the developing brain of the fetus. In other published studies, administration of either isoflurane or propofol for 5 hours on Gestation Day 120 resulted in increased neuronal and oligodendrocyte apoptosis in the developing brain of the offspring. With respect to brain development, this time period corresponds to the third trimester of gestation in the human. The clinical significance of these findings is not clear; however, studies in juvenile animals suggest neuroapoptosis correlates with long-term cognitive deficits (see WARNINGS, PEDIATRIC NEUROTOXICITY, PRECAUTIONS, PEDIATRIC USE, and ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY).

Labor and Delivery

In humans, measurable levels of midazolam were found in maternal venous serum, umbilical venous and arterial serum and amniotic fluid, indicating placental transfer of the drug. Following intramuscular administration of 0.05 mg/kg of midazolam, both the venous and the umbilical arterial serum concentrations were lower than maternal concentrations.

The use of injectable midazolam in obstetrics has not been evaluated in clinical studies. Because midazolam is transferred transplacentally and because other benzodiazepines given in the last weeks of pregnancy have resulted in neonatal CNS depression, midazolam is not recommended for obstetrical use.

Nursing Mothers

Midazolam is excreted in human milk. Caution should be exercised when midazolam hydrochloride is administered to a nursing woman.

Pediatric Use

The safety and efficacy of midazolam for sedation/anxiolysis/amnesia following single dose intramuscular administration, intravenously by intermittent injections and continuous infusion have been established in pediatric and neonatal patients. For specific safety monitoring and dosage guidelines (see BOXED WARNING, CLINICAL PHARMACOLOGY, INDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE and DOSAGE AND ADMINISTRATION). UNLIKE ADULT PATIENTS, PEDIATRIC PATIENTS GENERALLY RECEIVE INCREMENTS OF MIDAZOLAM ON A MG/KG BASIS. As a group, pediatric patients generally require higher dosages of midazolam (mg/kg) than do adults. Younger (less than six years) pediatric patients may require higher dosages (mg/kg) than older pediatric patients, and may require closer monitoring. In obese PEDIATRIC PATIENTS, the dose should be calculated based on ideal body weight. When midazolam is given in conjunction with opioids or other sedatives, the potential for respiratory depression, airway obstruction, or hypoventilation is increased. The health care practitioner who uses this medication in pediatric patients should be aware of and follow accepted professional guidelines for pediatric sedation appropriate to their situation.

Midazolam hydrochloride should not be administered by rapid injection in the neonatal population. Severe hypotension and seizures have been reported following rapid IV administration, particularly, with concomitant use of fentanyl.

Midazolam contain benzyl alcohol as a preservative. Benzyl alcohol, a component of this product, has been associated with serious adverse events and death, particularly in pediatric patients. The “gasping syndrome”, (characterized by central nervous system depression, metabolic acidosis, gasping respirations, and high levels of benzyl alcohol and its metabolites found in the blood and urine) has been associated with benzyl alcohol dosages greater than 99 mg/kg/day in neonates and low-birth-weight neonates. Additional symptoms may include gradual neurological deterioration, seizures, intracranial hemorrhage, hematologic abnormalities, skin breakdown, hepatic and renal failure, hypotension, bradycardia, and cardiovascular collapse. Although normal therapeutic doses of this product deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the “gasping syndrome”, the minimum amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birth-weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity. Practitioners administering this and other medications containing benzyl alcohol should consider the combined daily metabolic load of benzyl alcohol from all sources.

Animal Data

Published juvenile animal studies demonstrate that the administration of anesthetic and sedation drugs, such as Midazolam Injection USP, that either block NMDA receptors or potentiate the activity of GABA during the period of rapid brain growth or synaptogenesis, results in widespread neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis. Based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but may extend out to approximately 3 years of age in humans.

In primates, exposure to 3 hours of ketamine that produced a light surgical plane of anesthesia did not increase neuronal cell loss, however, treatment regimens of 5 hours or longer of isoflurane increased neuronal cell loss. Data from isoflurane-treated rodents and ketamine-treated primates suggest that the neuronal and oligodendrocyte cell losses are associated with prolonged cognitive deficits in learning and memory. The clinical significance of these nonclinical findings is not known, and healthcare providers

should balance the benefits of appropriate anesthesia in pregnant women, neonates, and young children who require procedures with the potential risks suggested by the nonclinical data (see WARNINGS, PEDIATRIC NEUROTOXICITY, PRECAUTIONS, PREGNANCY, and ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY).

Geriatric Use

Because geriatric patients may have altered drug distribution and diminished hepatic and/or renal function, reduced doses of midazolam are recommended. Intravenous and intramuscular doses of midazolam should be decreased for elderly and for debilitated patients (see WARNINGS and DOSAGE AND ADMINISTRATION) and subjects over 70 years of age may be particularly sensitive. These patients will also probably take longer to recover completely after midazolam administration for the induction of anesthesia. Administration of IM and IV midazolam to elderly and/or high-risk surgical patients has been associated with rare reports of death under circumstances compatible with cardiorespiratory depression. In most of these cases, the patients also received other central nervous system depressants capable of depressing respiration, especially narcotics (see DOSAGE AND ADMINISTRATION).

Specific dosing and monitoring guidelines for geriatric patients are provided in the DOSAGE AND ADMINISTRATION section for premedicated patients for sedation/anxiolysis/amnesia following IV and IM administration, for induction of anesthesia following IV administration and for continuous infusion.

CLOSE

ADVERSE REACTIONS

See WARNINGS concerning serious cardiorespiratory events and possible paradoxical reactions. Fluctuations in vital signs were the most frequently seen findings following parenteral administration of midazolam in adults and included decreased tidal volume and/or respiratory rate decrease (23.3% of patients following IV and 10.8% of patients following IM administration) and apnea (15.4% of patients following IV administration), as well as variations in blood pressure and pulse rate. The majority of serious adverse effects, particularly those associated with oxygenation and ventilation, have been reported when midazolam hydrochloride is administered with other medications capable of depressing the central nervous system. The incidence of such events is higher in patients undergoing procedures involving the airway without the protective effect of an endotracheal tube (e.g., upper endoscopy and dental procedures).

Adults

The following additional adverse reactions were reported after intramuscular administration:

headache (1.3%)	*Local effects at IM Injection site*
	pain (3.7%)
	induration (0.5%)
	redness (0.5%)
	muscle stiffness (0.3%)

Administration of IM midazolam hydrochloride to elderly and/or higher risk surgical patients has been associated with rare reports of death under circumstances compatible with cardiorespiratory depression. In most of these cases, the patients also received other central nervous system depressants capable of depressing respiration, especially narcotics (see DOSAGE AND ADMINISTRATION). The following additional adverse reactions were reported subsequent to intravenous administration as a single sedative/anxiolytic/amnestic agent in adult patients:

hiccoughs (3.9%)	***Local effects at the IV site***
nausea (2.8%)	tenderness (5.6%)
vomiting (2.6%)	pain during injection (5.0%)
coughing (1.3%)	redness (2.6%)
"oversedation" (1.6%)	induration (1.7%)
headache (1.5%)	phlebitis (0.4%)
drowsiness (1.2%)	

Pediatric Patients

The following adverse events related to the use of IV midazolam hydrochloride in pediatric patients were reported in the medical literature: desaturation 4.6%, apnea 2.8%, hypotension 2.7%, paradoxical reactions 2.0%, hiccough 1.2%, seizure-like activity 1.1% and nystagmus 1.1%. The majority of airway-related events occurred in patients receiving other CNS depressing medications and in patients where midazolam was not used as a single sedating agent.

Neonates

For information concerning hypotensive episodes and seizures following the administration of midazolam hydrochloride to neonates (see BOXED WARNING, CONTRAINDICATIONS, WARNINGS and PRECAUTIONS).

Other adverse experiences, observed mainly following IV injection as a single sedative/anxiolytic/amnesia agent and occurring at an incidence of 1.0% in adult and pediatric patients, are as follows:

Respiratory: Laryngospasm, bronchospasm, dyspnea, hyperventilation, wheezing, shallow respirations, airway obstruction, tachypnea

Cardiovascular: Bigeminy, premature ventricular contractions, vasovagal episode, bradycardia, tachycardia, nodal rhythm

Gastrointestinal: Acid taste, excessive salivation, retching

CNS/Neuromuscular: Retrograde amnesia, euphoria, hallucination, confusion, argumentativeness, nervousness, anxiety, grogginess, restlessness, emergence delirium or agitation, prolonged emergence from anesthesia, dreaming during emergence, sleep disturbance, insomnia, nightmares, athetoid movements, seizure-like activity, ataxia, dizziness, dysphoria, slurred speech, dysphonia, paresthesia

Special Senses: Blurred vision, diplopia, nystagmus, pinpoint pupils, cyclic movements of eyelids, visual disturbance, difficulty focusing eyes, ears blocked, loss of balance, light-headedness

Integumentary: Hive-like elevation at injection site, swelling or feeling of burning, warmth or coldness at injection site

Hypersensitivity: Allergic reactions including anaphylactoid reactions, hives, rash, pruritus

Miscellaneous: Yawning, lethargy, chills, weakness, toothache, faint feeling, hematoma

To report SUSPECTED ADVERSE REACTIONS, contact Alvogen at 1-866-770-3024 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

CLOSE

DRUG ABUSE AND DEPENDENCE

Midazolam hydrochloride contains midazolam, a Schedule IV control substance.

Midazolam was actively self-administered in primate models used to assess the positive reinforcing effects of psychoactive drugs.

Midazolam produced physical dependence of a mild to moderate intensity in cynomolgus monkeys after 5 to 10 weeks of administration. Available data concerning the drug abuse and dependence potential of midazolam suggest that its abuse potential is at least equivalent to that of diazepam.

Withdrawal symptoms, similar in character to those noted with barbiturates and alcohol (convulsions, hallucinations, tremor, abdominal and muscle cramps, vomiting and sweating), have occurred following abrupt discontinuation of benzodiazepines, including midazolam. Abdominal distention, nausea, vomiting, and tachycardia are prominent symptoms of withdrawal in infants. The more severe withdrawal symptoms have usually been limited to those patients who had received excessive doses over an extended period of time. Generally milder withdrawal symptoms (e.g., dysphoria and insomnia) have been reported following abrupt discontinuance of benzodiazepines taken continuously at therapeutic levels for several months. Consequently, after extended therapy, abrupt discontinuation should generally be avoided and a gradual dosage tapering schedule followed. There is no consensus in the medical literature regarding tapering schedules; therefore, practitioners are advised to individualize therapy to meet patient's needs. In some case reports, patients who have had severe withdrawal reactions due to abrupt discontinuation of high-dose long-term midazolam, have been successfully weaned off of midazolam over a period of several days.

CLOSE

OVERDOSAGE

Symptoms

The manifestations of midazolam overdosage reported are similar to those observed with other benzodiazepines, including sedation, somnolence, confusion, impaired coordination, diminished reflexes, coma and untoward effects on vital signs. No evidence of specific organ toxicity from midazolam hydrochloride overdosage has been reported.

Treatment

Treatment of injectable midazolam overdosage is the same as that followed for overdosage with other benzodiazepines. Respiration, pulse rate and blood pressure should be monitored and general supportive measures should be employed. Attention should be given to the maintenance of a patent airway and support of ventilation, including administration of oxygen. An intravenous infusion should be started. Should hypotension develop, treatment may include intravenous fluid therapy, repositioning, judicious use of vasopressors appropriate to the clinical situation, if indicated, and other appropriate countermeasures. There is no information as to whether peritoneal dialysis, forced diuresis or hemodialysis are of any value in the treatment of midazolam overdosage.

Flumazenil, a specific benzodiazepine-receptor antagonist, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines and may be used in situations when an overdose with a benzodiazepine is known or suspected. There are anecdotal reports of reversal of adverse hemodynamic responses associated with midazolam hydrochloride following administration of flumazenil to pediatric patients. Prior to the administration of flumazenil, necessary measures should be instituted to secure the airway, assure adequate ventilation, and establish adequate intravenous access. Flumazenil is intended as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. Patients treated with flumazenil should be monitored for resedation, respiratory depression and other residual benzodiazepine effects for an appropriate period after treatment. Flumazenil will only reverse benzodiazepine-induced effects but will not reverse the effects of other concomitant medications. The reversal of benzodiazepine effects may be associated with the onset of seizures in certain high-risk patients. The prescriber should be aware of a risk of seizure in association with flumazenil treatment, particularly in long-term benzodiazepine users and in cyclic antidepressant overdose. The complete flumazenil package insert, including CONTRAINDICATIONS, WARNINGS and PRECAUTIONS, should be consulted prior to use.

CLOSE

DOSAGE AND ADMINISTRATION

NOTE: CONTAINS BENZYL ALCOHOL (see WARNINGS and PRECAUTIONS, PEDIATRIC USE).

Midazolam injection is a potent sedative agent that requires slow administration and individualization of dosage. Clinical experience has shown midazolam hydrochloride to be 3 to 4 times as potent per mg as diazepam. BECAUSE SERIOUS AND LIFE-THREATENING CARDIORESPIRATORY ADVERSE EVENTS HAVE BEEN REPORTED, PROVISION FOR MONITORING, DETECTION AND CORRECTION OF THESE REACTIONS MUST BE MADE FOR EVERY PATIENT TO WHOM MIDAZOLAM INJECTION IS ADMINISTERED, REGARDLESS OF AGE OR HEALTH STATUS. Excessive single doses or rapid intravenous administration may result in respiratory depression, airway obstruction and/or arrest. The potential for these latter effects is increased in debilitated patients, those receiving concomitant medications capable of depressing the CNS, and patients without an endotracheal tube but undergoing a procedure involving the upper airway such as endoscopy or dental (see BOXED WARNING and WARNINGS).

Reactions such as agitation, involuntary movements, hyperactivity and combativeness have been reported in adult and pediatric patients. Should such reactions occur, caution should be exercised before continuing administration of midazolam hydrochloride (see WARNINGS).

Midazolam injection should only be administered IM or IV (see WARNINGS).

Care should be taken to avoid intra-arterial injection or extravasation (see WARNINGS).

Midazolam injection may be mixed in the same syringe with the following frequently used premedications: morphine sulfate, meperidine, atropine sulfate or scopolamine. Midazolam, at a concentration of 0.5 mg/mL, is compatible with 5% dextrose in water and 0.9% sodium chloride for up to 24 hours and with lactated Ringer's solution for up to 4 hours. The 5 mg/mL formulation of midazolam may be diluted with 0.9% sodium chloride or 5% dextrose in water.

Monitoring

Patient response to sedative agents, and resultant respiratory status, is variable. Regardless of the intended level of sedation or route of administration, sedation is a continuum; a patient may move easily from light to deep sedation, with potential loss of protective reflexes. This is especially true in pediatric patients. Sedative doses should be individually titrated, taking into account patient age, clinical status and concomitant use of other CNS depressants. Continuous monitoring of respiratory and cardiac function is required (i.e., pulse oximetry).

Adults and Pediatrics

Sedation guidelines recommend a careful presedation history to determine how a patient's underlying medical conditions or concomitant medications might affect their response to sedation/analgesia as well as a physical examination including a focused examination of the airway for abnormalities. Further recommendations include appropriate presedation fasting.

Titration to effect with multiple small doses is essential for safe administration. It should be noted that adequate time to achieve peak central nervous system effect (3 to 5 minutes) for midazolam should be allowed between doses to minimize the potential for oversedation. Sufficient time must elapse between doses of concomitant sedative medications to allow the effect of each dose to be assessed before subsequent drug administration. This is an important consideration for all patients who receive intravenous midazolam.

Immediate availability of resuscitative drugs and ***age- and size-appropriate*** equipment and personnel trained in their use and skilled in airway management should be assured (see WARNINGS).

Pediatrics

For deeply sedated pediatric patients a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.

Intravenous access is not thought to be necessary for all pediatric patients sedated for a diagnostic or therapeutic procedure because in some cases the difficulty of gaining IV access would defeat the purpose of sedating the child; rather, emphasis should be placed upon having the intravenous equipment available and a practitioner skilled in establishing vascular access in pediatric patients immediately available.

USUAL ADULT DOSE INTRAMUSCULARLY FOR PREOPERATIVE SEDATION/ANXIOLYSIS/AMNESIA	THE RECOMMENDED PREMEDICATION DOSE OF MIDAZOLAM FOR GOOD RISK (ASA PHYSICAL STATUS

(INDUCTION OF SLEEPINESS OR DROWSINESS AND RELIEF OF APPREHENSION AND TO IMPAIR MEMORY OF PERIOPERATIVE EVENTS). FOR INTRAMUSCULAR USE, MIDAZOLAM HYDROCHLORIDE SHOULD BE INJECTED DEEP IN A LARGE MUSCLE MASS.	I & II) ADULT PATIENTS BELOW THE AGE OF 60 YEARS IS 0.07 TO 0.08 MG/KG IM (APPROXIMATELY 5 MG IM) ADMINISTERED UP TO 1 HOUR BEFORE SURGERY. THE DOSE MUST BE INDIVIDUALIZED AND REDUCED WHEN IM MIDAZOLAM IS ADMINISTERED TO PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE, OTHER HIGHER RISK SURGICAL PATIENTS, PATIENTS 60 OR MORE YEARS OF AGE, AND PATIENTS WHO HAVE RECEIVED CONCOMITANT NARCOTICS OR OTHER CNS DEPRESSANTS (SEE ADVERSE REACTIONS). IN A STUDY OF PATIENTS 60 YEARS OR OLDER, WHO DID NOT RECEIVE CONCOMITANT ADMINISTRATION OF NARCOTICS, 2 TO 3 MG (0.02 TO 0.05 MG/KG) OF MIDAZOLAM PRODUCED ADEQUATE SEDATION DURING THE PREOPERATIVE PERIOD. THE DOSE OF 1 MG IM MIDAZOLAM HYDROCHLORIDE MAY SUFFICE FOR SOME OLDER PATIENTS IF THE ANTICIPATED INTENSITY AND DURATION OF SEDATION IS LESS CRITICAL. AS WITH ANY POTENTIAL RESPIRATORY DEPRESSANT, THESE PATIENTS REQUIRE OBSERVATION FOR SIGNS OF CARDIORESPIRATORY DEPRESSION AFTER RECEIVING IM MIDAZOLAM.
INTRAVENOUSLY Sedation/anxiolysis/amnesia for procedures (see INDICATIONS): Narcotic premedication results in less variability in patient response and a reduction in dosage of midazolam. For peroral procedures, the use of an appropriate topical anesthetic is recommended. For bronchoscopic procedures, the use of narcotic premedication is recommended.	When used for sedation/anxiolysis/amnesia for a procedure, dosage must be individualized and titrated. Midazolam hydrochloride should always be titrated slowly; administer over at least 2 minutes and allow an additional 2 or more minutes to fully evaluate the sedative effect. Individual response will vary with age, physical status and concomitant medications, but may also vary independent of these factors (see WARNINGS concerning cardiac/respiratory arrest/airway obstruction/hypoventilation.)
Midazolam hydrochloride 1 mg/mL formulation is recommended for sedation/anxiolysis/amnesia for procedures to facilitate slower injection. The 5 mg/mL formulation may be diluted with 0.9% sodium chloride or 5% dextrose in water.	ONSET IS WITHIN 15 MINUTES, PEAKING AT 30 TO 60 MINUTES. IT CAN BE ADMINISTERED CONCOMITANTLY WITH ATROPINE SULFATE OR SCOPOLAMINE HYDROCHLORIDE AND REDUCED DOSES OF NARCOTICS. ***Healthy Adults Below the Age of 60:*** Titrate slowly to the desired effect (e.g., the initiation of slurred speech). Some patients may respond to as little as 1 mg. No more than 2.5 mg should be given over a period of at least 2 minutes. Wait an additional 2 or more minutes to fully evaluate the sedative effect. If further titration is necessary, continue to titrate, using small increments, to the appropriate level of sedation. Wait an additional 2 or more minutes after each increment to fully evaluate the sedative effect. A total dose greater than 5 mg is not usually necessary to reach the desired endpoint. If narcotic premedication or other CNS depressants are used, patients will require approximately 30% less midazolam than unpremedicated patients. ***Patients Age 60 or Older, and Debilitated or Chronically Ill Patients:*** Because the danger of

	hypoventilation, airway obstruction, or apnea is greater in elderly patients and those with chronic disease states or decreased pulmonary reserve, and because the peak effect may take longer in these patients, increments should be smaller and the rate of injection slower. Titrate slowly to the desired effect (e.g., the initiation of slurred speech). Some patients may respond to as little as 1 mg. No more than 1.5 mg should be given over a period of no less than 2 minutes. Wait an additional 2 or more minutes to fully evaluate the sedative effect. If additional titration is necessary, it should be given at a rate of no more than 1 mg over a period of 2 minutes, waiting an additional 2 or more minutes each time to fully evaluate the sedative effect. Total doses greater than 3.5 mg are not usually necessary. If concomitant CNS depressant premedications are used in these patients, they will require at least 50% less midazolam than healthy young unpremedicated patients. ***Maintenance Dose:*** Additional doses to maintain the desired level of sedation may be given in increments of 25% of the dose used to first reach the sedative endpoint, but again only by slow titration, especially in the elderly and chronically ill or debilitated patient. These additional doses should be given only after a thorough clinical evaluation clearly indicates the need for additional sedation.
Induction of Anesthesia: For induction of general anesthesia, before administration of other anesthetic agents.	Individual response to the drug is variable, particularly when a narcotic premedication is not used. The dosage should be titrated to the desired effect according to the patient's age and clinical status. When midazolam is used before other intravenous agents for induction of anesthesia, the initial dose of each agent may be significantly reduced, at times to as low as 25% of the usual initial dose of the individual agents.

Unpremedicated Patients: In the absence of premedication, an average adult under the age of 55 years will usually require an initial dose of 0.3 to 0.35 mg/kg for induction, administered over 20 to 30 seconds and allowing 2 minutes for effect. If needed to complete induction, increments of approximately 25% of the patient's initial dose may be used; induction may instead be completed with inhalational anesthetics. In resistant cases, up to 0.6 mg/kg total dose may be used for induction, but such larger doses may prolong recovery.

Unpremedicated patients over the age of 55 years usually require less midazolam for induction; an initial dose of 0.3 mg/kg is recommended. Unpremedicated patients with severe systemic disease or other debilitation usually require less midazolam for induction. An initial dose of 0.2 to 0.25 mg/kg will usually suffice; in some cases, as little as 0.15 mg/kg may suffice.

Premedicated Patients: When the patient has received sedative or narcotic premedication, particularly narcotic premedication, the range of recommended doses is 0.15 to 0.35 mg/kg.

In average adults below the age of 55 years, a dose of 0.25 mg/kg, administered over 20 to 30 seconds and allowing 2 minutes for effect, will usually suffice.

The initial dose of 0.2 mg/kg is recommended for good risk (ASA I & II) surgical patients over the age of 55 years.

In some patients with severe systemic disease or debilitation, as little as 0.15 mg/kg may suffice.

Narcotic premedication frequently used during clinical trials included fentanyl (1.5 to 2 mcg/kg IV, administered 5 minutes before induction), morphine (dosage individualized, up to 0.15 mg/kg IM), and meperidine (dosage individualized, up to 1 mg/kg IM). Sedative premedications were hydroxyzine pamoate (100 mg orally) and sodium secobarbital (200 mg orally). Except for intravenous fentanyl, administered

	5 minutes before induction, all other premedications should be administered approximately 1 hour prior to the time anticipated for midazolam induction.
Injectable midazolam hydrochloride can also be used during maintenance of anesthesia, for surgical procedures, as a component of balanced anesthesia. Effective narcotic premedication is especially recommended in such cases.	Incremental injections of approximately 25% of the induction dose should be given in response to signs of lightening of anesthesia and repeated as necessary.
CONTINUOUS INFUSION For continuous infusion, midazolam hydrochloride 5 mg/mL formulation is recommended diluted to a concentration of 0.5 mg/mL with 0.9% sodium chloride or 5% dextrose in water.	***Usual Adult Dose:*** If a loading dose is necessary to rapidly initiate sedation, 0.01 to 0.05 mg/kg (approximately 0.5 to 4.0 mg for a typical adult) may be given slowly or infused over several minutes. This dose may be repeated at 10 to 15 minute intervals until adequate sedation is achieved. For maintenance of sedation, the usual initial infusion rate is 0.02 to 0.10 mg/kg/hr (1 to 7 mg/hr). Higher loading or maintenance infusion rates may occasionally be required in some patients. The lowest recommended doses should be used in patients with residual effects from anesthetic drugs, or in those concurrently receiving other sedatives or opioids. Individual response to midazolam is variable. The infusion rate should be titrated to the desired level of sedation, taking into account the patient's age, clinical status and current medications. In general, midazolam should be infused at the lowest rate that produces the desired level of sedation. Assessment of sedation should be performed at regular intervals and the midazolam infusion rate adjusted up or down by 25% to 50% of the initial infusion rate so as to assure adequate titration of sedation level. Larger adjustments or even a small incremental dose may be necessary if rapid changes in the level of sedation are indicated. In addition, the infusion rate should be decreased by 10% to 25% every few hours to find the minimum effective infusion rate. Finding the minimum effective infusion rate decreases the potential accumulation of midazolam and provides for the most rapid recovery once the infusion is terminated.

	Patients who exhibit agitation, hypertension, or tachycardia in response to noxious stimulation, but who are otherwise adequately sedated, may benefit from concurrent administration of an opioid analgesic. Addition of an opioid will generally reduce the minimum effective midazolam hydrochloride infusion rate.
PEDIATRIC PATIENTS	UNLIKE ADULT PATIENTS, PEDIATRIC PATIENTS GENERALLY RECEIVE INCREMENTS OF MIDAZOLAM HYDROCHLORIDE ON A MG/KG BASIS. As a group, pediatric patients generally require higher dosages of midazolam hydrochloride (mg/kg) than do adults. Younger (less than six years) pediatric patients may require higher dosages (mg/kg) than older pediatric patients, and may require close monitoring (see tables below). In obese PEDIATRIC PATIENTS, the dose should be calculated based on ideal body weight. When midazolam is given in conjunction with opioids or other sedatives, the potential for respiratory depression, airway obstruction, or hypoventilation is increased. For appropriate patient monitoring, see BOXED WARNING, WARNINGS, MONITORING subsection of DOSAGE AND ADMINISTRATION. The health care practitioner who uses this medication in pediatric patients should be aware of and follow accepted professional guidelines for pediatric sedation appropriate to their situation.

OBSERVER'S ASSESSMENT OF ALERTNESS/SEDATION (OAA/S)				
Assessment Categories				
Responsiveness	Speech	Facial Expression	Eyes	Composite Score
Responds readily to name spoken in normal tone	normal	normal	clear, no ptosis	5 (alert)
Lethargic response to name spoken in normal tone	mild slowing or thickening	mild relaxation	glazed or mild ptosis (less than half the eye)	4

Responds only after name is called loudly and/or repeatedly	slurring or prominent slowing	marked relaxation (slack jaw)	glazed and marked ptosis (half the eye or more)	3
Responds only after mild prodding or shaking	few recognizable words	–	–	2
Does not respond to mild prodding or shaking	–	–	–	1 (deep sleep)

FREQUENCY OF OBSERVER'S ASSESSMENT OF ALERTNESS/SEDATION COMPOSITE SCORES IN ONE STUDY OF PEDIATRIC PATIENTS UNDERGOING PROCEDURES WITH INTRAVENOUS MIDAZOLAM FOR SEDATION

Age Range (years)	n	OAA/S Score				
		1 (deep sleep)	2	3	4	5 (alert)
1-2	16	6 (38%)	4 (25%)	3 (19%)	3 (19%)	0
>2-5	22	9 (41%)	5 (23%)	8 (36%)	0	0
>5-12	34	1 (3%)	6 (18%)	22 (65%)	5 (15%)	0
>12-17	18	0	4 (22%)	14 (78%)	0	0
Total (1-17)	90	16 (18%)	19 (21%)	47 (52%)	8 (9%)	0

INTRAMUSCULARLY	USUAL PEDIATRIC DOSE (NON-NEONATAL)
FOR SEDATION/ANXIOLYSIS/AMNESIA PRIOR TO ANESTHESIA OR FOR PROCEDURES, INTRAMUSCULAR	SEDATION AFTER INTRAMUSCULAR MIDAZOLAM IS AGE AND DOSE DEPENDENT: HIGHER DOSES MAY RESULT IN DEEPER AND MORE PROLONGED

MIDAZOLAM CAN BE USED TO SEDATE PEDIATRIC PATIENTS TO FACILITATE LESS TRAUMATIC INSERTION OF AN INTRAVENOUS CATHETER FOR TITRATION OF ADDITIONAL MEDICATION.	SEDATION. DOSES OF 0.1 TO 0.15 MG/KG ARE USUALLY EFFECTIVE AND DO NOT PROLONG EMERGENCE FROM GENERAL ANESTHESIA. FOR MORE ANXIOUS PATIENTS, DOSES UP TO 0.5 MG/KG HAVE BEEN USED. ALTHOUGH NOT SYSTEMATICALLY STUDIED, THE TOTAL DOSE USUALLY DOES NOT EXCEED 10 MG. IF MIDAZOLAM IS GIVEN WITH AN OPIOID, THE INITIAL DOSE OF EACH MUST BE REDUCED.
INTRAVENOUSLY BY INTERMITTENT INJECTION For sedation/anxiolysis/amnesia prior to and during procedures or prior to anesthesia.	USUAL PEDIATRIC DOSE (NON-NEONATAL) It should be recognized that the depth of sedation/anxiolysis needed for pediatric patients depends on the type of procedure to be performed. For example, simple light sedation/anxiolysis in the preoperative period is quite different from the deep sedation and analgesia required for an endoscopic procedure in a child. For this reason, there is a broad range of dosage. For all pediatric patients, regardless of the indications for sedation/anxiolysis, it is vital to titrate midazolam hydrochloride and other concomitant medications slowly to the desired clinical effect. The initial dose of midazolam should be administered over 2 to 3 minutes. Since midazolam hydrochloride is water soluble, it takes approximately three times longer than diazepam to achieve peak EEG effects, therefore one must wait an additional 2 to 3 minutes to fully evaluate the sedative effect before initiating a procedure or repeating a dose. If further sedation is necessary, continue to titrate with small increments until the appropriate level of sedation is achieved. If other medications capable of depressing the CNS are coadministered, the peak effect of those concomitant medications must be considered and the dose of midazolam adjusted. The importance of drug titration to effect is vital to the safe sedation/anxiolysis of the pediatric patient. The total dose of midazolam will depend on patient response, the type and duration of the procedure, as well as the type and dose of concomitant medications. ***Pediatric Patients Less Than 6 Months of Age:*** Limited information is available in non-intubated pediatric patients less than 6 months of age. It is uncertain

	when the patient transfers from neonatal physiology to pediatric physiology, therefore the dosing recommendations are unclear. Pediatric patients less than 6 months of age are particularly vulnerable to airway obstruction and hypoventilation, therefore titration with small increments to clinical effect and careful monitoring are essential. ***Pediatric Patients 6 Months to 5 Years of Age:*** Initial dose 0.05 to 0.1 mg/kg; a total dose up to 0.6 mg/kg may be necessary to reach the desired endpoint but usually does not exceed 6 mg. Prolonged sedation and risk of hypoventilation may be associated with the higher doses. ***Pediatric Patients 6 to 12 Years of Age:*** Initial dose 0.025 to 0.05 mg/kg; total dose up to 0.4 mg/kg may be needed to reach the desired endpoint but usually does not exceed 10 mg. Prolonged sedation and risk of hypoventilation may be associated with the higher doses. ***Pediatric Patients 12 to 16 Years of Age:*** Should be dosed as adults. Prolonged sedation may be associated with higher doses; some patients in this age range will require higher than recommended adult doses but the total dose usually does not exceed 10 mg. The dose of midazolam hydrochloride must be reduced in patients premedicated with opioid or other sedative agents including midazolam. Higher risk or debilitated patients may require lower dosages whether or not concomitant sedating medications have been administered (see WARNINGS).
CONTINUOUS INTRAVENOUS INFUSION For sedation/anxiolysis/amnesia in critical care settings.	USUAL PEDIATRIC DOSE (NON-NEONATAL) To initiate sedation, an intravenous loading dose of 0.05 to 0.2 mg/kg administered over at least 2 to 3 minutes can be used to establish the desired clinical effect IN PATIENTS WHOSE TRACHEA IS INTUBATED. (Midazolam should not be administered as a rapid intravenous dose.) This loading dose may be followed

	by a continuous intravenous infusion to maintain the effect. An infusion of midazolam injection has been used in patients whose trachea was intubated but who were allowed to breathe spontaneously. Assisted ventilation is recommended for pediatric patients who are receiving other central nervous system depressant medications such as opioids. Based on pharmacokinetic parameters and reported clinical experience, continuous intravenous infusions of midazolam should be initiated at a rate of 0.06 to 0.12 mg/kg/hr (1 to 2 mcg/kg/min). The rate of infusion can be increased or decreased (generally by 25% of the initial or subsequent infusion rate) as required, or supplemental intravenous doses of midazolam hydrochloride can be administered to increase or maintain the desired effect. Frequent assessment at regular intervals using standard pain/sedation scales is recommended. Drug elimination may be delayed in patients receiving erythromycin and/or other P450-3A4 enzyme inhibitors (see PRECAUTIONS, DRUG INTERACTIONS) and in patients with liver dysfunction, low cardiac output (especially those requiring inotropic support), and in neonates. Hypotension may be observed in patients who are critically ill, particularly those receiving opioids and/or when midazolam is rapidly administered. When initiating an infusion with midazolam in hemodynamically compromised patients, the usual loading dose of midazolam hydrochloride should be titrated in small increments and the patient monitored for hemodynamic instability (e.g., hypotension). These patients are also vulnerable to the respiratory depressant effects of midazolam and require careful monitoring of respiratory rate and oxygen saturation.
CONTINUOUS INTRAVENOUS INFUSION For sedation in critical care settings.	USUAL NEONATAL DOSE Based on pharmacokinetic parameters and reported clinical experience in preterm and term neonates WHOSE TRACHEA WAS INTUBATED, continuous intravenous infusions of midazolam injection should be initiated at a rate of 0.03 mg/kg/hr (0.5 mcg/kg/min) in neonates <32 weeks and 0.06

	mg/kg/hr (1 mcg/kg/min) in neonates >32 weeks. Intravenous loading doses should not be used in neonates, rather the infusion may be run more rapidly for the first several hours to establish therapeutic plasma levels. The rate of infusion should be carefully and frequently reassessed, particularly after the first 24 hours so as to administer the lowest possible effective dose and reduce the potential for drug accumulation. This is particularly important because of the potential for adverse effects related to metabolism of the benzyl alcohol (see WARNINGS, USAGE IN PRETERM INFANTS AND NEONATES). Hypotension may be observed in patients who are critically ill and in preterm and term infants, particularly those receiving fentanyl and/or when midazolam is administered rapidly. Due to an increased risk of apnea, extreme caution is advised when sedating preterm and former preterm patients whose trachea is not intubated.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

CLOSE

HOW SUPPLIED

Midazolam Injection, USP is supplied as follows:

NDC	Midazolam Injection, USP (5 mg per mL)	Package Factor
47781-589-17	25 mg per 5 mL Multi-Dose Vial	10 vials per carton
47781-589-91	50 mg per 10 mL Multi-Dose Vial	10 vials per carton

Storage Conditions

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from light.

Sterile, Nonpyrogenic.

The container closure is not made with natural rubber latex.

CLOSE

ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY

Published studies in animals demonstrate that the use of anesthetic agents during the period of rapid brain growth or synaptogenesis results in widespread neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis. Based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester through the first several months of life, but may extend out to approximately 3 years of age in humans.

In primates, exposure to 3 hours of an anesthetic regimen that produced a light surgical plane of anesthesia did not increase neuronal cell loss, however, treatment regimens of 5 hours or longer increased neuronal cell loss. Data in rodents and in primates suggest that the neuronal and oligodendrocyte cell losses are associated with subtle but prolonged cognitive deficits in learning and memory. The clinical significance of these nonclinical findings is not known, and healthcare providers should balance the benefits of appropriate anesthesia in neonates and young children who require procedures against the potential risks suggested by the nonclinical data (see WARNINGS, PEDIATRIC NEUROTOXICITY and PRECAUTIONS, PREGNANCY and PEDIATRIC USE).

Manufactured by:
Gland Pharma Limited
D.P.Pally, Dundigal Post
Hyderabad-500 043, India

Product of India

Distributed by:
Alvogen, Inc.
Pine Brook, NJ 07058 USA

Revised: May 2017
PI589-00

CLOSE

PRINCIPAL DISPLAY PANEL

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – Carton

NDC 47781-589-17

Midazolam Injection, USP

C-IV

25 mg/5 mL

(5 mg/mL)

For Intramuscular or Intravenous Use. Sterile.

Rx only

APP0222

CONTAINS BENZYL ALCOHOL

CLOSE

PRINCIPAL DISPLAY PANEL

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – Carton

NDC 47781-589-91

Midazolam Injection, USP

C-IV

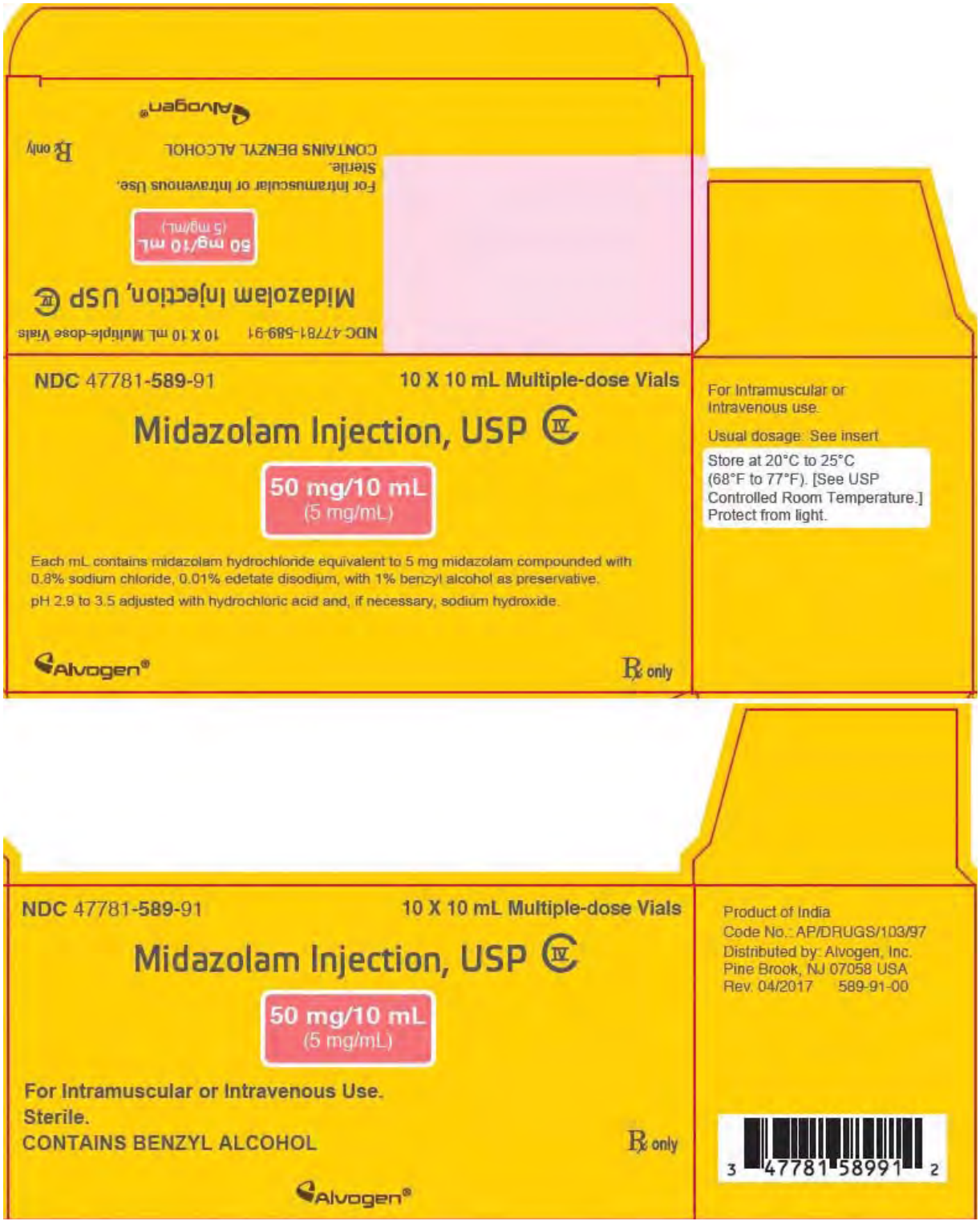
50 mg/10 mL

(5 mg/mL)

For Intramuscular or Intravenous Use. Sterile.

Rx only

CONTAINS BENZYL ALCOHOL



CLOSE

INGREDIENTS AND APPEARANCE

MIDAZOLAM
midazolam hydrochloride injection, solution

APP0225

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:47781-589
Route of Administration	INTRAVENOUS, INTRAMUSCULAR	**DEA Schedule**	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
midazolam hydrochloride (UNII: W7TTW573JJ) (midazolam - UNII:R60L0SM5BC)	midazolam	5 mg in 1 mL

INACTIVE INGREDIENTS	
Ingredient Name	**Strength**
sodium chloride (UNII: 451W47IQ8X)	
edetate disodium (UNII: 7FLD91C86K)	
benzyl alcohol (UNII: LKG8494WBH)	
sodium hydroxide (UNII: 55X04QC32I)	
hydrochloric acid (UNII: QTT17582CB)	

PACKAGING				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:47781-589-17	10 in 1 CARTON	08/11/2017	
1	NDC:47781-589-20	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:47781-589-91	10 in 1 CARTON	08/11/2017	
2	NDC:47781-589-22	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

MARKETING INFORMATION			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**

ANDA	ANDA090850	08/11/2017	

LABELER - ALVOGEN INC. (008057330)

CLOSE

VIEW ALL SECTIONS

FIND ADDITIONAL RESOURCES (also available in the left menu)

SAFETY

Boxed Warnings, Report Adverse Events, FDA Safety Recalls, Presence in Breast Milk

RELATED RESOURCES

Medline Plus, Clinical Trials, PubMed, Biochemical Data Summary

MORE INFO ON THIS DRUG

View Label Archives, RxNorm, Get Label RSS Feed

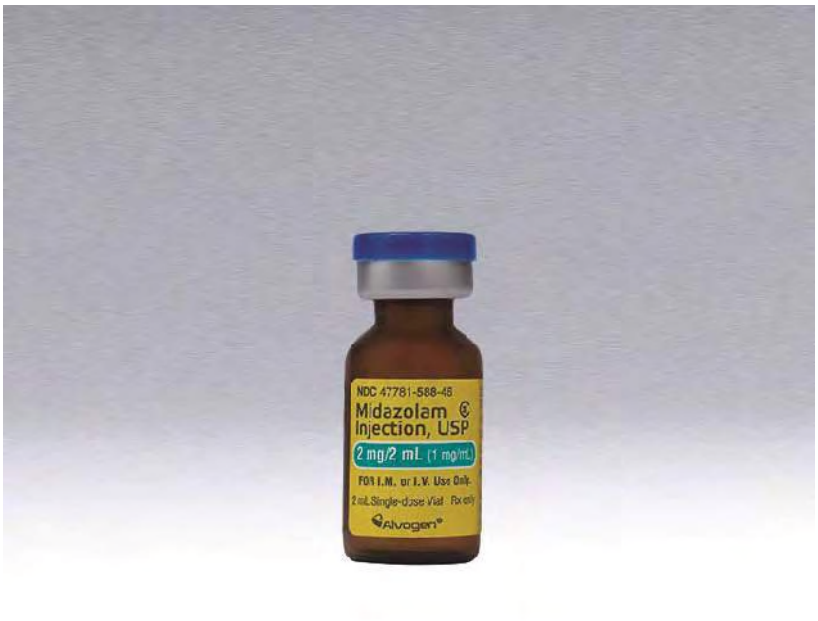
NIH NLM

EXHIBIT B

Midazolam Injection, USP C-IV Single Dose Vial

This product contains boxed warnings. See full prescribing information for this product.

Alvogen endorses the use of its products in accordance with FDA-approved indications. To this end, Alvogen has undertaken controls to avoid diversion of this product for use in execution protocols. In furtherance of this effort, Alvogen does not accept direct orders from prison systems or departments of correction. In addition, Alvogen is working to ensure that its distributors and wholesalers do not resell, either directly or indirectly this product, to prison systems or departments of correction.



MIDAZOLAM INJECTION, USP C-IV SINGLE DOSE VIAL

	NDC#	STRENGTH	PKG SIZE	GCN	GCN SEQ#	
	47781-588-68	2 mg/2 mL (1 mg/mL)	25			PRESCRIBING INFO **With Boxed Warnings**

APP0229

EXHIBIT C

CONTROLLED DISTRIBUTION PROGRAM SCHEDULE

1. Services. In consideration for the Service Fees described in this Controlled Distribution Program Schedule, Cardinal Health will provide the following services (collectively, the "Controlled Distribution Program Services"):

a . identification of existing eligible/ineligible customers
b. identification of new eligible/ineligible customers
c. order blocking/ restriction of sales to ineligible customers
d. customer facing communication outlining customer eligibility
e. monthly auditing of eligible / ineligible customers
f. restrict sales to all prison and retail customers

2. Supplier Obligations. In order to ensure that Cardinal Health is performing the Controlled Distribution Program Services as agreed by the Parties, Supplier agrees to:

a. provide customer facing communication outlining change in distribution request by Supplier to Cardinal Health
b. communicate Product adds/deletes
c. provide supplier contact to address customer specific classification inquiries
d. timely respond to inquiries regarding Eligibility inquiries

3. Products subject to the Controlled Distribution Program Agreement. Cardinal Health will perform the Controlled Distribution Program Services with respect to the following Products (collectively, the "Controlled Distribution Products"):

NDC-11	Product Description
47781-0589-17	Midazolam Inj Vial 25mg/5ml 10ct
47781-0588-68	Midazolam Inj Vial 2mg/2ml 25ct
47781-0589-91	Midazolam Inj Vial 50mg/10ml 10ct
47781-0616-17	Rocuronium Brom Inj Vial 50mg/5mL 10ct
47781-0617-91	Rocuronium Brom InjVial 100mg/10mL 10ct

4. Service Fees. In consideration for the Controlled Distribution Program Services, Supplier will pay Cardinal Health a service fee as follows (the "Controlled Distribution Program Service Fee"):

[redacted]

Definitions.

(i) Eligibility means those customers that Supplier has communicated are eligible or ineligible to purchase the products subject to the Controlled Distribution Program.

CONTROLLED DISTRIBUTION PROGRAM

THIRD AMENDMENT TO GENERIC WHOLESALE SERVICE AGREEMENT

This Controlled Distribution Program Amendment ("Amendment") is by and between Alvogen Inc. ("Supplier") and Cardinal Health* ("Cardinal Health").

RECITALS

Cardinal and Supplier are parties to a Generic Wholesale Service Agreement dated as of March 1, 2010 ("Agreement"). The parties desire to amend the Agreement as provided in this Amendment.

Effective May 28, 2018, the parties agree as follows:

1. The designation of those subsidiaries of Cardinal Health, Inc. included in the definition of "Cardinal Health" hereunder is hereby ratified and, as such, those subsidiaries will be included in the definition of "Cardinal Health" for purposes of the Original Agreement

2. ***Amendment to Section 1.*** The following Sentence is hereby added to the end of Section 1 of the Agreement:

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

2. Addition of Schedule. The Agreement is hereby amended to add the Controlled Distribution Program Schedule attached to this Amendment at the end of the Agreement.

3. No Other Changes. Except as specifically set forth in this Amendment, the Agreement will continue in full force and effect without change.

4. Interpretation. To the extent there are any inconsistencies between the provisions of this Amendment and the provisions of the Agreement, the provisions of this Amendment will control. Capitalized terms not otherwise defined herein shall have the same meaning given those terms in the Agreement, it being the intent of the parties that the Agreement and this Amendment will be applied and construed as a single instrument. The Agreement, as modified by this Amendment, constitutes the entire agreement between Supplier and Cardinal regarding the subject matter of this Amendment and supersedes all prior or contemporaneous writings and understandings between the parties regarding the same.

5. Authorized Signatories. All signatories to this Amendment represent that they are authorized by their respective companies to execute and deliver this Amendment on behalf of their respective companies, and to bind such companies to the terms herein.

* * * * *

Alvogen Inc.

By: _____

Print Name: Richard Harker

Title: VP, Commercialization - Injectables

Address of Supplier:
10 Bloomfield Ave, Bldg B
Pine Brook, NJ 07058

Cardinal Health*

By: _____

Print Name: CRAIG COWRAN

Title: EVP Global Sourcing

Address of Cardinal Health:
7000 Cardinal Place
Attention: SVP – Generic Sourcing
Dublin, Ohio 43017

*The term "Cardinal" or "Cardinal Health" means Cardinal Health 3, LLC; Cardinal Health 104 LP; Cardinal Health 107, LLC; Cardinal Health 110, LLC; Cardinal Health 112, LLC; Cardinal Health P.R. 120, Inc.; The Harvard Drug Group, L.L.C.; and any other affiliate of Cardinal Health, Inc., an Ohio corporation ("CHI"), as may be designated by CHI.

EXHIBIT D

Drug company threatens legal action to prevent drug from being used in Dozier's execution

foxreno.com /news/local/new-drug-in-nevada-execution-plan-linked-to-botched-executions-in-other-states

by Ben Margiott

Thursday, July 5th 2018

New drug in Nevada execution plan linked to botched executions in other states

RENO, Nev. (News 4 & Fox 11) — UPDATE: According to an Alvogen spokesperson, the company is considering taking legal action to prevent their drug from being used in Wednesday's scheduled execution in Ely.

Alvogen makes one of the drugs used that will be used in Scott Dozier's execution.

Statement from spokesperson Halldór Kristmannsson:

> "Alvogen does not market, promote or condone the use of any of its approved prescription drug products, including midazolam, for use in state sponsored executions. To avoid any improper, off label use of our products, Alvogen does not accept direct orders from prison systems or departments of correction. Alvogen works with our distributors and wholesalers to restrict any resale, either directly or indirectly, of our midazolam product to any prison system or department of correction.
>
> With respect to the alleged intent of the State of Nevada Department of Corrections to use our midazolam product in an execution, we are exploring all potential avenues, including legal recourse, to prevent the improper use of our product in this particular execution."

Nevada is just two days away from executing its first inmate in over a decade, but questions still linger about the controversial three-drug lethal injection combination the Department of Corrections plans to use.

After NDOC's supply of the sedative Diazepam recently expired, the state obtained adequate dosages of the sedative Midazolam, which has been linked to multiple botched executions in other states.

The new sedative drug Midazolam was made by the pharmaceutical company Alvogen, and distributed by Cardinal Health, according to a sales invoice obtained by News 4.

According to the Lethal Injection Information Center, "Alvogen is working to ensure that its distributors and wholesalers do not resell, either directly or indirectly, [Alvogen products] to prison systems or departments of correction."

Midazolam has factored into botched executions in Ohio, Oklahoma, Arizona and Alabama, according to the nonprofit and nonpartisan Death Penalty Information Center.

The sedative was also used in an April 2017 Arkansas execution where witnesses described the inmate "coughing, convulsing, lurching and jerking."

Kelly Kissel, a longtime Associated Press news editor and the current metro editor at The Advocate, has witnessed over 10 executions, including the recent Arkansas one.

"Three or four minutes into the execution was when he started lurching forward. His forehead was pressing against the restraint that was around his forehead," Kissel said.

> "For lack of a better term, it was the most violent execution that I had seen."

According to DPIC, the use of Midazolam factored into an Alabama inmate "heaving and gasping for breath" for about 15 minutes.

Both Florida and Arizona recently abandoned the use of Midazolam in three-drug lethal injection combinations.

Questions remain about the other drugs in the lethal injection combination — the opioid Fentanyl and the paralytic Cisatracurium.

The paralytic element Cisatracurium was the focus of court challenges late last year, with critics arguing that the drug would mask signs of possible suffering, or lead to so-called air hunger.

Fentanyl is in both Nevada and Nebraska's execution protocols, but has never been used in an execution in the United States.

Nevada plans to execute convicted murderer Scott Dozier, now 47, on July 11th at 8:00 p.m. at the Ely State Prison.

Dozier has voluntarily waived all his appeals and maintains that he wants to be executed.

EXHIBIT E

Nevada releases records on sedative to be used in execution

AP apnews.com /79a2e272ac954e5bae7c0e63218fa51e

LAS VEGAS (AP) — Nevada prison officials released records Friday afternoon about where and when a sedative was obtained for use next week in the state's first execution since 2006.

Records from the Nevada Department of Corrections show midazolam slated for use in Scott Raymond Dozier's lethal injection Wednesday was purchased in May from the state's regular pharmaceutical distributor, Cardinal Health, and manufactured by pharmaceutical company Alvogen.

The U.S. Supreme Court ruled in 2015 that midazolam can be used in lethal injections. But the drug has been blamed in recent years for problem executions in several other states.

Messages seeking comment from Alvogen on Friday afternoon were not immediately returned. The company, however, said on a webpage for the product that it opposes the drug's use in lethal injections.

The company says it has taken steps to try to avoid having midazolam be used in executions and does not accept orders from prison systems or corrections departments. The company says it is also working to ensure its distributors and wholesalers do not directly or indirectly resell the drug to prisons or corrections departments.

A message seeking comment from Cardinal Health was not immediately returned Friday.

The American Civil Liberties Union of Nevada points to Arizona's decision to stop using the drug after a 2014 lethal injection that took nearly two hours to kill Joseph Rudolph Wood. The organization has criticized the plan for Dozier's lethal injection as being less human than putting down a pet.

Nevada plans to use midazolam injections to be followed by high doses of the powerful synthetic opioid fentanyl and muscle-paralyzing drug cisatracurium. Fentanyl and cisatracurium have never before been used for executions.

Dozier has been on death row since 2007 after being convicted in murders in Phoenix and Las Vegas. The 47-year-old has waived appeals in his case and has said he wants to die and doesn't care if he suffers.

ACLU of Nevada spokesman Wesley Juhl said the organization was reviewing the Nevada records Friday afternoon and figuring out its next steps.

EXHIBIT 2

DECLARATION OF ANDREA SWEET IN SUPPORT OF PLAINTIFF'S *EX PARTE* APPLICATION FOR TEMPORARY RESTRAINING ORDER AND MOTION FOR PRELIMINARY INJUNCTION; *EX PARTE* MOTION FOR ORDER SHORTENING TIME

I, ANDREA SWEET, declare as follows:

1. I am Alvogen's Vice President of Legal Affairs, and am competent to testify to the matters stated herein based upon personal knowledge, except for those matters stated upon information and belief, and to those matters, I believe them to be true.

2. If called as a witness, I would testify competently thereto.

3. I make this Declaration in support of Alvogen, Inc.'s ("Alvogen") *Ex Parte* Application for Temporary Restraining Order and Motion for Preliminary Injunction; *Ex Parte* Motion for Order Shortening Time.

4. On April 20, 2018, I sent letters to the Governors, Attorneys General, and Department of Corrections Directors in every state that has a death penalty, including Nevada Governor Brian Sandoval, Nevada Attorney General Adam Laxalt, Nevada Department of Corrections ("NDOC") Director James Dzurenda, and the NDOC facility at Ely State Prison, where Nevada's newly-constructed death penalty chamber is located, stating "in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment" and demanding that the state immediately return Alvogen's product for a full refund if it was purchased for use in capital punishment procedures. Attached as Exhibit A to this Declaration are true and correct copies of the letters sent to these Nevada officials. The envelopes addressed to these Nevada officials are attached as Exhibit B hereto.

5. In the early morning hours of Saturday July 7, 2018, I was contacted by a member of our PR team regarding an inquiry from the press, who conveyed that Nevada had announced its intent to conduct the execution of Scott Raymond Dozier on Wednesday, July 11, 2018 by use of a three-drug cocktail, including midazolam distributed by Alvogen and obtained through

PISANELLI BICE PLLC
400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

Cardinal Health ("Cardinal"). A true and correct copy of that email is attached hereto as Exhibit C. I promptly undertook action consistent with the statements and policies referenced in my April 20, 2018 letters.

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

Executed on July 9, 2018.

ANDREA SWEET

PISANELLI BICE PLLC
400 SOUTH 7TH STREET, SUITE 300
LAS VEGAS, NEVADA 89101

EXHIBIT A

State Governor
State Attorney General
Director of the State Department of Corrections

April 20, 2018

Dear Attorney General Laxalt,

My name is Andrea Sweet and I am a Vice President, Legal Affairs at Alvogen, Inc.

Alvogen is aware that certain medicines we manufacture for specific healthcare applications are currently sought by some correctional facilities in the US for use in lethal injection executions.

I am writing to communicate in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment. While Alvogen takes no position on the death penalty itself, our products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

To ensure our products are not purchased for use in lethal injection executions, Alvogen does not accept orders from any state departments of corrections. Further, Alvogen has controls in place and directs its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions. These controls reflect our company's policy of ensuring the appropriate use of our medicines.

The use of Alvogen products, such as midazolam or rocuronium, in executions clearly runs counter to the FDA-approved indication for these products. If your state has purchased products manufactured by Alvogen for use in capital punishment procedures – either directly or indirectly – we ask that you immediately return our products in exchange for a full refund.

Finally, I have been informed that some states have implemented "secrecy policies/laws" which they hope will enable them to bypass company control systems and purchase manufactured medicines for use in executions. Alvogen closely tracks the distribution of its medicines as required by law and will take action in case of such diversions. Transparency across the supply chain is important to protect public health and the commercial interests of healthcare companies.

If you require further clarification regarding our opposition to the misuse of medicines in executions or have questions about specific products you have purchased from Alvogen, please do not hesitate to contact me; I would be glad to discuss these issues further.

Sincerely,

Andrea Sweet
Vice President, Legal Affairs

10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Phone 973 796 3400
Fax 973 796 3439

info@alvogen.com
www.alvogen.com

State Governor
State Attorney General
Director of the State Department of Corrections

April 20, 2018

Dear Governor Sandoval,

My name is Andrea Sweet and I am a Vice President, Legal Affairs at Alvogen, Inc.

Alvogen is aware that certain medicines we manufacture for specific healthcare applications are currently sought by some correctional facilities in the US for use in lethal injection executions.

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Sincerely,

Andrea Sweet
Vice President, Legal Affairs

10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Phone 973 796 3400
Fax 973 796 3439

info@alvogen.com
www.alvogen.com

State Governor
State Attorney General
Director of the State Department of Corrections

April 20, 2018

Dear Mr. Dzurenda,

My name is Andrea Sweet and I am a Vice President, Legal Affairs at Alvogen, Inc.

Alvogen is aware that certain medicines we manufacture for specific healthcare applications are currently sought by some correctional facilities in the US for use in lethal injection executions.

I am writing to communicate in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment. While Alvogen takes no position on the death penalty itself, our products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

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Sincerely,

Andrea Sweet
Vice President, Legal Affairs

10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Phone 973 796 3400
Fax 973 796 3439

info@alvogen.com
www.alvogen.com

State Governor
State Attorney General
Director of the State Department of Corrections

April 20, 2018

Dear Warden Filson,

My name is Andrea Sweet and I am a Vice President, Legal Affairs at Alvogen, Inc.

Alvogen is aware that certain medicines we manufacture for specific healthcare applications are currently sought by some correctional facilities in the US for use in lethal injection executions.

I am writing to communicate in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment. While Alvogen takes no position on the death penalty itself, our products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

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Sincerely,

Andrea Sweet
Vice President, Legal Affairs

10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Phone 973 796 3400
Fax 973 796 3439

info@alvogen.com
www.alvogen.com

EXHIBIT B

Alvogen
10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Attorney General Adam Paul Laxalt
Old Supreme Ct. Bldg
100 N. Carson St.
Carson City, NV 89701

Alvogen
10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Governor Brian Sandoval
Capitol Building
Carson City, NV 89701

Alvogen
10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Attorney General James Dzurenda
5500 Snyder Ave,
P.O. Box 7011
Carson City, Nevada, 89701

Alvogen
10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Warden Timothy Filson
Ely State Prison
P.O. Box 1989
4569 North State Rt.
Ely, Nevada 89301

EXHIBIT C

From: Halldor Kristmannsson
Sent: Saturday, July 7, 2018 3:53 AM
To: Lisa Graver <Lisa.Graver@alvogen.com>; Andrea J Sweet <Andrea.Sweet@alvogen.com>
Cc: Arni Hardarson <arni.hardarson@alvogen.com>
Subject: FW: Use of Midazolam in Nevada Execution?

Hello guys, pls see below.

Halldor

From: Michelle Rindels <michelle@thenvindy.com>
Sent: föstudagur, 6. júlí 2018 22:48
To: Halldor Kristmannsson <halldor.kristmannsson@alvogen.com>
Subject: Use of Midazolam in Nevada Execution?

Hello,

I wanted to reach out because the Nevada Department of Corrections has said it will be using midazolam for an upcoming execution next week, and the photos they provided show it's an Alvogen product purchased through wholesaler Cardinal Health.

Wondering if the company has a statement on the use of its product for an execution, and if it is taking any steps to prevent that?

Please let me know. Thanks so much,

--

Michelle Rindels

Reporter

The Nevada Independent

Twitter: @MichelleRindels

Cell: 209-986-7411

www.thenevadaindependent.com

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing **APPENDIX TO PETITION TO DISSOLVE STAY OF EXECUTION UNDER NRS 176.492 AND PETITION FOR WRIT OF MANDAMUS OR PROHIBITION (VOLUMES 1 and 2)** with the Clerk of the Court for the Nevada Supreme Court by Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

I further certify that a courtesy copy was emailed to counsel for Respondents simultaneously with the filing of the foregoing.

A copy was also provided to the following:

James J. Pisanelli, Esq.
Todd Bice, Esq.
Debra Spinelli, Esq.
PISANELLI BICE, PLLC
400 South 7th Street, Suite 300
Las Vegas, NV 89101

Kenneth Schuler
Michael Faris
Alex Grabowski
LATHAM & WATKINS, LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611

Angela Walker
LATHAM & WATKINS, LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004-1304

Hon. Elizabeth Gonzalez
Eighth Judicial District Court
Department 11

200 Lewis Avenue
Las Vegas, NV 89155

/s/ *Barbara Fell*
An employee of the
Office of the Attorney General

IN THE SUPREME COURT OF THE STATE OF NEVADA

*****

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

Petitioners,

vs.

THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA, IN AND FOR THE COUNTY OF CLARK; AND THE HONORABLE ELIZABETH GONZALEZ, DISTRICT COURT JUDGE,

Respondents,

and

ALVOGEN, INC.,

Real Party in Interest.

Supreme Court Case No.:
District Court No.: A-18-777312-B

APPENDIX TO PETITION TO DISSOLVE STAY OF EXECUTION UNDER NRS 176.492 AND PETITION FOR WRIT OF MANDAMUS OR PROHIBITION

VOLUME 1 OF 2

ADAM PAUL LAXALT
Attorney General
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APPENDIX - TABLE OF CONTENTS

FILED
JUN 19 2018
CLERK OF COURT

ORDE
STEVEN B. WOLFSON
Clark County District Attorney
Nevada Bar #001565
JONATHAN E. VANBOSKERCK
Chief Deputy District Attorney
Nevada Bar #006528
200 Lewis Avenue
Las Vegas, Nevada 89155-2212
(702) 671-2500
Attorney for Plaintiff

DISTRICT COURT
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

SCOTT RAYMOND DOZIER, aka, Chad Wyatt, #0927782

Defendant.

CASE NO: 05C215039

DEPT NO: IX

THIRD SUPPLEMENTAL ORDER OF EXECUTION

A JUDGMENT OF DEATH having been entered on the 3rd day of October, 2007, against the above named Defendant, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, as a result of his having been found guilty of COUNT 1 – MURDER OF THE FIRST DEGREE, by a duly and legally impaneled Jury of twelve persons; and

WHEREAS, this Court has made inquiry into the facts and found no legal reasons against the execution of the Judgment of Death.

IT IS ORDERED that the Director of the State of Nevada Department of Corrections shall execute the Judgment of Death, during the week commencing on the 9th day of July, 2018.

DATED this 19th day of June, 2018.

Jennifer P. Togliatti
DISTRICT JUDGE
NL

FILED
JUN 19 2018
CLERK OF COURT

WARE
STEVEN B. WOLFSON
Clark County District Attorney
Nevada Bar #001565
JONATHAN E. VANBOSKERCK
Chief Deputy District Attorney
Nevada Bar #006528
200 Lewis Avenue
Las Vegas, Nevada 89155-2212
(702) 671-2500
Attorney for Plaintiff

DISTRICT COURT
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

SCOTT RAYMOND DOZIER, aka,
Chad Wyatt, #0927782

Defendant.

CASE NO: 05C215039

DEPT NO: IX

THIRD SUPPLEMENTAL WARRANT OF EXECUTION

TO: THE SHERIFF OF CLARK COUNTY, NEVADA; and
THE DIRECTOR OF THE STATE OF NEVADA DEPARTMENT OF CORRECTIONS:

WHEREAS, on September 25, 2007, SCOTT RAYMOND DOZIER, aka, Chad Wyatt was found guilty of COUNT 1 – MURDER OF THE FIRST DEGREE WITH USE OF A DEADLY WEAPON by a duly and legally impaneled jury of twelve persons; and

WHEREAS, on October 3, 2007, that same jury returned a verdict of death against SCOTT RAYMOND DOZIER, aka, Chad Wyatt as to COUNT 1 – MURDER OF THE FIRST DEGREE WITH USE OF A DEADLY WEAPON; and

WHEREAS, on December 20, 2007, SCOTT RAYMOND DOZIER, aka, Chad Wyatt filed an appeal with the Supreme Court of the State of Nevada; and

WHEREAS, on January 20, 2012, the Nevada Supreme Court filed an ORDER AFFIRMING IN PART, REVERSING IN PART AND REMANDING SCOTT RAYMOND DOZIER, aka, Chad Wyatt's conviction for MURDER OF THE FIRST DEGREE WITH USE

OF A DEADLY WEAPON, wherein the Supreme Court of the State of Nevada remanded the matter to the district court to strike the deadly weapon enhancement attendant to the murder conviction, but affirmed the conviction of MURDER OF THE FIRST DEGREE as well as the Jury's imposition of the Death Penalty, with an Amended Judgment of Conviction being filed on June 4, 2012; and

WHEREAS, on June 4, 2012, the Court filed an Amended Judgment of Conviction striking the deadly weapon enhancement attendant to COUNT 1 – MURDER OF THE FIRST DEGREE; and

WHEREAS, on July 27, 2012, SCOTT RAYMOND DOZIER, aka, Chad Wyatt filed a Petition for Writ of Habeas Corpus (Post-Conviction); and

WHEREAS, on October 31, 2016, SCOTT RAYMOND DOZIER, aka, Chad Wyatt contacted this Court by letter and indicated a desire to cease habeas litigation, waive all post-conviction and appellate remedies and submit to his sentence of death. SCOTT RAYMOND DOZIER, aka, Chad Wyatt has consistently maintained this position; and

WHEREAS, out of an abundance of caution, this Court ordered a psychological evaluation of SCOTT RAYMOND DOZIER, aka, Chad Wyatt. Dr. Michael Krelstein authored a report dated July 9, 2017, that concluded that SCOTT RAYMOND DOZIER, aka, Chad Wyatt was competent to decide whether to cease habeas litigation, waive all post-conviction and appellate remedies and submit to his sentence of death; and

WHEREAS, the parties have agreed to stay the Petition for Writ of Habeas Corpus filed on July 27, 2012, in order to facilitate imposition of sentence. The parties have further agreed that should the STATE OF NEVADA not be able to carry out SCOTT RAYMOND DOZIER, aka, Chad Wyatt's execution that the stay be lifted and habeas litigation may proceed in the ordinary course, meaning that SCOTT RAYMOND DOZIER, aka, Chad Wyatt will be in the same procedural posture as he was before attempting to carry out the execution; and

WHEREAS, on November 27, 2017, this Court entered an order enjoining the use of a paralytic drug in Dozier's execution; and

WHEREAS, on June 1, 2018, this Court entered an order vacating the order enjoining the use of a paralytic drug in Dozier's execution; and

WHEREAS, the Court, in which the conviction was had and pursuant to NRS 176.505, has inquired into the facts and determined that no legal reasons exist against the execution of the judgment of death, and there being no stay entered as provided for in NRS 176.486 or 176.487 and pursuant to NRS 176.495 has entered a third supplemental order to execute the judgment and sentence of death,

NOW THEREFORE, it is hereby

ORDERED that the County Clerk of the County of Clark, State of Nevada, shall forthwith, execute, in triplicate, under the Seal of the Court, certified copies of the Third Supplemental Warrant of Execution, the Amended Judgment of Conviction, and of the entry thereof in the Court Minutes. The original of the triplicate copies of the Amended Judgment of Conviction, Third Supplemental Warrant of Execution, and entry thereof in the Court Minutes, shall be filed in the Office of the County Clerk, and two of the triplicate copies shall be immediately delivered by the Clerk to the Sheriff of Clark County, State of Nevada.

IT IS FURTHER ORDERED that one of the triplicate copies be delivered by the Sheriff to the Director of the State of Nevada Department of Corrections or to such person as the Director shall designate. The Sheriff is hereby directed to take charge of the said Defendant, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, and transport and safely deliver the prisoner, forthwith, to the Director of the State of Nevada Department of Corrections, and said prisoner, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, is to be surrendered to the custody of the said Director of the State of Nevada Department of Corrections or to such authorized person so designated by the Director of the State of Nevada Department of Corrections, in the event he is not already so imprisoned, for the imprisonment and execution of the said Defendant, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, in accordance with the provisions of this Third Supplemental Warrant of Execution.

IT IS FURTHER ORDERED that in connection with the above facts and pursuant to the provisions of NRS 176.345, 176.355, 176.357 and/or 176.495, the Director of the State of

Nevada Department of Corrections, or such person as shall by him be designated, shall carry out said Judgment and Sentence by executing the said SCOTT RAYMOND DOZIER, aka, Chad Wyatt, by the administration to him, said Defendant, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, an injection of a lethal drug(s), the drug or combination of drugs to be used for the execution to be selected by the Director of the State of Nevada Department of Corrections after consulting with the Chief Medical Officer, *See* NRS 176.355. Said execution to be within the limits of the State Prison, located at or near Ely, State of Nevada, during the week commencing on July 9, 2018, in the presence of the Director of the State of Nevada Department of Corrections, and notify those members of the immediate family of the victim who have, pursuant to NRS 176.357, requested to be informed of the time, date and place scheduled for the execution, and invite a competent physician, the county coroner, a psychiatrist, and not less than six reputable citizens over the age of twenty-one (21) years to be present at the execution. The Director shall determine the maximum number of persons who may be present for the execution. The Director shall give preference to those eligible members or representatives of the immediate family of the victim who requested, pursuant to NRS 176.357, to attend the execution. The execution must take place at the state prison and a person who has not been invited by the Director may not witness the execution.

ORDERED that said Defendant shall be safely kept and imprisoned by said Director until the Defendant is put to death by the injection of a lethal drug, or combination of drugs, and these presents shall be your authority so to do.

HEREIN FAIL NOT.

WITNESS, the HONORABLE JENNIFER TOGLIATTI, this 19th day of June, 2018.

Jennifer P. Togliatti
DISTRICT JUDGE

NL

WITNESS my hand and seal this 19th day of June, 2018.
STEVEN D. GRIERSON, Clerk

BY Steven D. Grierson

Name: Amy Rose, NV Bar 12081
Mailing Address: 601 S. Rancho Dr. Ste B-11
City, State, Zip: Las Vegas, NV 89106
Telephone: 702-366-1536

In The First Judicial District Court of the State of Nevada
In and for Carson City

American Civil Liberties Union of Nevada, A Non Profit Org.
Plaintiff,

vs.

State of Nevda ex rel, the Nev. Dept. of Corrections; James Dzurenda in his official capacity
Defendant.

Case No.: 18 OC 00143 1B

Dept. No.: I

Add 1

SUMMONS

THE STATE OF NEVADA SENDS GREETINGS TO THE ABOVE-NAMED DEFENDANT:

NOTICE! YOU HAVE BEEN SUED. THE COURT MAY DECIDE AGAINST YOU WITHOUT YOUR BEING HEARD UNLESS YOU RESPOND WITHIN 20 DAYS.

READ THE INFORMATION BELOW.

TO THE DEFENDANT: A civil Complaint has been filed by the plaintiff against you.

1. If you wish to defend this lawsuit, you must, within 20 days after this Summons is served on you, exclusive of the day of service, file with this Court a written pleading* in response to this Complaint.
2. Unless you respond, your default will be entered upon application of the plaintiff, and this Court may enter a judgment against you for the relief demanded in the Complaint**, which could result in the taking of money or property or the relief requested in the Complaint.
3. If you wish to seek the advice of an attorney in this matter, you should do so promptly so that your response may be filed on time.
4. You are required to serve your response upon plaintiff's attorney, whose address is:

Amy Rose, Esq.
American Civil Liberties Union
601 S. Rancho Dr. Suite B-11
Las Vegas, NV 89106

SUSAN MERRIWETHER, Clerk of the Court

By: _____, Deputy Clerk

Date: July 3, 2018.

*There is a fee associated with filing a responsive pleading. Please refer to fee schedule.
**Note – When service by publication, insert a brief statement of the object of the action. See Rule 4.

RETURN OF SERVICE ON REVERSE SIDE

AFFIDAVIT OF SERVICE (For General Use)

STATE OF _____)
) **ss.**
COUNTY OF _____)

_____, declares under penalty of perjury:
That affiant is, and was on the day when (s)he served the within Summons, over 18 years of age, and not a party to, nor interested in, the within action; that the affiant received the Summons on the _____ day of _____, 20_____, and personally served the same upon _____ the within named defendant, on the _____ day of _____, 20_____, by delivering to the said defendant, personally, in _____, County of _____, State of _____, a copy of the Summons attached to a copy of the Complaint.
I declare under penalty of perjury under the law of the state of Nevada that the foregoing is true and correct.
Executed this _____ day of _____, 20___. _____
Signature of person making service

NEVADA SHERIFF'S RETURN
(for use of Sheriff of Carson City)

STATE OF NEVADA)
) **ss.**
CARSON CITY)
I hereby certify and return that I received the within Summons on the _____ day of _____, 20_____, and personally served the same upon _____, the within named defendant, on the _____ day of _____, 20_____, by delivering to the said defendant, personally, in Carson City, State of Nevada, a copy of the Summons attached to a copy of the Complaint.
KENNY FURLONG, Sheriff of Carson City, Nevada
Date: _____, 20_____. By:_____, Deputy

AFFIDAVIT OF MAILING
(For use when service is by publication and mailing)

STATE OF _____)
) **ss.**
COUNTY OF _____)

_____, declares under penalty of perjury:
That affiant is, and was when the herein described mailing took place, over 18 years of age, and not a party to, nor interested in, the within action; that on the _____ day of _____, 20____, affiant deposited in the Post Office at _____, Nevada, a copy of the within Summons attached to a copy of the Complaint, enclosed in a sealed envelope upon which first class postage was fully prepaid, addressed to _____ the within named defendant, at _____; that there is a regular communication by mail between the place of mailing and the place so addressed.
I declare under penalty of perjury under the law of the State of Nevada that the foregoing is true and correct.
Executed this _____ day of _____, 20___. _____

NOTE - If service is made in any manner permitted by Rule 4 other than personally upon the defendant, or is made outside the United States, a special affidavit or return must be made.

TRICT COURT CIVIL COVER SH.

Carson City County, Nevada

Case No. REC'D & FILED

(Assigned by Clerk's Office)

2018 JUL -3 PM 3:17

I. Party Information *(provide both home and mailing addresses if different)*

Plaintiff(s) (name/address/phone):	Defendant(s) (name/address/phone):
	SUSAN MERRIWETHER
The American Civil Liberties Union of Nevada Foundation, a non-profit organization.	State of Nevada ex rel. the Nevada Department of Corrections, James Dzurenda, in his official capacity as Director.
601 S. Rancho Dr. Ste B-11, Las Vegas, NV 89106	5500 Snyder avenue Bldg. 17, Carson City, NV 89701
702-366-1536	(775) 887-3285
Attorney (name/address/phone):	Attorney (name/address/phone):
Amy Rose	Nevada Attorney General
601 S. Rancho Dr. Ste B-11, Las Vegas, NV 89016	100 North Carson St. Carson City, NV 89701
702-366-1536	775-684-1100

II. Nature of Controversy *(please select the one most applicable filing type below)*

Civil Case Filing Types

Real Property

Landlord/Tenant
- ☐ Unlawful Detainer
- ☐ Other Landlord/Tenant

Title to Property
- ☐ Judicial Foreclosure
- ☐ Foreclosure Mediation Assistance
- ☐ Other Title to Property

Other Real Property
- ☐ Condemnation/Eminent Domain
- ☐ Other Real Property

Torts

Negligence
- ☐ Auto
- ☐ Premises Liability
- ☐ Other Negligence

Malpractice
- ☐ Medical/Dental
- ☐ Legal
- ☐ Accounting
- ☐ Other Malpractice

Other Torts
- ☐ Product Liability
- ☐ Intentional Misconduct
- ☐ Employment Tort
- ☐ Insurance Tort
- ☐ Other Tort

Probate

Probate *(select case type and estate value)*
- ☐ Summary Administration
- ☐ General Administration
- ☐ Special Administration
- ☐ Set Aside ☐ Surviving Spouse
- ☐ Trust/Conservatorship
- ☐ Other Probate

Estate Value
- ☐ Greater than $300,000
- ☐ $200,000-$300,000
- ☐ $100,001-$199,999
- ☐ $25,001-$100,000
- ☐ $20,001-$25,000
- ☐ $2,501-20,000
- ☐ $2,500 or less

Construction Defect & Contract

Construction Defect
- ☐ Chapter 40
- ☐ Other Construction Defect

Contract Case
- ☐ Uniform Commercial Code
- ☐ Building and Construction
- ☐ Insurance Carrier
- ☐ Commercial Instrument
- ☐ Collection of Accounts
- ☐ Employment Contract
- ☐ Other Contract

Judicial Review/Appeal

Judicial Review
- ☐ Petition to Seal Records
- ☐ Mental Competency

Nevada State Agency Appeal
- ☐ Department of Motor Vehicle
- ☐ Worker's Compensation
- ☐ Other Nevada State Agency

Appeal Other
- ☐ Appeal from Lower Court
- ☐ Other Judicial Review/Appeal

Civil Writ

Civil Writ
- ☐ Writ of Habeas Corpus
- ☒ Writ of Mandamus
- ☐ Writ of Quo Warrant
- ☐ Writ of Prohibition
- ☐ Other Civil Writ

Other Civil Filing

Other Civil Filing
- ☐ Compromise of Minor's Claim
- ☐ Foreign Judgment
- ☐ Other Civil Matters

Business Court filings should be filed using the Business Court civil coversheet.

3rd July 2018
Date

Signature of initiating party or representative

See other side for family-related case filings.

Nevada AOC - Research Statistics Unit
Pursuant to NRS 3.275

Amy M. Rose (Bar No. 12081)
Lauren Kaufman (Bar No. 14677C)
AMERICAN CIVIL LIBERTIES UNION OF NEVADA
601 S. Rancho Drive, Suite B11
Las Vegas, NV 89106
(702) 366-1536
rose@aclunv.org
kaufman@aclunv.org
Attorneys for Petitioner

THE FIRST JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR CARSON CITY

The American Civil Liberties Union of Nevada Foundation, a non-profit organization.

Petitioner,

vs.

State of Nevada *ex rel,* the Nevada Department of Corrections; James Dzurenda, in his official capacity as Director.

Respondents.

Case No. [redacted]
Dept. [redacted]

EMERGENCY

EMERGENCY PETITION FOR WRIT OF MANDAMUS TO COMPEL THE NEVADA DEPARTMENT OF CORRECTIONS TO PRODUCE PUBLIC RECORDS RELATING TO ITS LETHAL INJECTION PROCEDURES AND SCOTT DOZIER'S JULY 11, 2018 EXECUTION

Petitioner, the American Civil Liberties Union of Nevada, through its attorneys, hereby petitions this Court pursuant to the Nevada Public Recrods Act, NRS 239 *et. seq* for a writ of mandamus directing the Respondents, Nevada Department of Corrections, and James Dzurenda in his official capacity as Director to provide Petitioner with the requested public records on the following grounds:

INTRODUCTION

1. Scott Dozier is scheduled to be executed by the State of Nevada on July 11, 2018.

2. Despite this upcoming execution, Respondents, the Nevada Department of Corrections and its Director, James Dzurenda, (collectively "NDOC") are unlawfully refusing to release to the ACLU of Nevada ("ACLUNV") time-sensitive public records pertaining to NDOC's lethal injection drugs and procedures.

3. NDOC has not only kept records from the ACLU of Nevada, but has completely failed to inform the public about any details of this upcoming execution and has offered only misinformation and shifting explanations.

4. The requested public records are essential for the ACLUNV to both inform the public of how the State of Nevada plans to execute one of its citizens and for the ACLUNV to assess whether the execution will take place in a constitutional manner and then take appropriate steps if it determines the execution will not.

5. "[T]he Eighth Amendment not only protects the right of individuals not to be victims of cruel and unusual punishment, but that it also expresses a fundamental interest of society in ensuring that state authority is not used to administer barbaric punishments." *Gilmore v. Utah*, 429 U.S. 1012, 1019 (1976) (Marshall, J., dissenting).

6. NDOC's restriction of access to public records is especially egregious as this is the first execution in Nevada in over a decade and it will take place in a newly built and untested execution chamber. The precedent set by this execution will affect not only Mr. Dozier, but all other inmates currently sitting on death row. Full and immediate transparency from NDOC is essential to ensuring constitutional compliance.

7. The ACLUNV files this petition pursuant to NRS 239.011, which allows a party whose request for inspection was denied to apply to the district court for an order permitting the requestor to inspect or copy the record, or obtain a copy.

8. Accordingly, this Petition seeks to obtain a court order directing NDOC to immediately produce the records requested by the ACLUNV under the Nevada Public Records Act, NRS 239 *et seq.*

9. As per NRS 239.011, the ACLUNV respectfully requests that this Court "give this matter priority over other civil matters to which priority is not given by other statutes," and to treat this as an Emergency Petition in light of Mr. Dozier's upcoming execution on July 11, 2018.

JURISDICTION & VENUE

10. This Court has the authority to issue a writ of mandamus pursuant to Nev. Const. Art. 6, § 6 and NRS 34.160.

11. An affidavit pursuant to NRS 34.170 attesting to the factual allegations in this application is attached.

12. Venue is proper in this Court as the records at issue are being held by the Nevada Department of Corrections, whose central administration is located in Carson City. NRS 239.011(1).

PARTIES

A. PETITIONER

13. The ACLUNV is a non-profit, non-partisan, organization operating in Nevada.

14. The ACLUNV works to defend and advance the civil liberties and civil rights of all Nevadans. Grounded in the principles of liberty, justice, democracy and equality, the ACLUNV works in three areas: public education, advocacy, and litigation when necessary. The ACLUNV's public education efforts serve to help the public understand their liberties, rights, and responsibilities, its advocacy efforts serve to inform and educate public officials about their liberties and rights,

and their litigation work serves to defend the rights and liberties of individuals when they have been violated.

15. The ACLUNV's work encompasses protecting the constitutional rights of those subject to a sentence of death, and holding the government accountable in carrying out a sentence of death.

16. The ACLUNV engages in governmental oversight by routinely researching and investigating matters of public concern and publishing those results.[1] The ACLUNV accomplishes this oversight and public education, in part, by utilizing records obtained through the Nevada Public Records Act.

B. DEFENDANTS

17. Defendant, State of Nevada *ex rel* the Department of Corrections is an Executive Department of the State of Nevada.

18. The Nevada Department of Corrections ("NDOC") is a governmental entity as defined in NRS 239.005(5)(b) for purposes of Nevada's Public Records Act.

19. Defendant, James Dzurenda, is the Director of the Nevada Department of Corrections. In his official capacity, he is required to "[s]upervise the administration of all institutions and facilities of the Department." NRS 209.131(2). He is also required to execute a sentence of death, select the execution drugs, and otherwise generally oversee the death penalty in the State of Nevada. NRS 176.355.

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[1] *See e.g. Unlocking Solitary Confinement: Ending Extreme Isolation in Nevada State Prisons*, (ACLU of Nev., Solitary Watch, and Nev. Disability Advoc. & L. Ctr, Feb. 2017) *available at* https://www.aclunv.org/sites/default/files/aclunv_unlocking_solitary_confinement_report.pdf); *Youth Confinement In Nevada: Facility Assessment And Recommendations For Housing Youth Sentenced*" (ACLU of Nev. & the Campaign For Youth Just.,June 2018) *available at* https://www.aclunv.org/en/news/aclu-nevada-releases-report-youth-confinement.

FACTUAL ALLEGATIONS

MR. DOZIER'S ORIGINALLY SCHEDULED NOVEMBER 2017 EXECUTION

20. Mr. Dozier was previously scheduled to be executed on November 14, 2017, using a three (3) drug cocktail of diazepam (a sedative), fentanyl (a pain medication), and cisatracurium (a paralytic). This combination of drugs has never been used in an execution in the United States.[2]

21. Although Mr. Dozier volunteered for execution, he still recognized the State's independent responsibility to act in a constitutional manner and brought a motion to determine the lawfulness of the method of his execution. Mr. Dozier argued that use of a paralytic needlessly risked causing him a tortious and unconstitutional death.[3]

22. The District Court agreed with Mr. Dozier and found that the use of a paralytic carries a substantial and "objectively intolerable risk of harm" to Mr. Dozier, all in violation of Mr. Dozier's Eighth Amendment rights under the United States Constitution and corresponding rights under Article 1, Section 6 of the Nevada Constitution. The District Court prohibited NDOC from using a paralytic in Mr. Dozier's execution. [4]

23. NDOC objected to this prohibition and filed a writ of mandamus with the Nevada Supreme Court.[5]

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[2] Marcella Corona, *How Will Scott Dozier Die? Experts Weigh In On Nevada's Experimental Execution Cocktail*, RENO GAZETTE J., Nov. 9, 2017, https://www.rgj.com/story/news/2017/11/03/medical-experts-explain-effects-lethal-injection-drugs-nevada-execution/822497001/

[3] Michelle Rindels, *Judge's Order Throws Off Execution Timeline; State Says Nov. 14 Date Canceled*, THE NEV. INDEP, Nov. 9, 2017, https://thenevadaindependent.com/article/judges-order-throws-execution-timeline-into-jeopardy-state-says-nov-14-date-canceled

[4] *Id.*

[5] Michelle Rindels, *Supreme Court Hears Arguments On Untested Lethal Injection Method For Inmate Who's Asking To Die*, THE NEV. INDEP, May, 8, 2018, https://thenevadaindependent.com/article/supreme-court-to-hear-arguments-on-untested-lethal-injection-method-for-inmate-whos-asking-to-die

24. The Nevada Attorney General's Office represented in its briefing to the Nevada Supreme Court that one of the planned execution drugs, diazepam, expired on May 1, 2018. [6] It also made this representation at oral arguments held on May 8, 2018.[7]

25. On May 10, 2018, the Nevada Supreme Court overturned the District Court ruling on procedural grounds, and never reached the issue of whether using a paralytic was unconstitutional.

26. The ACLU of Nevada vehemently and publicly opposed Mr. Dozier's execution and the use of a paralytic.[8] It made many public statements about the unconstitutionality of using a paralytic in an execution, demanded transparency from NDOC regarding the execution procedures and process, submitted public records requests to NDOC regarding the planned November 2017 execution, organized and submitted a petition to Governor Sandoval asking him to stop the execution, and submitted an *amicus* brief in support of Mr. Dozier's opposition to the Nevada Attorney General's Nevada Supreme Court Writ Petition.

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[6] *Nevada Department of Corrections v. The Eighth Judicial District Court of the State of Nevada, et al. and Scott Raymond Dozier,* Petitioner's Emergency Petition Writ of Mandamus or Prohibition at 4. (Exhibit 9).

[7] Michelle Rindels, *Supreme Court Hears Arguments On Untested Lethal Injection Method For Inmate Who's Asking To Die,* THE NEV. INDEP, May, 8, 2018, https://thenevadaindependent.com/article/supreme-court-to-hear-arguments-on-untested-lethal-injection-method-for-inmate-whos-asking-to-die ("Jordan Smith, arguing on behalf of the attorney general's office, said the state's supply of diazepam — the first drug in the three-drug protocol — expired on May 1.").

[8] *ACLU Wants Governor to Stop Nevada's 1st Execution Since '06*, ASSOCIATED PRESS, Nov. 2, 2017, https://www.usnews.com/news/best-states/nevada/articles/2017-11-02/aclu-wants-governor-to-stop-nevadas-1st-execution-since-06; Denise Rosch, *Defense Attorney, ACLU Want Answers About Execution Cocktail Planned For Dozier,* NBC NEWS 3, LAS VEGAS, Aug. 27, 2017 http://news3lv.com/news/local/defense-attorney-aclu-want-answers-about-execution-cocktail-planned-for-dozier; David Ferrara, *ACLU Opposes Drug Cocktail Planned For Nevada Inmate's* Execution, LAS VEGAS REVIEW-JOURNAL, AUG. 18, 2017, https://www.reviewjournal.com/crime/courts/aclu-opposes-drug-cocktail-planned-for-nevada-inmates-execution/

ACLUNV REQUESTS RECORDS FROM NDOC REGARDING LETHAL INJECTION DRUGS AND EXECUTION PROCEDURES

27. After the Nevada Supreme Court's decision, the ACLU of Nevada continued its work in conducting oversight and public education regarding executions in Nevada and submitted a public records request to NDOC on June 15, 2018, requesting documents pertaining to NDOC's lethal injection drugs and procedures. (Exhibit 1).

28. The ACLUNV requested records related to the acquisition of lethal injections drugs, including records of the lethal injection drugs on hand and related details such as the purchase or acquisition orders and expiration dates of the drugs; the execution manual currently in effect; records regarding NDOC employees' communications regarding lethal injection drugs, records relating to the Ely State Prison pharmacy and records relating to the authority of Ely State Prison to handle controlled substances. *Id.*

NDOC GIVES CONFLICTING INFORMATION TO THE PUBLIC REGARDING MR. DOZIER'S NEWLY SCHEDULED EXECUTION

29. On June 19, 2018, a new warrant of execution was signed by the District Court, setting Mr. Dozier's execution for the week of July 9, 2018. (Exhibit 2).

30. On June 20, 2018, NDOC, through its Public Information Officer, Brooke Santina, told the Associated Press (AP), that NDOC planned to go forward with Mr. Dozier's execution on July 11, 2018, that NDOC "ha[s] what [they] need to complete the execution order," that they were going to use "[t]he same three drugs," to carry out Mr. Dozier's execution, and that despite previous representations regarding the diazepam expiring NDOC "ha[s] some [drugs] that are not expired."[9]

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[9] Ken Ritter, *Nevada Sets 1st Execution Since 2006 After Fight Over Drugs*, ASSOCIATED PRESS, June 20, 2018, https://www.washingtonpost.com/national/judge-oks-nevada-execution-but-questions-about-drugs-remain/2018/06/20/96aa9cde-74bc-11e8-bda1-18e53a448a14_story.html?utm_term=.67769e197e52

31. However, just a few days later, NDOC, again through its Public Information Officer, changed its story and told the media that the protocol was "evolving."[10]

32. Since the last statement to the media regarding the "evolving" protocol, NDOC has made no further statements regarding Mr. Dozier's execution. Nor has it put out a press release alerting Nevadans that an execution is going to take place.

33. Instead, it is operating in extreme secrecy, despite Nevada's open records laws, and refuses to even disclose the names of the drugs it plans to use for Mr. Dozier's execution.

34. On June 22, 2018, concerned about Mr. Dozier's upcoming execution and the lack of reliable information being disseminated by NDOC, the ACLUNV wrote to NDOC following-up on its public records request. It informed NDOC that in light of Mr. Dozier's July 11th execution, it was imperative that NDOC release records immediately. (Exhibit 3)

35. Despite this urgent need for the public to be informed of Mr. Dozier's upcoming execution, NDOC informed the ACLUNV later on June 22, 2018, that none of the requested records were readily available and that it "anticipate[d]" being able to respond within sixty (60) days. (Exhibit 4).

36. Under NDOC's proposed timeline, Mr. Dozier will have already been executed by the time any information is finally produced.

ACLUNV PRIORITIZES AND NARROWS REQUESTS; NDOC STILL REFUSES TO PRODUCE TIMELY RECORDS

37. In response, on June 25, 2018, the ACLUNV wrote NDOC explaining that the sixty (60) day response time is unacceptable in light of Mr. Dozier's upcoming execution, which, at the time was sixteen (16) days away. (Exhibit 5).

[10] Ken Ritter ASSOCIATED PRESS, *Q&A: Plan Evolving For Nevada's First Execution In 12 Years,* June 25, 2018 http://www.chicagotribune.com/sns-bc-us--nevada-execution-challenge-qa-20180621-story.html

38. The ACLUNV further explained in its June 25, 2018, letter that the information needed to be produced immediately for the ACLUNV to properly assess whether Mr. Dozier's execution will take place in a constitutional manner and take appropriate steps if it was determined that it will not. *Id.*

39. The ACLUNV also explained in its June 25, 2018 letter that beyond simply needing this information to assess the constitutionality of NDOC's actions, one of ACLUNV's main functions is disseminating information to the public about issues of concern to the ACLUNV and its members and how the state plans to execute Mr. Dozier is of the utmost concern to the ACLUNV and to Nevadans. *Id.*

40. The ACLUNV reminded NDOC that provision of timely records and transparency by NDOC is especially important as Mr. Dozier's execution will be the first in Nevada in over a decade. *Id.*

41. In an effort to expedite production, in its June 25, 2018, letter, the ACLUNV prioritized and narrowed some requests. *Id.*

42. The ACLUNV informed NDOC that the priority requests pertained to (1) the details of the lethal injection drugs obtained by NDOC, (2) the execution manual in place, and (2) to records regarding authorization for Ely State Prison to handle controlled substances. *Id.*

43. The ACLUNV asked, at the very least, that NDOC produce immediately:

    a. Records relating to the lethal injection drugs planned to be used in Mr. Dozier's July 11th execution, including, the names and quantities of the drugs to be used, and purchase or acquisition orders; and

    b. The current Nevada Department of Corrections Execution Manual which will govern Mr. Dozier's July 11th execution.

44. As NDOC plans to go forward with Mr. Dozier's execution in just eight (8) days, there is no reasonable explanation for why at least those narrow sets of documents would not be readily available to NDOC.

45. The ACLUNV asked NDOC to produce the narrowed records requested by the close of business on June 25, 2018, and the remainder of the outstanding records by June 27, 2018. *Id.*

46. Because of the urgent need for these records, the ACLUNV informed NDOC that failure to produce readily available records would constitute a denial under NRS 239 *et seq*. *Id.*

47. After receiving no response from NDOC, on June 28, 2018, the ACLUNV again wrote to NDOC confirming that as NDOC had completely failed to produce readily available time-sensitive records this was a denial of the ACLUNV's requests and that they would take the appropriate legal action. (Exhibit 6) .

48. NDOC responded on July 2, 2018, stating that it had received the ACLUNV's June 25, 2018, letter and that it "anticipate[d]" being able to respond within sixty (60) days. (Exhibit 7).

49. As of the date of this Petition, NDOC has still not produced any information requested by the ACLUNV in its public records request.

50. Accordingly, the ACLUNV respectfully petitions this Court, pursuant to NRS 239.011, for a writ of mandamus compelling NDOC to allow for inspection and copying of all public records requested by the ACLUNV and directing such other and further relief as this Court deems proper.

LEGAL AUTHORITY

51. The purpose of Nevada's robust Public Records Act, "is to foster democratic principles by providing members of the public with access to inspect and copy public books and records to the extent permitted by law." NRS 239.001(1); *see PERS v. Reno Newspapers Inc.*, 129 Nev. 833, 836-837 (2013) (" The [Nevada Public Records] Act's purpose is to promote government

transparency and accountability by facilitating public access to information regarding government activities.")

52. The provisions of the Act "must be construed liberally to carry out this important purpose." NRS 239.001(2).

53. Courts "begin with the presumption that all government-generated records are open to disclosure." *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 628 (2011).

54. Except for the public records identified by statute to be confidential, "all public books and public records of a governmental entity must be open at all times. . ." NRS 239.010(1).

55. Once a public records request is made, the governmental entity is required to respond "[n]ot later than the end of the fifth business day after the date on which the person who has legal custody or control of a public book or record of a governmental entity receives a written or oral request from a person to inspect, copy or receive a copy of the public book or record." NRS 239.0107(1).

56. The governmental entity is required to either allow inspection or copying, or provide a copy of the record requested. NRS 239.0107(1)(a).

57. "If the governmental entity does not have legal custody or control of the public book or record, provide to the person, in writing: (1) Notice of that fact; and (2) The name and address of the governmental entity that has legal custody or control of the public book or record, if known." NRS 239.0107(b)(1-2).

58. "If a public book or record of a governmental entity is readily available for inspection or copying, the person who has legal custody or control of the public book or record shall allow a person who has submitted a request to inspect, copy or receive a copy of a public book or record." NRS 239.0107(2).

59. Here, the ACLUNV has requested information under the Nevada Public Records Act relating to NDOC's lethal injection drugs and procedures, and the upcoming execution of Mr. Dozier (Exhibits 1 and 5).

THE ACLUNV IS ENTITLED TO RELIEF UNDER NRS 239.011

60. The ACLUNV is entitled to relief because it requested a public book or record that is open to inspection pursuant to NRS 239.010 and NRS 239.0107, yet NDOC unlawfully denied its requests for inspection.

61. The ACLUNV did not request any information that is confidential pursuant to NRS 239.0105.

A Request was Made for Inspection of a Public Book or Record Open to Inspection

62. As described in paragraphs 27 and 37 above, ACLUNV made a request to NDOC for inspection of public records open to inspection relating to NDOC's lethal injection drugs and procedures on June 15, 2018 and again on June 25, 2018.

63. Nevada Administrative Code 239.101 defines a public record as any "information that is created or received pursuant to a law or ordinance, or in connection with the transaction of the official business of any office or department of a local governmental entity. . ."

64. Here, the ACLUNV requested records belonging to NDOC, a governmental entity subject to the Public Records Act, and the requested records are created or received, or in connection with the transaction of NDOC's official business, namely conducting executions. (Exhibits 1 and 5).

65. NDOC has not indicated that any of the requested records are not in fact public records.

66. Although NDOC responded in form letters that it will need to review responsive documents for confidentiality, it has not affirmatively indicated that any of the requested records are in fact confidential.

ACLUNV's Request to Inspect or Copy was Denied

67. The ACLUNV made it explicitly known to NDOC that the ACLUNV requested these records in connection with Mr. Dozier's upcoming execution for the purpose of performing its oversight function and informing the public about Mr. Dozier's execution. (Exhibits 3, 5, and 6)

68. Despite knowing this, NDOC has refused to timely provide records and does not plan to provide any records until well after the State executes Mr. Dozier. (Exhibits 4 and 7).

69. The purpose of requesting these public records will be frustrated if NDOC does not timely produce records before it executes Mr. Dozier.

70. Timely production of these records is all the more important given NDOC's failure to provide meaningful information about this upcoming execution to the public on its own.

71. The First Judicial District Court has found, in previous litigation surrounding a similar subject matter, that writ relief should be granted when a request to inspect or copy has been explicitly been denied or that "there has not been a timely response to their request." *Reno Newspapers Inc. v. State of Nevada,* Case No. 06-0551A (First Judicial Dist. Ct. April 24, 2006).(Exhibit 8).

72. Federal Courts have also granted mandamus petitions requesting immediate production of public records when failure to do so would cause the public record to lose its "newsworthiness." *Valley Broadcasting Co. V. U.S. District Court for the District of Nevada*, 798 F.2d 1289, 1292 (9th Cir. 1986).

73. The Federal Freedom of Information Act (FOIA) is also instructive here. Under FOIA, a request for public records will be given "expedited processing" when there exits: "An urgency to inform the public about an actual or alleged Federal Government activity, if made by a person who is primarily engaged in disseminating information." 28 § CFR 16.5(e)(1)(ii).

74. Here there is certainly an "urgency to inform the public" about NDOC's activities as Mr. Dozier will be executed in just eight (8) days, and the ACLUNV regularly engages in disseminating information to the public about this subject matter. Obtaining information about government activity, analyzing that information, and widely publishing and disseminating that information to the press and public are critical and substantial components of the ACLUNV's work. In fact, Courts have found that the ACLU, as well as other organizations with similar missions that engage in information-dissemination activities similar to the ACLU are "primarily engaged in disseminating information." *See, e.g., Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 260 (D.D.C. 2005); *ACLU v. U.S. Dep't of Justice*, 321 F. Supp. 2d 24, 29 n.5 (D.D.C. 2004); *Elec. Privacy Info. Ctr. v. U.S. Dep't of Defense*, 241 F. Supp. 2d 5, 11 (D.D.C. 2003).

75. If records regarding NDOC's lethal injection drugs and Mr. Dozier's execution are not produced until after NDOC actually executes Mr. Dozier, the purpose of producing the documents will be frustrated.

76. For all these reasons, NDOC has denied the ACLUNV's public records request.

NDOC Must Immediately Produce "Readily Available" as Defined in NRS 239.0107(2)

77. Moreover, Nevada Statutes require that "[i]f a public book or record of a governmental entity is readily available for inspection or copying, the person who has legal custody or control of the public book or record shall allow a person who has submitted a request to inspect, copy or receive a copy of a public book or record." NRS 239.0107(2).

78. A public record is "readily available" if: (1) the public record is easily retrievable by an officer, employee or agent of the agency who has legal custody or control of the record; (2) the public record does not contain any confidential information; and (3) the nature of the public record is

such that an officer, employee or agent of the agency who has legal custody or control of the record is not required to review the record to determine whether the record includes confidential information." NAC 239.860.

79. As NDOC is going to execute Mr. Dozier in just eight (8) days, it defies logic that **no records** regarding NDOC's lethal injection drugs and procedures are available.

80. Further, as the ACLUNV's records request has been outstanding for over eighteen (18) days, NDOC has had more than enough time to review documents for confidentiality. This is especially true considering the extraordinary and time-sensitive nature of the requests in relation to Mr. Dozier's looming execution.

81. NDOC must immediately produce to the ACLUNV all records responsive to its requests that are readily available.

CLAIM FOR RELIEF

VIOLATION OF NEVADA PUBLIC RECORDS ACT NRS 239. *et seq.*

82. Plaintiffs re-allege and incorporate by reference Paragraphs 1 through 81 of this Petition.

83. NDOC has failed to comply with the Nevada Public Records Act, NRS 239 *et seq.* by failing to timely provide the ACLUNV with access to the time-sensitive public records regarding its lethal injection drugs and procedures and Mr. Dozier's upcoming July 11th execution which are not otherwise confidential

84. A writ of mandamus is necessary to compel NDOC to comply with the Nevada Public Records Act.

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...

...

RELIEF REQUESTED

WHEREFORE, Petitioner respectfully request that this Court:

1. Issue a writ of mandamus compelling Respondents, the Nevada Department of Corrections, and James Dzurenda, in his official capacity as Director to allow Petitioners, the American Civil Liberties Union of Nevada Foundation, to inspect and copy the public records requested in its letter to NDOC;

2. Award Petitioner, the American Civil Liberties Union of Nevada Foundation, its reasonable attorneys' fees and costs incurred in this action, as provided by NRS 239.011; and

3. Any other further relief that the Court deems just and proper.

Respectfully submitted this 3rd day of July 2018.

Amy M. Rose (Bar No. 12081)
Lauren Kaufman (Bar No. 14677C)
AMERICAN CIVIL LIBERTIES UNION OF NEVADA
601 S. Rancho Drive, Suite B11
Las Vegas, NV 89106
(702) 366-1536
rose@aclunv.org
kaufman@aclunv.org
Attorneys for Petitioner

By: Amy Rose
Amy M. Rose

EXHIBIT 1

June 15, 2018

Via E-mail, USPS, and Fax
Brooke Keast
Public Information Officer
Nevada Department of Corrections
P.O. Box 7011
Carson City, NV 89701
bkeast@doc.nv.gov
Fax: 775-887-3253

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Re: Public Records Request Regarding Current or Proposed Execution Drugs

Dear Ms. Keast:

Please allow this letter to serve as a request under the Nevada Public Records Act, NRS § 239.010 *et seq.*, by the American Civil Liberties Union of Nevada (ACLUNV) for the public records held by the Nevada Department of Corrections, or its associated subdivisions as detailed below.

A. The Requester

The ACLUNV is a statewide affiliate of the American Civil Liberties Union, a national organization whose work protects the civil liberties and civil rights of all people. Our mission includes safeguarding the basic constitutional rights to due process, equal protection, and includes protections against the imposition of cruel and unusual punishment. The ACLUNV is responsible for serving the population in the State of Nevada. One of ACLUNV's main functions is disseminating information to the public about issues of concern to the ACLUNV and its members.

B. Request

The ACLUNV requests the following records in your custody or under your control:

1. All records relating to NDOC's acquisition or attempted acquisition of lethal injection drugs[1] since November 9, 2017 from actual or prospective suppliers,

[1] For the purposes of all requests in this letter, "lethal injection drugs" includes: (1) any and all drugs previously used in connection with an execution in Nevada; (2) any and all drugs included in any death penalty protocol in Nevada whether ultimately used or not; and (3) any and all drugs NDOC seeks or sought to acquire for the purposes of carrying out an execution.

distributors and/or manufacturers including, but not limited to correspondence, memorandums, e-mails, and notes, and voice messages.

2. All records relating to NDOC's acquisition or attempted acquisition of lethal injection drugs since November 9, 2017 from any other State's Department of Corrections (or otherwise named agency which oversees the state's prison population), or any other State's government or state agency, including, but not limited to correspondence, memorandums, e-mails, and notes, and voice messages.

3. All records pertaining to any lethal injections drugs obtained since November 9, 2017, including, but not limited to:

    a. records indicating the current amount of any such drug in NDOC's custody or control;
    b. the date of purchase or acquisition;
    c. purchase or acquisition orders;
    d. licensing information;
    e. batch number; and
    f. expiration dates.

4. All records since November 9, 2017, including, but not limited to memorandums, notes, voice messages, text messages, and e-mails, between and among any NDOC employees that relate to the acquisition or attempted acquisition of lethal injection drugs.

5. All records since November 9, 2017, including, but not limited to memorandums, notes, voice messages, text messages, and e-mails, between and among NDOC's medical staff relating to lethal injection drugs.

6. All copies or drafts of any proposed or actual edits, since November 9, 2017, to the Nevada Department Corrections Execution Manual or any other policies or procedures related to carrying out and/or preparing for executions in Nevada.

7. All records documenting the maintenance and inspection of the Ely State Prison pharmacy.

8. All records from the Drug Enforcement Agency that demonstrate authorization to handle controlled substances at Ely State Prison.

The ACLUNV does not request any information considered confidential pursuant to state law or statute.

C. **Waiver of Fees**

The ACLUNV requests a waiver of any and all fees associated with this request.

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In relation to both federal and state public records requests, fees are generally waived for nonprofit organizations seeking the copies of materials without commercial interest and for the purpose of contributing to public understanding. See *Friends of the Coast Fork v. U.S. Dep't of the Interior*, 110 F.3d 53 (9th Cir. 1997); *Friends of Oceano Dunes, Inc. v. Salazar*, No. C-11-1476 EMC, 2011 WL 6748575 (N.D. Cal. Dec. 22, 2011); *North Cnty. Parents Org. for Children with Special Needs v. Dep't of Educ.*, 23 Cal. App. 4th 144 (Cal. Ct. App. 1994).

Here, the documents requested benefit the public's knowledge and oversight of the Department of Corrections and are not sought for commercial interest. As a nonprofit 501(c)(3) and 501(c)(4) organization, the ACLUNV is well situated to disseminate information it gains from this request to the general public as well as to other targeted communities. Dissemination of information to the public is a critical and substantial component of ACLUNV's mission and work.

D. **Fulfillment of Request**

The State of Nevada mandates that all state agency records are public unless declared confidential by law. NRS § 239.010. The Public Records Act favors transparency in government and open access to agency records. The provisions of the Public Records Act must be construed liberally in order to maximize the public's right of access to agency records. NRS § 239.001.

If all or any part of this request is denied, please provide the ACLUNV with a written statement of the grounds for the denial, citing the law or regulations under which you believe you may deny access for each document. Furthermore, if you determine that some portions of the requested records are exempt from disclosure, we expect that you provide us with any reasonable severable portion of the records sought.

Please be advised that if any refusal to disclose is based on confidentiality, then "[t]he public official or agency bears the burden of establishing the existence of privilege based upon confidentiality. It is settled that privileges, whether creatures of statute or the common law, should be interpreted and applied narrowly." *D.R Partners v. Board of County Com'rs of Clark County*, 116 Nev. 616, 622 (2000).

Pursuant to state law, we request copies and/or access to these public records be forwarded to the ACLUNV within five (5) business days of this letter, **June 22, 2018.**

Please forward copies of documents as they are identified, even if production is not fully complete.

You can contact me directly at (702) 366-1536 or rose@aclunv.org

Best,

Amy M. Rose
Legal Director
American Civil Liberties Union of Nevada

CC: Director James Dzurenda

ACLU
AMERICAN CIVIL LIBERTIES UNION
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EXHIBIT 2

FILED
JUN 19 2018
CLERK OF COURT

WARE
STEVEN B. WOLFSON
Clark County District Attorney
Nevada Bar #001565
JONATHAN E. VANBOSKERCK
Chief Deputy District Attorney
Nevada Bar #006528
200 Lewis Avenue
Las Vegas, Nevada 89155-2212
(702) 671-2500
Attorney for Plaintiff

DISTRICT COURT
CLARK COUNTY, NEVADA

THE STATE OF NEVADA,

Plaintiff,

-vs-

SCOTT RAYMOND DOZIER, aka,
Chad Wyatt, #0927782

Defendant.

CASE NO: 05C215039

DEPT NO: IX

THIRD SUPPLEMENTAL WARRANT OF EXECUTION

TO: THE SHERIFF OF CLARK COUNTY, NEVADA; and
THE DIRECTOR OF THE STATE OF NEVADA DEPARTMENT OF CORRECTIONS:

WHEREAS, on September 25, 2007, SCOTT RAYMOND DOZIER, aka, Chad Wyatt was found guilty of COUNT 1 – MURDER OF THE FIRST DEGREE WITH USE OF A DEADLY WEAPON by a duly and legally impaneled jury of twelve persons; and

WHEREAS, on October 3, 2007, that same jury returned a verdict of death against SCOTT RAYMOND DOZIER, aka, Chad Wyatt as to COUNT 1 – MURDER OF THE FIRST DEGREE WITH USE OF A DEADLY WEAPON; and

WHEREAS, on December 20, 2007, SCOTT RAYMOND DOZIER, aka, Chad Wyatt filed an appeal with the Supreme Court of the State of Nevada; and

WHEREAS, on January 20, 2012, the Nevada Supreme Court filed an ORDER AFFIRMING IN PART, REVERSING IN PART AND REMANDING SCOTT RAYMOND DOZIER, aka, Chad Wyatt's conviction for MURDER OF THE FIRST DEGREE WITH USE

OF A DEADLY WEAPON, wherein the Supreme Court of the State of Nevada remanded the matter to the district court to strike the deadly weapon enhancement attendant to the murder conviction, but affirmed the conviction of MURDER OF THE FIRST DEGREE as well as the Jury's imposition of the Death Penalty, with an Amended Judgment of Conviction being filed on June 4, 2012; and

WHEREAS, on June 4, 2012, the Court filed an Amended Judgment of Conviction striking the deadly weapon enhancement attendant to COUNT 1 – MURDER OF THE FIRST DEGREE; and

WHEREAS, on July 27, 2012, SCOTT RAYMOND DOZIER, aka, Chad Wyatt filed a Petition for Writ of Habeas Corpus (Post-Conviction); and

WHEREAS, on October 31, 2016, SCOTT RAYMOND DOZIER, aka, Chad Wyatt contacted this Court by letter and indicated a desire to cease habeas litigation, waive all post-conviction and appellate remedies and submit to his sentence of death. SCOTT RAYMOND DOZIER, aka, Chad Wyatt has consistently maintained this position; and

WHEREAS, out of an abundance of caution, this Court ordered a psychological evaluation of SCOTT RAYMOND DOZIER, aka, Chad Wyatt. Dr. Michael Krelstein authored a report dated July 9, 2017, that concluded that SCOTT RAYMOND DOZIER, aka, Chad Wyatt was competent to decide whether to cease habeas litigation, waive all post-conviction and appellate remedies and submit to his sentence of death; and

WHEREAS, the parties have agreed to stay the Petition for Writ of Habeas Corpus filed on July 27, 2012, in order to facilitate imposition of sentence. The parties have further agreed that should the STATE OF NEVADA not be able to carry out SCOTT RAYMOND DOZIER, aka, Chad Wyatt's execution that the stay be lifted and habeas litigation may proceed in the ordinary course, meaning that SCOTT RAYMOND DOZIER, aka, Chad Wyatt will be in the same procedural posture as he was before attempting to carry out the execution; and

WHEREAS, on November 27, 2017, this Court entered an order enjoining the use of a paralytic drug in Dozier's execution; and

WHEREAS, on June 1, 2018, this Court entered an order vacating the order enjoining the use of a paralytic drug in Dozier's execution; and

WHEREAS, the Court, in which the conviction was had and pursuant to NRS 176.505, has inquired into the facts and determined that no legal reasons exist against the execution of the judgment of death, and there being no stay entered as provided for in NRS 176.486 or 176.487 and pursuant to NRS 176.495 has entered a third supplemental order to execute the judgment and sentence of death,

NOW THEREFORE, it is hereby

ORDERED that the County Clerk of the County of Clark, State of Nevada, shall forthwith, execute, in triplicate, under the Seal of the Court, certified copies of the Third Supplemental Warrant of Execution, the Amended Judgment of Conviction, and of the entry thereof in the Court Minutes. The original of the triplicate copies of the Amended Judgment of Conviction, Third Supplemental Warrant of Execution, and entry thereof in the Court Minutes, shall be filed in the Office of the County Clerk, and two of the triplicate copies shall be immediately delivered by the Clerk to the Sheriff of Clark County, State of Nevada.

IT IS FURTHER ORDERED that one of the triplicate copies be delivered by the Sheriff to the Director of the State of Nevada Department of Corrections or to such person as the Director shall designate. The Sheriff is hereby directed to take charge of the said Defendant, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, and transport and safely deliver the prisoner, forthwith, to the Director of the State of Nevada Department of Corrections, and said prisoner, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, is to be surrendered to the custody of the said Director of the State of Nevada Department of Corrections or to such authorized person so designated by the Director of the State of Nevada Department of Corrections, in the event he is not already so imprisoned, for the imprisonment and execution of the said Defendant, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, in accordance with the provisions of this Third Supplemental Warrant of Execution.

IT IS FURTHER ORDERED that in connection with the above facts and pursuant to the provisions of NRS 176.345, 176.355, 176.357 and/or 176.495, the Director of the State of

Nevada Department of Corrections, or such person as shall by him be designated, shall carry out said Judgment and Sentence by executing the said SCOTT RAYMOND DOZIER, aka, Chad Wyatt, by the administration to him, said Defendant, SCOTT RAYMOND DOZIER, aka, Chad Wyatt, an injection of a lethal drug(s), the drug or combination of drugs to be used for the execution to be selected by the Director of the State of Nevada Department of Corrections after consulting with the Chief Medical Officer, *See* NRS 176.355. Said execution to be within the limits of the State Prison, located at or near Ely, State of Nevada, during the week commencing on July 9, 2018, in the presence of the Director of the State of Nevada Department of Corrections, and notify those members of the immediate family of the victim who have, pursuant to NRS 176.357, requested to be informed of the time, date and place scheduled for the execution, and invite a competent physician, the county coroner, a psychiatrist, and not less than six reputable citizens over the age of twenty-one (21) years to be present at the execution. The Director shall determine the maximum number of persons who may be present for the execution. The Director shall give preference to those eligible members or representatives of the immediate family of the victim who requested, pursuant to NRS 176.357, to attend the execution. The execution must take place at the state prison and a person who has not been invited by the Director may not witness the execution.

ORDERED that said Defendant shall be safely kept and imprisoned by said Director until the Defendant is put to death by the injection of a lethal drug, or combination of drugs, and these presents shall be your authority so to do.

HEREIN FAIL NOT.

WITNESS, the HONORABLE JENNIFER TOGLIATTI, this 19th day of June, 2018.

Jennifer P. Togliatti
DISTRICT JUDGE

NL

WITNESS my hand and seal this 19th day of June, 2018.
STEVEN D. GRIERSON, Clerk

BY Steven D. Grierson

EXHIBIT 3

Subject: Public Records Request Re: Execution
Date: Friday, June 22, 2018 at 11:47:34 AM Pacific Daylight Time
From: Amy Rose
To: bsantina@doc.nv.gov
CC: Lauren Kaufman
Priority: High
Attachments: PRA_NDOC_Execution Drugs_061518.pdf, image001.png

Hi Brooke,

I'm writing to follow-up on the ACLU of Nevada's June 15th letter requesting multiple documents related to execution drugs and other documents associated with NDOC's execution manual and procedures. I attached the request here again for your reference.

In light of Mr. Dozier's upcoming execution on July 11th, compounded by the fact that NDOC plans to amend its previous execution protocol and introduce a new drug to carry out Mr. Dozier's lethal injection, it is imperative to obtain these records immediately.

As requested in our June 15th letter, please forward all relevant records to me by the close of business **today, June 22nd**. If you are unable to do so, or plan to deny any part of this request, please let me know immediately in writing. Please feel free to reach out to me if you have any questions about fulfillment of this request. I can be reached via e-mail, my direct line at 702-366-1902, or on my cellphone 626-488-315.

I appreciate your immediate attention to issue of great importance.

Best,

Amy M. Rose
Legal Director

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ACLU
Nevada

EXHIBIT 4

Northern Administration
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Carson City, NV 89701
(775) 887-3285

Southern Administration
3955 W. Russell Rd.
Las Vegas, NV 89118
(702) 486-9938

State of Nevada
Department of Corrections

Brian Sandoval
Governor

James Dzurenda
Director

Brooke Santina
Public Information Officer

June 22, 2018

Sent via email to: rose@aclunv.org

Dear Amy:

Pursuant to Nevada Revised Statutes 239.0107, this letter shall serve as notice that on June 21, 2018 the Nevada Department of Corrections (NDOC) received your correspondence via email which was dated June 15, 2018 in which you request the following:

1. All records relating to NDOC's acquisition or attempted acquisition of lethal injection drugs since November 9, 2017 from actual or prospective suppliers, distributors and/or manufacturers including, but not limited to correspondence, memorandums, e-mails, and notes, and voice messages.

2. All records relating to NDOC's acquisition or attempted acquisition of lethal injection drugs since November 9, 2017 from any other State's Department of Corrections (or otherwise named agency which oversees the state's prison population), or any other State's government or state agency, including, but not limited to correspondence, memorandums, e-mails, and notes, and voice messages.

3. All records pertaining to any lethal injections drugs obtained since November 9, 2017, including, but not limited to:
   a. records indicating the current amount of any such drug in NDOC's custody or control;
   b. the date of purchase or acquisition;
   c. purchase or acquisition orders;
   d. licensing information;
   e. batch number; and
   f. expiration dates.

4. All records since November 9, 2017, including, but not limited to memorandums, notes, voice messages, text messages, and e-mails, between and among any NDOC employees that relate to the acquisition or attempted acquisition of lethal injection drugs.

5. All records since November 9, 2017, including, but not limited to memorandums, notes, voice messages, text messages, and e-mails, between and among NDOC's medical staff relating to lethal injection drugs.

6. All copies or drafts of any proposed or actual edits, since November 9, 2017, to the Nevada Department Corrections Execution Manual or any other policies or procedures related to carrying out and/or preparing for executions in Nevada.

7. All records documenting the maintenance and inspection of the Ely State Prison pharmacy.

8. All records from the Drug Enforcement Agency that demonstrate authorization to handle controlled substances at Ely State Prison.

Your request is being processed. This request is not readily available and requires not only a search of potentially responsive documents but also a review of potentially responsive documents for any confidential, e.g. personal information. Given that the request requires extensive searches and consultation, I anticipate being able to respond to you within sixty (60) days.

Sincerely,

Brooke Santina
Public Information Officer
Nevada Department of Corrections

EXHIBIT 5

Subject: Re: Public Records Request Re: Execution
Date: Monday, June 25, 2018 at 11:00:18 AM Pacific Daylight Time
From: Amy Rose
To: Brooke Santina
CC: James Dzurenda, Lauren Kaufman, Holly Welborn
Priority: High
Attachments: Ltr to Brook Santina_06252018_Re Execution.pdf, image001.png, image002.png

Brooke,

Please see the attached response to your letter. As explained, a sixty (60) day response time is unacceptable in light of Scott Dozier's' July 11th execution, which is just sixteen days away now. Although our June 15, 2018 records request should still be complied with in full, to allow for expedited production we have prioritized and narrowed some requests in the attached. Please provide by the close of business **today, June 25, 2018,** all readily available and responsive documents to the ACLUNV's requests.

Feel free to call with any questions or concerns. You can reach me on my cell phone, 626-488-3154.

Best,

Amy M. Rose
Legal Director

ACLU of Nevada
601 S. Rancho Drive, Suite B11 | Las Vegas, Nevada 89106
702-366-1536 (phone) | 702-366-1331 (fax)
www.aclunv.org | Facebook | Twitter

ACLU Nevada

From: Brooke Santina <bsantina@doc.nv.gov>
Date: Friday, June 22, 2018 at 2:57 PM
To: Amy Rose <rose@aclunv.org>
Cc: Lauren Kaufman <kaufman@aclunv.org>
Subject: Re: Public Records Request Re: Execution

Amy and Lauren,
Please see attached 5 day response to your public record request.

Brooke Santina
Public Information Officer
Nevada Department of Corrections
office 775-887-3309
cell 775-350-0037

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and Twitter https://twitter.com/NV_Corrections?cn=Zm9sbG93ZXI%3D&refsrc=email

From: Amy Rose <rose@aclunv.org>
To: "bsantina@doc.nv.gov" <bsantina@doc.nv.gov>
CC: Lauren Kaufman <kaufman@aclunv.org>
Date: 6/22/2018 11:47 AM
Subject: Public Records Request Re: Execution

Hi Brooke,

I'm writing to follow-up on the ACLU of Nevada's June 15th letter requesting multiple documents related to execution drugs and other documents associated with NDOC's execution manual and procedures. I attached the request here again for your reference.

In light of Mr. Dozier's upcoming execution on July 11th, compounded by the fact that NDOC plans to amend its previous execution protocol and introduce a new drug to carry out Mr. Dozier's lethal injection, it is imperative to obtain these records immediately.

As requested in our June 15th letter, please forward all relevant records to me by the close of business **today, June 22nd**. If you are unable to do so, or plan to deny any part of this request, please let me know immediately in writing. Please feel free to reach out to me if you have any questions about fulfillment of this request. I can be reached via e-mail, my direct line at 702-366-1902, or on my cellphone 626-488-315.

I appreciate your immediate attention to issue of great importance.

Best,

Amy M. Rose
Legal Director

ACLU of Nevada
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702-366-1536 (phone) | 702-366-1331 (fax)
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ACLU
Nevada

June 25, 2018

Via E-mail, USPS, and Fax
Brooke Santina
Public Information Officer
Nevada Department of Corrections
P.O. Box 7011
Carson City, NV 89701
bsantina@doc.nv.gov
Fax: 775-887-3253

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AMERICAN CIVIL LIBERTIES UNION
Nevada

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P/775.786.1033
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Re: Public Records Request Regarding Current or Proposed Execution Drugs

Dear Ms. Santina:

We are in receipt of your June 22, 2018, letter explaining that you do not plan to produce any of the records we requested under NRS §239 *et seq.* pertaining to NDOC's lethal injection drugs and procedures for sixty (60) days. As Scott Dozier's execution is now scheduled to take place on July 11, 2018, which is just **sixteen (16) days away,** that timeline is unacceptable.

The requested information must be provided as soon as possible for the ACLU of Nevada to both properly assess whether Mr. Dozier's execution will take place in a constitutional manner and take appropriate steps if we determine it will not. Moreover, one of ACLUNV's main functions is disseminating information to the public about issues of concern to the ACLUNV and its members. How the state plans to execute Mr. Dozier is of the utmost concern to the ACLUNV and to Nevadans. **Under your proposed schedule, Mr. Dozier will not be alive by the time you produce the requested records.** Due to the rapidly approaching execution date, it is imperative that we receive this information immediately.

Your refusal to provide timely records is especially egregious as this will be the first execution in Nevada in over a decade. The execution is a little over two weeks away, yet NDOC has not formally acknowledged the pending execution through a press release nor has it publicly stated what drugs it will use to carry out Mr. Dozier's execution. The lack of transparency regarding this important matter is troubling.

Although our June 15, 2018 records request should still be complied with in full, to allow for expedited production, the following requests are the priority for production:

1. All records pertaining to any lethal injections drugs obtained since November 9, 2017, including, but not limited to:

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a. records indicating the current amount of any such drug in NDOC's custody or control;
b. the date of purchase or acquisition;
c. purchase or acquisition orders;
d. licensing information;
e. batch number; and
f. expiration dates.

2. All copies or drafts of any proposed or actual edits, since November 9, 2017, to the Nevada Department Corrections Execution Manual or any other policies or procedures related to carrying out and/or preparing for executions in Nevada.

3. All records from the Drug Enforcement Agency that demonstrate authorization to handle controlled substances at Ely State Prison.

At the very least, please produce immediately:

a) Records relating to the lethal injection drugs planned to be used in Mr. Dozier's July 11th execution, including, the names and quantities of the drugs to be used, and purchase or acquisition orders.

b) The current Nevada Department of Corrections Execution Manual which will govern Mr. Dozier's July 11th execution.

As NDOC plans to go forward with Mr. Dozier's execution in just sixteen (16) days, we see no reason that you should not have readily available both information regarding the specific drugs being used and the execution manual that will govern this execution. (NAC § 239.860 defines "readily available" as "easily retrievable by an officer, employee or agent of the agency who has legal custody or control of the record.").

You are very well aware of both the importance of these records and the public's urgency to be informed about Mr. Dozier's looming execution. Please provide by the close of business **today, June 25, 2018,** all readily available and responsive documents to the ACLUNV's requests. Please provide all other requested information no later than **close of business June 27, 2018**. If you are not able to meet these production dates, please let me know immediately in writing the reasons why you are unable to complete the requests and the exact date that you will provide the requested information.

Your failure to provide readily available documents will constitute a denial under NRS §239 *et seq.* and we will pursue all available legal remedies to obtain the requested information.

If you have any questions, you can contact me directly at (702) 366-1902 or rose@aclunv.org

Best,

ACLU
AMERICAN CIVIL LIBERTIES UNION
Nevada

Amy M. Rose
Legal Director
American Civil Liberties Union of Nevada

CC: Director James Dzurenda

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EXHIBIT 6

Subject: Re: Public Records Request Re: Execution
Date: Thursday, June 28, 2018 at 10:21:34 AM Pacific Daylight Time
From: Amy Rose
To: Brooke Santina
CC: James Dzurenda, Lauren Kaufman, Holly Welborn, Ann McDermott
Priority: High
Attachments: Ltr to Brooke Santina_06282018_Re Execution.pdf, image001.png, image002.png, image003.png

Brooke,

Please see the attached letter following-up on the letter I sent to you on Monday. Your timely response to the ACLU of Nevada's records request is vital as you have otherwise completely failed to inform the public about any details of Mr. Dozier's upcoming execution and have offered only misinformation and shifting explanations. To ensure that the State's actions comport with its constitutional responsibilities it is essential that the state proceed with transparency. It is deeply troubling that you are acting otherwise.

The attached letter confirms that the ACLUNV considers your complete failure to provide any timely information about NDOC's lethal injection procedures to be a denial of our requests and we plan to take action accordingly.

If you or anyone else would like to discuss this matter, you can reach me at 626-488-3154.

Best,

Amy M. Rose
Legal Director

ACLU of Nevada
601 S. Rancho Drive, Suite B11 | Las Vegas, Nevada 89106
702-366-1536 (phone) | 702-366-1331 (fax)
www.aclunv.org | Facebook | Twitter

ACLU Nevada

From: Amy Rose <rose@aclunv.org>
Date: Monday, June 25, 2018 at 11:00 AM
To: Brooke Santina <bsantina@doc.nv.gov>
Cc: James Dzurenda <jedzurenda@doc.nv.gov>, Lauren Kaufman <kaufman@aclunv.org>, Holly Welborn <Welborn@aclunv.org>
Subject: Re: Public Records Request Re: Execution

Brooke,

Please see the attached response to your letter. As explained, a sixty (60) day response time is unacceptable in light of Scott Dozier's' July 11th execution, which is just sixteen days away now. Although our June 15, 2018

records request should still be complied with in full, to allow for expedited production we have prioritized and narrowed some requests in the attached. Please provide by the close of business **today, June 25, 2018,** all readily available and responsive documents to the ACLUNV's requests.

Feel free to call with any questions or concerns. You can reach me on my cell phone, 626-488-3154.

Best,

Amy M. Rose
Legal Director

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www.aclunv.org | Facebook | Twitter

ACLU Nevada

From: Brooke Santina <bsantina@doc.nv.gov>
Date: Friday, June 22, 2018 at 2:57 PM
To: Amy Rose <rose@aclunv.org>
Cc: Lauren Kaufman <kaufman@aclunv.org>
Subject: Re: Public Records Request Re: Execution

Amy and Lauren,
Please see attached 5 day response to your public record request.

Brooke Santina
Public Information Officer
Nevada Department of Corrections
office 775-887-3309
cell 775-350-0037

Follow us on Facebook https://www.facebook.com/NevadaDOC
and Twitter https://twitter.com/NV_Corrections?cn=Zm9sbG93ZXI%3D&refsrc=email

From: Amy Rose <rose@aclunv.org>
To: "bsantina@doc.nv.gov" <bsantina@doc.nv.gov>
CC: Lauren Kaufman <kaufman@aclunv.org>
Date: 6/22/2018 11:47 AM
Subject: Public Records Request Re: Execution

Hi Brooke,

I'm writing to follow-up on the ACLU of Nevada's June 15th letter requesting multiple documents related to execution drugs and other documents associated with NDOC's execution manual and procedures. I attached the request here again for your reference.

In light of Mr. Dozier's upcoming execution on July 11th, compounded by the fact that NDOC plans to amend its previous execution protocol and introduce a new drug to carry out Mr. Dozier's lethal injection, it is imperative to obtain these records immediately.

As requested in our June 15th letter, please forward all relevant records to me by the close of business **today, June 22nd**. If you are unable to do so, or plan to deny any part of this request, please let me know immediately in writing. Please feel free to reach out to me if you have any questions about fulfillment of this request. I can be reached via e-mail, my direct line at 702-366-1902, or on my cellphone 626-488-315.

I appreciate your immediate attention to issue of great importance.

Best,

Amy M. Rose
Legal Director

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601 S. Rancho Drive, Suite B11 | Las Vegas, Nevada 89106
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ACLU
Nevada

June 28, 2018

Via E-mail and Fax
Brooke Santina
Public Information Officer
Nevada Department of Corrections
P.O. Box 7011
Carson City, NV 89701
bsantina@doc.nv.gov
Fax: 775-887-3253

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RENO, NV 89502
P/775.786.1033
F/775.786.0805

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Re: Public Records Request Regarding Current or Proposed Execution Drugs

Dear Ms. Santina:

As you are aware I sent correspondence to you on Monday, June 25, 2018 explaining that your proposed sixty (60) day timeline for production of records relating to NDOC's lethal injection drugs and procedures was unacceptable give Mr. Scott Dozier's pending execution on July 11, 2018, now just thirteen (13) days away.

In an effort to expedite at least some of these records, my June 25th letter prioritized and narrowed our original requests. I requested a response no later than close of business on June 27, 2018. As of today, you have failed to produce even one responsive document.

Your timely response to the ACLU of Nevada's records request is vital as you have otherwise completely failed to inform the public about any details of this upcoming execution and have offered only misinformation and shifting explanations. You first claimed the same three drug protocol would be used and that none of the drugs had in fact expired – despite the Nevada Attorney General's representation to the Nevada Supreme Court that the State's supply of Diazepam had expired.[1] Then, just a few days later, you claimed that the protocol was "evolving."[2]

---

[1] *See* https://www.washingtonpost.com/national/judge-oks-nevada-execution-but-questions-about-drugs-remain/2018/06/20/96aa9cde-74bc-11e8-bda1-18e53a448a14_story.html?utm_term=.4642bb30c214 (June 20, 2018)(quoting you saying: "The same three drugs. We have some that are not expired."); https://thenevadaindependent.com/article/nevada-supreme-court-overturns-lower-court-ban-on-using-a-paralytic-in-scott-dozier-execution-citing-procedural-issues (May 10, 2018)(noting Nevada Attorney General's representation to Nevada Supreme Court that the State's supply of Diazepam had expired)

[2] http://www.chicagotribune.com/sns-bc-us--nevada-execution-challenge-qa-20180621-story.html

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In the face of this most consequential action of executing Mr. Dozier, you are acting with extreme and unlawful secrecy. You have produced absolutely no information about the lethal injection drugs leaving the public left to wonder about the drugs' sources and their efficacy. The public still does not even know whether the mysterious drug combination was developed with guidance from a medical professional or how staff will be trained and prepared to take on this tremendous responsibility. The public's right to know and perform oversight of NDOC is all the more important here because Mr. Dozier's execution will be the first execution carried out in Nevada since 2006, and will take place in a newly built and untested execution chamber.

To ensure that the State's actions comport with its constitutional responsibilities it is essential that the state proceed with transparency.

It is deeply troubling that you are acting otherwise.

Accordingly, please allow this letter to confirm that the ACLUNV considers your complete failure to provide any timely information about NDOC's lethal injection procedures to be a denial of our requests and we plan to take action accordingly.

If you have any questions, you can contact me directly at (702) 366-1902 or rose@aclunv.org

Best,

Amy M. Rose
Legal Director
American Civil Liberties Union of Nevada

CC: Director James Dzurenda
Ann McDermott

EXHIBIT 7

Northern Administration
5500 Snyder Ave.
Carson City, NV 89701
(775) 887-3285

Southern Administration
3955 W. Russell Rd.
Las Vegas, NV 8918
(702) 486-9938

State of Nevada
Department of Corrections

Brian Sandoval
Governor

James Dzurenda
Director

Brooke Santina
Public Information Officer

July 2, 2018

Sent via email to: rose@aclunv.org

Dear Ms. Rose:

Pursuant to Nevada Revised Statutes 239.0107, this letter shall serve as notice that on June 25, 2018 the Nevada Department of Corrections (NDOC) received your correspondence via email which was dated June 25, 2018 in which you refer to the public record request sent to the PIO office on June 15th where you request the following:

1. All records relating to NDOC's acquisition or attempted acquisition of lethal injection drugs since November 9, 2017 from actual or prospective suppliers, distributors and/or manufacturers including, but not limited to correspondence, memorandums, e-mails, and notes, and voice messages.

2. All records relating to NDOC's acquisition or attempted acquisition of lethal injection drugs since November 9, 2017 from any other State's Department of Corrections (or otherwise named agency which oversees the state's prison population), or any other State's government or state agency, including, but not limited to correspondence, memorandums, e-mails, and notes, and voice messages.

3. All records pertaining to any lethal injections drugs obtained since November 9, 2017, including, but not limited to:
   a. records indicating the current amount of any such drug in NDOC's custody or control;
   b. the date of purchase or acquisition;
   c. purchase or acquisition orders;
   d. licensing information;
   e. batch number; and
   f. expiration dates.

4. All records since November 9, 2017, including, but not limited to memorandums, notes, voice messages, text messages, and e-mails, between and among any NDOC employees that relate to the acquisition or attempted acquisition of lethal injection drugs.

5. All records since November 9, 2017, including, but not limited to memorandums, notes, voice messages, text messages, and e-mails, between and

among NDOC's medical staff relating to lethal injection drugs.

6. All copies or drafts of any proposed or actual edits, since November 9, 2017, to the Nevada Department Corrections Execution Manual or any other policies or procedures related to carrying out and/or preparing for executions in Nevada.

7. All records documenting the maintenance and inspection of the Ely State Prison pharmacy.

8. All records from the Drug Enforcement Agency that demonstrate authorization to handle controlled substances at Ely State Prison.

Your request is being processed. This request is not readily available and requires not only a search of potentially responsive documents but also a review of potentially responsive documents for any confidential, e.g. personal information. Given that the request requires extensive searches and consultation, I anticipate being able to respond to you within sixty (60) days.

Sincerely,

Brooke Santina
Public Information Officer
Nevada Department of Corrections

EXHIBIT 8

Case No. 06-00551A

Dept. No. 2

REC'D & FILED

'06 APR 24 AM 11:11

ALAN GLOVER
CLERK
BY
DEPUTY

IN THE FIRST JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR CARSON CITY

-ooo-

RENO NEWSPAPERS, INC., a Nevada corporation doing business as RENO GAZETTE-JOURNAL; and MARTHA BELLISLE, an individual,

Petitioners,

vs.

STATE OF NEVADA, ex rel. DEPARTMENT OF CORRECTIONS; GLEN WHORTON, in his Capacity as Director of the Nevada Department of Corrections; and WILLIAM DONAT, in his Capacity as Warden of the Nevada State Prison,

Respondents.

ORDER FOR ISSUANCE OF ALTERNATIVE WRIT OF MANDAMUS

This Court has reviewed the Petition for Writ of Mandamus for Disclosure of Public Records Pursuant to NRS 239.005, et seq., filed on behalf of the Petitioners on April 20, 2006. Based upon that review, it appears that Petitioners have set forth issues of arguable merit that their request to the Respondents for inspection or copying of a public book or record open to inspection has been denied or that their request has not been a timely response to their request. Pursuant to NRS 239.011 it appears that a Writ of Mandamus should issue:

IT IS THEREFORE ORDERED that an Alternative Writ of Mandamus be issued out of and under the seal of this Court, directed to Respondents, State of Nevada, ex Rel. Department of Corrections; Glen Whorton, in his Capacity as Director of the Nevada

Department of Corrections; and William Donat, in his Capacity as Warden of the Nevada State Prison, commanding them to allow Petitioners to inspect or copy the public books or records they have requested in their letter of April 10, 2006, or appear before this Court on the 8th day of May, 2006, at 1:30 p.m., and show cause why a Writ of Mandamus should not issue compelling such inspection or copying.

Both parties or their counsel shall provide the Court with a Memorandum of Points and Authorities setting forth their respective positions no later than five days prior to the time the hearing is set in this matter.

DATED this 24th day of April, 2006.

William A. Maddox
District Judge

by NDOC's current protocol, as required by the second prong of the Supreme Court's test.

Instead, the District Court accepted Dozier's "legal team's" effort to fill the evidentiary void left by Waisel. The "legal team" or "defense team" contrived an alternative method of execution using only the first two drugs that have never been used before and are thus not a "known" method of execution. Waisel never endorsed the "alternative" two-drug cocktail and the drafter of NDOC's protocol, Dr. DiMuro, declared that removing the paralytic would actually be less humane and prolong the time to death. Despite this evidence, the lower court struck down NDOC's protocol, directed NDOC to rewrite it without specific medical guidance as to dosages or rates of administration, and ordered NDOC to carry out the execution using this medically unsupported lethal injection protocol in less than three business days. The District Court's ruling is wrong on the Constitution, medicine, and record in this case. Therefore, a writ of mandamus or prohibition must issue to correct the District Court's manifest abuse of discretion and clearly erroneous application of the law.

Without this Court's emergency action, some of the drugs in NDOC's protocol—and the District Court's revised protocol—will begin to expire. Specifically, NDOC's supply of Diazepam expires on May 1, 2018 and its supply of Cisatracurium starts to expire on April 1, 2018. This Court and, potentially, the United States Supreme Court will need to rule with sufficient time for NDOC to obtain a new execution warrant before the drugs begin to expire on April 1, 2018. A new execution warrant

Amy Rose
Nevada Bar No. 12081
rose@aclunv.org
Lauren Kaufman
Nevada Bar No. 14677C
kaufman@aclunv.org
American Civil Liberties Union of Nevada
601 S. Rancho Drive, Suite B-11
Las Vegas, NV 89106
Telephone (702) 366-1536
Attorneys for the Plaintiffs

The American Civil Liberties Union of Nevada Foundation, a non-profit organization.

Petitioners,

vs.

State of Nevada *ex rel,* the Nevada Department of Corrections; James Dzurenda, in his official capacity as Director.

Respondents.

Case No. [illegible]

Dept. A

EMERGENCY

EMERGENCY PETITION FOR WRIT OF MANDAMUS TO COMPEL THE NEVADA DEPARTMENT OF CORRECTIONS TO PRODUCE ITS LETHAL INJECTION PROCEDURES AND PUBLIC RECORDS RELATING TO SCOTT DOZIER'S JULY 11, 2018 EXECUTION

AFFIRMATION Pursuant to NRS 239B.030/603A.040

(Initial Appearance)

The undersigned does hereby affirm that the document entitled Emergency Petition For Writ Of Mandamus To Compel The Nevada Department Of Corrections To Produce Its Lethal Injection Procedures And Public Records Relating To Scott Dozier's July 11, 2018 Execution does not contain "Personal Information" and agrees that upon the filing of additional documents in the above matter, an Affirmation will be provided ONLY if the document contains a social security number (NRS 239B.030) or "personal information" (NRS 603A.040), which means a

natural person's first name or first initial and last name in combination with any one or more of the following data elements: 1. Social Security number. 2. Driver's license number, driver authorization card number or identification card number. 3. Account number, credit card number or debit card number, in combination with any required security code, access code or password that would permit access to the person's financial account. 4. A medical identification number or a health insurance identification number. 5. A user name, unique identifier or electronic mail address in combination with a password, access code or security question and answer that would permit access to an online account. The term does not include publicly available information that is lawfully made available to the general public.

The purpose of this initial affirmation is to ensure that each person who initiates a case, or upon first appearing in a case, acknowledges their understanding that no further affirmations are necessary unless a pleading which is filed contains personal information.

Dated this 3rd day of July, 2018

Amy Rose
Nevada Bar No. 12081
rose@aclunv.org
Lauren Kaufman
Nevada Bar No. 14677C
American Civil Liberties Union of Nevada
601 S. Rancho Drive, Suite B-11
Las Vegas, NV 89106
Telephone (702) 366-1536
Attorneys for the Plaintiffs

IN THE FIRST JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR CARSON CITY

The AMERICAN CIVIL LIBERTIES UNION of NEVADA FOUNDATION, a non-profit organization,

Petitioner,

vs.

STATE OF NEVADA *ex rel*, The NEVADA DEPARTMENT of CORRECTIONS; JAMES DZURENDA, in his official capacity as DIRECTOR,

Defendant.

_____/

CASE NO. 18 OC 00163 1B

DEPT. 2

ORDER GRANTING IN-PART EMERGENCY PETITION ISSUING WRIT OF MANDAMUS

Before the Court is Petitioner, American Civil Liberties Union of Nevada Foundation's (ACLUNV), Emergency Petition for Writ Of Mandamus To Compel The Nevada Department Of Corrections To Produce Public Records Relating To Its Lethal Injection Procedures And Scott Dozier's July 11, 2018 Execution. The Petition was filed at 3:15 p.m. on July 3, 2018 less than four judicial days before the scheduled execution by lethal injection of Nevada inmate Scott Dozier.

The ACLUNV sent a communication to the Court that was not filed. The Court has not seen that communication or been told what it says.

The Court first saw the Petition the morning of July 5, 2018. The Court's July 5 morning calendar was full so the Court could only quickly review the Petition. The Court instructed staff to arrange a telephone conference with counsel for the ACLUNV and NDOC. NDOC had hardly any time to investigate or prepare a response to the Petition.

The Court had little time to review the Petition and prepare for the hearing. The Court decided to proceed with a telephonic hearing in spite of NDOC's and the Court's lack of time to prepare for the hearing because Dozier's execution date was only four judicial days away. The Court heard oral argument by ACLUNV and NDOC's respective counsel during a telephonic hearing at 2:00 p.m. on July 5. The Court received no evidence other than the affidavit of Amy M. Rose and the copies of documents attached to the Petition. Because NDOC had hardly any time to prepare the Court informed NDOC it was not waiving any objections or defenses it may have in this action. Some of the Court's questions and statements during oral argument were made because of a lack of time to prepare for the hearing. All of the reasons for the Court's decision are contained in this order and anything the Court asked or said during oral argument that are inconsistent did not play any part in the Court's decision.

It appears at least some of the rush to hearing could have been avoided had the ACLUNV filed the Petition earlier. It knew or should have known a new death warrant would be issued.

The Court instructed ACLUNV to prepare a draft order and NDOC to file any objections as to any variations between what the Court stated on the record as the order and ACLUNV's draft and the parties complied. The Court used ACLUNV's draft as a starting point and this order is the Court's product based upon that process and it differs somewhat from the oral order. The differences are intentional.

The Court has not made findings of fact because NDOC had no opportunity to rebut information provided by ACLUNV or affirmatively produce evidence of its own.

The Third Supplemental Warrant of Execution for Dozier's execution was filed on June 19, 2018. Mr. Scott Dozier was previously scheduled to be executed on November 14, 2017, using a three (3) drug cocktail of diazepam (a sedative), fentanyl (a pain medication), and cisastracurium (a paralytic). Although Mr. Dozier volunteered for execution, he brought a motion to determine the lawfulness of the method of his execution and challenged the use of a paralytic as unconstitutional. The sentencing

District Court agreed with Mr. Dozier and found that the use of a paralytic carries a substantial and "objectively intolerable risk of harm" to Mr. Dozier and prohibited the NDOC from using a paralytic in Mr. Dozier's execution. NDOC objected to this prohibition and filed a writ of mandamus with the Nevada Supreme Court. On May 10, 2018, the Nevada Supreme Court overturned the sentencing District Court's ruling on procedural grounds.

On June 15, 2018, after the Nevada Supreme Court's decision, the ACLUNV submitted a public records request (Ex. 1) to NDOC under NRS 239 et seq., requesting documents pertaining to NDOC's lethal injection drugs and procedures. On June 19, 2018, a new warrant of execution (Ex. 2) was signed by the sentencing District Court, setting Mr. Dozier's execution for the week of July 9, 2018. On June 22, 2018, the ACLUNV wrote to NDOC (Ex. 3) following-up on its public records request, informing NDOC that in light of Mr. Dozier's upcoming execution, immediate completion of its records request was necessary. NDOC informed the ACLUNV later on June 22, 2018, (Ex. 4) that the request was being processed and that:

> "This request is not readily available and requires not only a search of potentially responsive documents but also a review of potentially responsive documents for any confidential e.g. personal information. Given that the request requires extensive searches and consultation, [NDOC] anticipate[s] being able to respond to you within sixty (60) days."

In response, on June 25, 2018, the ACLUNV wrote to NDOC again (Ex. 5) explaining the importance of these requests in light of Mr. Dozier's upcoming execution. The ACLUNV prioritized and offered to narrow some requests in order to receive documents immediately. On June 28, 2018, the ACLUNV again wrote to NDOC (Ex 6) stating that as NDOC had not produced the documents requested the ACLUNV planned to take legal action. NDOC responded on July 2, 2018 (Ex. 7) stating that it had received the ACLUNV's June 25, 2018, request and again stated the request is not readily available and NDOC anticipated being able to respond to you within 60 days.

The ACLUNV initiated the instant Emergency Writ to obtain the requested documents from NDOC under the Nevada Public Records Act, NRS 239 et seq.

On the same day the ACLUNV's Petition was filed, NDOC released a redacted execution protocol and a press release naming the drugs it plans to use in Mr. Dozier's execution. The execution protocol was signed by James Dzurenda, the Director of the Department of Corrections on June 11, 2018.

At the July 5th hearing, Counsel for NDOC could not tell this Court what measures were taken to fulfill the ACLUNV's requests before both the June 22, and July 2, form letters were sent to the ACLUNV saying that no records were readily available. When asked by this Court what steps had been taken to comply with the ACLUNV's June 15, 2018 records request, Counsel for NDOC represented that NDOC took steps to obtain and redact part of the executional manual but represented that he did not have knowledge of whether other steps were taken.

Counsel for NDOC stated that there are United States Supreme Court cases, such as *Glossip v. Gross*, which point out that anti-death penalty advocates use information about where a state obtains execution drugs, such as that requested by the ACLUNV, to persuade the manufacturer and others to cease selling that drug for execution purposes. Counsel for the ACLUNV represented that NDOC has previously publicly released an invoice for a drug to be used in an execution with no redactions for confidentiality.

ANALYSIS

The purpose of Nevada's robust Public Records Act, "is to foster democratic principles by providing members of the public with access to inspect and copy public books and records to the extent permitted by law." NRS 239.001(1); see *PERS v. Reno Newspapers Inc.*, 129 Nev. 833, 836-837 (2013) ("The [Nevada Public Records] Act's purpose is to promote government transparency and accountability by facilitating public access to information regarding government activities.")

Courts "begin with the presumption that all government-generated records are open to disclosure." *Reno Newspapers, Inc. v. Gibbons*, 127 Nev. 873, 880, 628 (2011). The provisions of the Act "must be construed liberally to carry out this important

purpose." NRS 239.001(2).

Except for the public records identified by statute to be confidential, "all public books and public records of a governmental entity must be open at all times. . ." NRS 239.010(1).

Once a public records request is made, the governmental entity is required to respond "[n]ot later than the end of the fifth business day after the date on which the person who has legal custody or control of a public book or record of a governmental entity receives a written or oral request from a person to inspect, copy or receive a copy of the public book or record." NRS 239.0107(1).

The governmental entity is required to either allow inspection or copying, or provide a copy of the requested record. NRS 239.0107(1)(a).

If the governmental entity does not have legal custody or control of the public book or record, it must provide to the person, in writing: "(1) Notice of that fact; and (2) The name and address of the governmental entity that has legal custody or control of the public book or record, if known." NRS 239.0107(b)(1-2).

"If the governmental entity is unable to make the public book or record available by the end of the fifth business day after the date on which the person who has legal custody or control of the public book or record received the request," it must, provide in writing "(1) Notice of that fact; and (2) A date and time after which the public book or record will be available for the person to inspect or copy or after which a copy of the public book or record will be available to the person." NRS 239.0107(c).

"If a public book or record of a governmental entity is readily available for inspection or copying, the person who has legal custody or control of the public book or record shall allow a person who has submitted a request to inspect, copy or receive a copy of a public book or record." NRS 239.0107(2).

NDOC argued and the Court understands that Dozier is not a party to this action. The Court concludes the people of the State of Nevada have a substantial interest in how the State intends to carry out the process of killing a human being under a death

warrant. The Court concludes that whatever potential prejudice NDOC may suffer as a result of this order, whether this order is ultimately found to be right or wrong, the potential prejudice to the people of the State of Nevada from the process of killing Dozier not being transparent before the execution is far greater.

From the documents, representations, and argument presented to this Court, considering the nature of the records requested, and considering Mr. Dozier's July 11th execution, at least the following records requested by the ACLUNV should on their face be readily available and should be immediately produced in good faith by NDOC:

1. For the lethal injection drugs planned to be used in Mr. Dozier's July 11th, records reflecting the names and quantities of the drugs to be used;

2. For any lethal injections drugs obtained by Respondent since November 9, 2017:

   a. Records indicating the current amount of any such drugs in NDOC's custody or control;

   b. The date of purchase or acquisition of those drugs; and

   c. Expiration dates.

"Lethal injection drugs" means any drug NDOC will or may inject into Dozier as any part of the process of executing him.

3. Records from the Drug Enforcement Agency that demonstrate authorization to handle controlled substances at Ely State Prison.

ORDER

IT IS ORDERED:

A Writ of Mandamus be issued directing and ordering Respondents, State of Nevada ex rel the Nevada Department of Corrections and James Dzurenda, in his official capacity as Director of the Nevada Department of Corrections, to produce to Petitioner, the ACLUNV, by July 9, 2018, the following records that are in its custody or control:

/////

1. For the lethal injection drugs planned to be used in Mr. Dozier's July 11th, records reflecting the names and quantities of the drugs to be used;

2. For any lethal injections drugs obtained by Respondent since November 9, 2017:

a. Records indicating the current amount of any such drugs in NDOC's custody or control;

b. The date of purchase or acquisition of those drugs; and

c. Expiration dates.

"Lethal injection drugs" means any drug NDOC will or may inject into Dozier as any part of the process of executing him.

3. Records from the Drug Enforcement Agency that demonstrate authorization to handle controlled substances at Ely State Prison.

Respondent is not required to produce information declared by law to be confidential, however, as per NRS 239.0107(d), if there is a statutory or legal reason for withholding information for the purposes of confidentiality it must provide "a citation to specific statute or legal authority that makes the public book for record, or a part thereof, confidential."

ACLUNV may file a motion for attorney's fees and NDOC may file an opposition.

July 6, 2018.

DISTRICT JUDGE
JAMES E. WILSON JR.

*The Court's law clerk is in a relationship with the stepson of one of Dozier's trial counsel. The Court received no information or input from the law clerk regarding this action.

CERTIFICATE OF SERVICE

I certify that I am an employee of the First Judicial District Court of Nevada; that on July 16, 2018, I served a copy of this document by placing a true copy in an envelope addressed to:

Amy M. Rose 601 S. Rancho Drive, Suite B11 Las Vegas, NV 89106 rose@aclunv.org	Jordan Smith 555 E. Washington Ave., Suite 3900 Las Vegas, NV 89101 jsmith@ag.nv.gov

the envelope sealed and then deposited in the Court's central mailing basket in the Court Clerk's Office for delivery to the United States Post Office at 1111 South Roop Street, Carson City, Nevada for mailing.

Baylie Hellman
Law Clerk

SUMM

DISTRICT COURT

CLARK COUNTY, NEVADA

ALVOGEN, INC.

Plaintiff(s),

-VS-

STATE OF NEVADA, et al.,

Defendant(s).

CASE NO. A-18-777312-B

DEPT. NO. XXVII

SUMMONS - CIVIL

NOTICE! YOU HAVE BEEN SUED. THE COURT MAY DECIDE AGAINST YOU WITHOUT YOUR BEING HEARD UNLESS YOU RESPOND WITHIN 20 DAYS. READ THE INFORMATION BELOW.

TO THE DEFENDANT(S): A civil Complaint has been filed by the Plaintiff(s) against you for the relief set forth in the Complaint.

1. If you intend to defend this lawsuit, within 20 days after this Summons is served on you, exclusive of the day of service, you must do the following:
   (a) File with the Clerk of this Court, whose address is shown below, a formal written response to the Complaint in accordance with the rules of the Court, with the appropriate filing fee.
   (b) Serve a copy of your response upon the attorney whose name and address is shown below.

2. Unless you respond, your default will be entered upon application of the Plaintiff(s) and failure to so respond will result in a judgment of default against you for the relief demanded in the Complaint, which could result in the taking of money or property or other relief requested in the Complaint.

3. If you intend to seek the advice of an attorney in this matter, you should do so promptly so that your response may be filed on time.

4. The State of Nevada, its political subdivisions, agencies, officers, employees, board members, commission members and legislators each have 45 days after service of this Summons within which to file an Answer or other responsive pleading to the Complaint.

STEVEN D. GRIERSON
CLERK OF COURT

Submitted by:

#13442

By: _____ Date JUL 10 2018
Deputy Clerk

STHACEY ALVAREZ
Regional Justice Center
200 Lewis Avenue
Las Vegas, NV 89155

NOTE: When service is by publication, add a brief statement of the object of the action. See Nevada Rules of Civil Procedure 4(b).

AFFIDAVIT OF SERVICE

STATE OF)
) ss:
COUNTY OF)

_____, being duly sworn, says: That at all times herein affiant was and is over 18 years of age, not a party to nor interested in the proceeding in which this affidavit is made. That affiant received _____ copy(ies) of the Summons and Complaint, _____ on the _____ day of _____, 20_____ and served the same on the _____ day of _____, 20_____ by:

(Affiant must complete the appropriate paragraph)

1. Delivering and leaving a copy with the Defendant _____ at (state address) _____

2. Serving the Defendant _____ by personally delivering and leaving a copy with _____, a person of suitable age and discretion residing at the Defendant's usual place of abode located at (state address) _____

[Use paragraph 3 for service upon agent, completing (a) or (b)]

3. Serving the Defendant _____ by personally delivering and leaving a copy at (state address) _____

   (a) With _____ as _____, an agent lawfully designated by statute to accept service of process;

   (b) With _____, pursuant to NRS 14.020 as a person of suitable age and discretion at the above address, which address is the address of the resident agent as shown on the current certificate of designation filed with the Secretary of State.

4. Personally depositing a copy in a mail box of the United States Post Office, enclosed in a sealed envelope, postage prepaid (Check appropriate method):

   ☐ Ordinary mail
   ☐ Certified mail, return receipt requested
   ☐ Registered mail, return receipt requested

addressed to the Defendant _____ at Defendant's last known address which is (state address) _____.

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

EXECUTED this _____ day of _____, 20_____.

_____
Signature of person making service

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Attorneys for Plaintiff

DISTRICT COURT

CLARK COUNTY, NEVADA

ALVOGEN, INC.,

Plaintiff,

v.

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.: Department 27

COMPLAINT FOR EMERGENCY INJUNCTIVE RELIEF AND RETURN OF ILLEGALLY-OBTAINED PROPERTY

(Business Court Requested)

COMES NOW Alvogen, Inc. ("Alvogen"), and for its Complaint for Emergency Injunctive Relief states as follows:

PARTIES, JURISDICTION AND VENUE

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

2. Defendant State of Nevada ("Nevada") is the sovereign government of Nevada.

3. 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 3955 West Russell Road, Las Vegas, Nevada, 89118.

4. 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.

5. Defendant John Doe I is an individual who will serve as the attending physician at the planned execution of inmate Scott Raymond Dozier. To the extent that there are multiple individuals who will serve attending physicians at the planned execution, they are named herein as John Doe II, John Doe III, et seq.

6. Jurisdiction over Defendants is appropriate in this Court as each of them is an entity or agent of the State of Nevada, conducting business in Nevada. Venue in this Court is appropriate, including pursuant to NRS 13.020, as material events giving rise to this action – including the Defendants' illegitimate acquisition of the drug midazolam – occurred in Clark County, Nevada.

INTRODUCTION

7. Defendants have announced plans to utilize an Alvogen drug they illegitimately acquired called midazolam in the upcoming planned execution of Scott Raymond Dozier, scheduled to take place on Wednesday, July 11, 2018 at 8:00 pm in Nevada's Ely State Prison. Defendants acquired that drug despite a clear and unambiguous prior warning from Alvogen that they could not acquire it directly from Alvogen and could likewise not legitimately acquire it through a third-party distributor. Midazolam is not approved for use in such an application. Past

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attempts by other states to use the medicine in lethal injections have been extremely controversial, and have led to widespread concern that prisoners have been exposed to cruel and unusual treatment. Several attempts have been characterized by media as "botched" executions.

8. Not only did Alvogen warn Defendants that they could not legitimately acquire midazolam from Alvogen or an intermediary, it also demanded that Defendants immediately return any such product in exchange for a full refund. Nonetheless, after Defendants received that notification, Defendants purchased a quantity of Plaintiff's medicine by subterfuge with the undisclosed and improper intent to use it for the upcoming execution in complete disregard of Plaintiff's rights. Plaintiff's executives learned of this plan for the first time on Saturday, July 7, 2018, by way of an inquiry from the press.

9. Notably, one or more of Defendants have acknowledged that they have taken efforts to maintain the secrecy of and/or conceal the fact of their acquisition of Alvogen midazolam 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." *Order, ACLU Nevada Foundation v. State of Nevada*, No. 18-OC-00163, July 6, 2018 at 4.

10. Plaintiff has already been the subject of unfavorable press coverage regarding Defendants' proposed use of its medicine in the upcoming execution. If Defendants are allowed to proceed with the misuse of the illegitimately-acquired midazolam, Plaintiff will suffer immediate and irreparable harm.

ALVOGEN AND APPROVED AND UNAPPROVED USES OF MIDAZOLAM

11. Alvogen is a leading pharmaceutical company focused on developing, manufacturing and selling life-saving and life-enhancing products around the world.

12. Alvogen distributes Midazolam Hydrochloride Injection, Solution (Abbreviated New Drug Application number 090850) (the "Alvogen Midazolam Product"). The Alvogen Midazolam Product is an injectable medication approved by the U.S. Food and Drug Administration ("FDA") for use in inducing general anesthesia and preoperative sedation/anxiolysis/amnesia. Midazolam is on the World Health Organization's List of Essential

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Medicines, the most safe and effective medicines for use in any health system for priority conditions. Midazolam is also a Schedule IV controlled substance.

13. In addition to its uses by physicians, midazolam has been used by some state correctional facilities as a component of those states' and facilities' capital punishment regimens. Midazolam acts as a sedative to render the condemned prisoner unconscious, at which time other drugs are administered to stop the prisoner's breathing and heart, but it is not approved by FDA for this purpose.

14. Midazolam was introduced in executions by lethal injection to replace pentobarbital in some states' capital punishment regimen when the manufacturer of pentobarbital disallowed that drug's use for executions.

15. The use of midazolam in executions is extremely controversial, in part because of the role it played in Oklahoma's high-profile "botched" execution of Clayton Lockett in April, 2014. Lockett apparently regained consciousness and started speaking midway through his execution, after Oklahoma prison officials began administering an untested three-drug cocktail using 100 mg of midazolam. Prison officials reportedly cancelled the execution and discussed taking him to the hospital before he was pronounced dead of a heart attack 40 minutes after the execution began.

16. In July, 2014, Arizona attempted to execute Joseph R. Wood III with a combination of drugs that included midazolam. Observers reported that Wood gasped, snorted and convulsed for well over an hour after the drugs were injected. The entire procedure, which should have taken approximately ten minutes, took almost two hours.

17. On December 8, 2016, Alabama attempted to execute Ronald Bert Smith by lethal injection using midazolam. According to reports, the execution went awry soon after midazolam was administered. His execution took 34 minutes. During the 13 minutes after being administered midazolam, Smith appeared to be struggling for breath and heaved, coughed, and clenched his left fist, while his lips moved and one eye appeared to be slightly open.

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18. As a result of these and other instances of prolonged and botched executions, manufacturers of pharmaceuticals used in lethal injection have prohibited the sale of these medicines for use in lethal injections.

DEFENDANTS OBTAIN THE ALVOGEN MIDAZOLAM PRODUCT FOR UNAPPROVED EXECUTIONS BY SUBTERFUGE

19. Upon information and belief, the Nevada Department of Corrections, along with corrections departments around the country in states with the death penalty, was well aware of manufacturers' restrictions on the distribution of drugs for lethal injection. As reported by the Las Vegas Review-Journal on October 7, 2016, after its stockpile of at least one drug used in executions expired, the Nevada Department of Corrections on September 2, 2016 sent out 247 requests for proposals to manufacturers for the purchase of those drugs. Not one supplier offered to fulfill the request. Nevada prison officials were quoted as saying that the state, in light of its inability to obtain such drugs through this process, would have to "explore its options" to carry out executions. A true and correct copy of that article is attached hereto as Exhibit 1.

20. In an article published May 13, 2016, the New York Times listed some of the ways in which state departments of corrections have attempted to obtain drugs for lethal injections. Some have resorted to obtaining supplies that are not FDA approved, such as from compounding pharmacies. Others have obtained supplies surreptitiously from unsuspecting manufacturers by purchasing under assumed names or by misrepresenting to the seller the intended use of the drug, since drugs like midazolam have FDA.-approved therapeutic uses potentially applicable to clinics associated with corrections facilities.

21. Alvogen began distributing its Midazolam Product in or around August, 2017. A true and correct copy of the approved labeling for the Alvogen Midazolam Product is attached hereto as Exhibit 2.

22. As a result of the controversy over the use of midazolam in lethal injections, Alvogen has maintained a policy of not allowing midazolam to be diverted for use in execution protocols.

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23. On April 20, 2018, Alvogen sent letters to the Governors, Attorneys General, and Department of Corrections Directors in every state that has a death penalty. In that letter, Alvogen stated "in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment." Alvogen specifically identified its Midazolam Product as one that should not be used in executions, and noted that use of midazolam or other products in executions "clearly runs counter to the FDA-approved indication for these products." The letter went on to explain:

> To ensure our products are not purchased for use in lethal injection executions, Alvogen does not accept orders from any state departments of corrections. Further, Alvogen has controls in place and directs its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions. These controls reflect our company's policy of ensuring the appropriate use of our medicines.

24. In its April 20, 2018 letter, Alvogen specifically requested that any state that obtained products for execution return them immediately for a full refund:

> If your state has purchased products manufactured by Alvogen for use in capital punishment procedures – either directly or indirectly – we ask that you immediately return our products in exchange for a full refund.

25. In addition, Alvogen warned Defendants against attempting to obtain its Midalozam Product for executions surreptitiously, illicitly, and/or by subterfuge:

> I have been informed that some states have implemented "secrecy policies/laws" which they hope will enable them to bypass company control systems and purchase manufactured medicines for use in executions. Alvogen closely tracks the distribution of its medicines as required by law and will take action in case of such diversions. Transparency across the supply chain is important to protect public health and the commercial interests of healthcare companies.

26. One of Alvogen's April 20, 2018 letters was sent directly to the Nevada Department of Corrections' facility at Ely State Prison, where Nevada's newly-constructed death penalty chamber is located. A true and correct copy of the letter, along with the envelope in which it was contained (addressed to "Warden Timothy Filson, Ely State Prison, P.O. Box 1989, 4569 North State Rt., Ely, NV 89301") is attached hereto as Exhibit 3.

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27. Alvogen also sent a letter to Defendant Dzurenda. A true and correct copy of that letter is attached hereto as Exhibit 4.

28. Alvogen has also sought to reinforce this message by including the following notice on its website's description of its Midazolam Product:

> Alvogen endorses the use of its products in accordance with FDA-approved indications. To this end, Alvogen has undertaken controls to avoid diversion of this product for use in execution protocols. In furtherance of this effort, Alvogen does not accept direct orders from prison systems or departments of correction. In addition, Alvogen is working to ensure that its distributors and wholesalers do not resell, either directly or indirectly this product, to prison systems or departments of correction.

29. A true and correct copy of the webpage (accessible at http://alvogenus.com/products/product/midazolam) is attached hereto as Exhibit 5.

30. One of Alvogen's wholesale distributors is Cardinal Health. When Alvogen began distributing its Midazolam Product in the United States, Alvogen understood from communications with Cardinal Health that it would not distribute the Alvogen Midazolam Product to corrections facilities for use in lethal injection protocols. Alvogen and Cardinal Health also entered into negotiations regarding a formal amendment to their Generic Wholesale Service Agreement to memorialize the terms on which Cardinal Health would restrict such sales. The final agreement was executed in May, 2018. During the course of those negotiations, Alvogen understood that Cardinal Health would not sell the Alvogen Midazolam Product to prisons for use in lethal injections.

31. On or about July 7, 2018, Alvogen was contacted by members of the press and told that Nevada had announced its intent to conduct the execution of Scott Raymond Dozier on Wednesday, July 11, 2018 by use of a three-drug cocktail that included the Alvogen Midazolam Product. Alvogen subsequently learned that the NDOC had adopted a new execution protocol on July 3, 2018 that included the use of midazolam. In addition, Alvogen learned from disclosures made in response to litigation by the Nevada branch of the American Civil Liberties Union that NDOC had acquired the midazolam it intends to use in the execution from Cardinal Health by way of purchase orders from May 2018 that were to be completed in June 2018.

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32. Upon information and belief, when NDOC officials, under the direction of the Nevada Chief Medical Officer, acquired the Alvogen Midazolam Product from Cardinal Health, they knew that all manufacturers of FDA-approved products, including Alvogen, had prohibited the distribution, sale, and transfer of such drugs for purposes of use in execution protocols. Upon information and belief, NDOC nonetheless acquired the Alvogen Midazolam Product by use of subterfuge through a source that was not authorized to sell to the NDOC for the non-approved use in an execution.

33. On information and belief, following their receipt of the letters attached as Exhibits 3 and 4 (The "April Alvogen Letters"), Defendants thereafter sought to circumvent Alvogen's policy by purchasing the Alvogen Midazolam Product through an unsuspecting intermediary and without disclosing to said intermediary the contents of the April Alvogen Letters and/or the fact that they planned to use the Alvogen Midazolam Product for a non-therapeutic use. Defendants were thus able to illicitly and through subterfuge obtain the Alvogen Midazolam Product in a manner that they would not have been able to accomplish had they disclosed the contents of said letter to the intermediary and/or the fact that they planned to use the Alvogen Midazolam Product for a non-therapeutic use.

34. In the April Alvogen Letters, Alvogen specifically demanded that should Defendants somehow circumvent Alvogen's controls, intentions, and property rights to illicitly obtain any of Alvogen's Midazolam Product, Defendants should immediately return said Midazolam products in exchange for a full refund. In spite of said demand, Defendants have refused to return the Midazolam products that they illicitly and improperly obtained.

35. Defendants have announced plans to use Alvogen's Midazolam Product for a purpose for which it is neither indicated nor intended to be used – to wit, to intentionally cause death. Defendants' proposed use for the Alvogen's Midazolam Product clearly runs counter to the FDA-approved indication for this product. While Alvogen takes no position on the death penalty itself, Alvogen's products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

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36. To make its purchases, NDOC had to provide Cardinal Health proof of a medical license issued to NDOC's medical director.

37. Under the Nevada controlled substances statute, "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 may not use a non-physician to evade that prohibition.

38. On information and belief, NDOC's May 2018 purchase orders to Cardinal Health leveraged the Nevada Chief Medical Officer's license to surreptitiously, evasively, illicitly, and by subterfuge obtain the Alvogen Midazolam Product. 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 the Nevada controlled substances statute and Nevada State Board of Medical Examiners regulations.

39. On information and belief, Defendants failed to disclose to the unsuspecting intermediary that they intended to use the Alvogen Midazolam Product for executions.

40. On information and belief, Defendants sought to circumvent Alvogen's controls by issuing purchase orders for the Alvogen Midazolam Product for completion in June 2018 with an unsuspecting distributor.

41. To further the implication that the midazolam was for a legitimate medical purpose, NDOC had the midazolam 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.

42. Defendants undertook these actions with full knowledge that Alvogen does not permit sales of midazolam to state correctional facilities nor to any entity for purposes of capital punishment.

IF DEFENDANTS ARE NOT ENJOINED FROM USING THE ALVOGEN MIDAZOLAM PRODUCT IN THE UPCOMING EXECUTION OF SCOTT RAYMOND DOZIER, ALVOGEN WILL SUFFER IMMEDIATE AND IRREPARABLE INJURY

43. There has been significant public discussion of NDOC's intent to execute Scott Raymond Dozier within days after adopting an entirely new and untested protocol using the

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Alvogen Midazolam Product, including several critical reports linking midazolam to multiple botched executions. A true and correct copy of the July 5, 2018 Fox News article, "Drug company threatens legal action to prevent drug from being used in Dozier's execution" is attached as Exhibit 6. A true and correct copy of the July 7, 2018 Associated Press article, "Nevada releases records on sedative to be used in execution" is attached as Exhibit 7.

44. As a result of the intense public backlash against Defendants' plans, Alvogen has been publicly identified as the manufacturer of the drug to be used in this controversial execution. As more fully set forth herein, Defendants' actions have caused, and will continue to cause unless enjoined, substantial and irreparable injury to Alvogen, its reputation, and its goodwill.

COUNT I: ACQUISITION OF A CONTROLLED SUBSTANCE BY MISREPRESENTATION, FRAUD, DECEPTION OR SUBTERFUGE

45. Paragraphs 1 through 44 are incorporated by reference as if fully set forth herein.

46. On information and belief, Defendants sought to circumvent Alvogen's controls by issuing purchase orders for the Alvogen Midazolam Product for completion in June 2018 with an unsuspecting distributor. Thus, on or about May 9, May 11, and May 29, 2018, the NDOC Pharmacy submitted a purchase order for the Alvogen Midazolam Product Midazolam to Cardinal Health, a wholesaler for the Alvogen Midazolam Product, for use in the execution of Raymond Scott Dozier scheduled for July 11, 2018. Midazolam is a Schedule IV controlled substance. The purchase orders were scheduled to be completed in June 2018.

47. Nevada law makes it unlawful for "a person to knowingly and intentionally ... [a]cquire or obtain or attempt to acquire or obtain possession of a controlled substance ... by misrepresentation, fraud, forgery, deception, subterfuge or alteration." Nevada Revised Statute (NRS) § 453.331(1)(d). Defendants each qualify as a "person" for the foregoing.

48. As described above in Paragraphs 19 through 29, Defendants knew that Alvogen is strongly opposed to the use of its products, including the Alvogen Midazolam Product, in execution protocols. Indeed, on April 20, 2018, Alvogen sent a letter to Defendants informing them "in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment" and that Alvogen was actively taking steps "to ensure that [its] products are

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not purchased for use in lethal injection executions." As described above in Paragraph 9, the NDOC's own statements in other litigation related to this 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.

49. On information and belief, following their receipt of the April Alvogen Letters, Defendants thereafter sought to circumvent Alvogen's policy by purchasing the Alvogen Midazolam Product through an unsuspecting intermediary and without disclosing to said intermediary the contents of the April Alvogen Letters and/or the fact that they sought to obtain the Alvogen Midazolam Product for non-therapeutic purposes (*i.e.*, an execution). Defendants were thus able to illicitly and through subterfuge obtain the Alvogen Midazolam Product 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 the Alvogen Midazolam Product to the intermediary.

50. On information and belief, Defendants sought to circumvent Alvogen's controls by issuing purchase orders for the Alvogen Midazolam Product for completion in June 2018 with an unsuspecting distributor. Upon information and belief, Defendants acted in concert with one another to acquire the Alvogen Midazolam Product from Cardinal Health. At the time of their actions, Defendants knew and had been placed on notice that Alvogen, along with all other sources of FDA-approved products, 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 the Alvogen Midazolam Product by use of subterfuge through a source that was not authorized to sell to the NDOC for the non-approved use in an execution.

51. To further the implication that the midazolam was for a legitimate medical purpose, Defendants specified that the Alvogen Midazolam Product 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.

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By way of the foregoing, Defendants thus tacitly and erroneously misrepresented that the Midazolam would be used for legitimate medical purposes.

52. Defendants undertook these actions with full knowledge that Alvogen does not permit sales of midazolam to state correctional facilities nor to any entity for purposes of capital punishment.

53. Based on the foregoing, and on information and belief, NDOC's purchases from Cardinal Health leveraged the NDOC Chief Medical Officer's license to surreptitiously, evasively, illicitly, and by subterfuge obtain the Alvogen Midazolam Product. 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 the Nevada controlled substances statute and Nevada State Board of Medical Examiners regulations.

54. Because of Defendants' wrongdoing, Alvogen 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 (iii) other irreparable harm to be proven at trial.

COUNT II: ACQUISITION BY A PHYSICIAN OF A CONTROLLED SUBSTANCE BY MISREPRESENTATION, FRAUD, DECEPTION OR SUBTERFUGE

55. Paragraphs 1 through 54 are incorporated by reference as if fully set forth herein.

56. On information and belief, Defendants sought to circumvent Alvogen's controls by issuing purchase orders for the Alvogen Midazolam Product for completion in June 2018 with an unsuspecting distributor. Thus, on or about May 9, May 11, and May 29, 2018, the NDOC Pharmacy submitted a purchase order for the Alvogen Midazolam Product Midazolam to Cardinal Health, a wholesaler for the Alvogen Midazolam Product, for use in the execution of Raymond Scott Dozier scheduled for July 11, 2018. Midazolam is a Schedule IV controlled substance. The purchase orders were scheduled to be completed in June 2018.

57. Upon information and belief, including the procedures outlined in the NDOC Execution Manual, Defendant Azzam, the Nevada Chief Medical Officer, a licensed physician,

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acquired and/or directed the acquisition of the Alvogen Midazolam Product by or for Defendants and in active concert with the other Defendants.

58. Nevada law prohibits a physician from "[a]cquir[ing] any controlled substances from any pharmacy or other source by misrepresentation, fraud, deception or subterfuge." Nevada Administrative Code (NAC) § 630.230(d).

59. As described above in Paragraphs 19-29, Defendants knew that Alvogen is strongly opposed to the use of its product, including the Alvogen Midazolam Product, in execution protocols. Indeed, on April 20, 2018, Alvogen sent a letter to Defendants informing them "in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment" and that Alvogen was actively taking steps "to ensure that [its] products are not purchased for use in lethal injection executions." As described above in Paragraph 9, the NDOC's own statements in other litigation related to this 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.

60. On information and belief, following their receipt of the April Alvogen Letters, Defendants, at the direction of and/or with the approval of Defendant Azzam, thereafter sought to circumvent Alvogen's policy by purchasing the Alvogen Midazolam Product through an unsuspecting intermediary and without disclosing to said intermediary the contents of the April Alvogen Letters and/or the fact that they sought to obtain the Alvogen Midazolam Product for non-therapeutic purposes (*i.e.*, an execution). Defendants were thus able to illicitly and through subterfuge obtain the Alvogen Midazolam Product 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 the Alvogen Midazolam Product to the intermediary.

61. On information and belief, Defendants sought to circumvent Alvogen's controls by issuing purchase orders for the Alvogen Midazolam Product for completion in June 2018 with an unsuspecting distributor. Upon information and belief, Defendants, including Defendant Azzam, acted in concert with one another to acquire the Alvogen Midazolam Product from Cardinal

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Health. At the time of their actions, Defendants knew and had been placed on notice that Alvogen, 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 the Alvogen Midazolam Product by use of subterfuge through a source that was not authorized to sell to the NDOC for the non-approved use in an execution.

62. To further the implication that the midazolam was for a legitimate medical purpose, Defendants specified that the Alvogen Midazolam Product 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 the Midazolam would be used for legitimate medical purposes.

63. Defendants undertook these actions with full knowledge that Alvogen does not permit sales of midazolam to state correctional facilities nor to any entity for purposes of capital punishment.

64. Based on the foregoing, and on information and belief, NDOC's purchases from Cardinal Health leveraged the NDOC Chief Medical Officer's license to surreptitiously, evasively, illicitly, and by subterfuge obtain the Alvogen Midazolam Product. 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 the Nevada controlled substances statute and Nevada State Board of Medical Examiners regulations.

65. Because of Defendants' wrongdoing, Alvogen 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 (iii) other irreparable harm to be proven at trial.

COUNT III: UNLAWFUL OBTAINMENT OF A CONTROLLED SUBSTANCE

66. Paragraphs 1 through 65 are incorporated by reference as if fully set forth herein.

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

68. Defendants obtained the Alvogen Midazolam Product in an unlawful manner because, *inter alia*, it was obtained from Alvogen and/or Cardinal Health – both of whom are "authorized to . . . dispense or possess controlled substances" – by way of misrepresentation, deception, evasion, and/or subterfuge, in violation of NRS § 453.331(1)(d); NAC § 630.230(d).

69. Further, Defendants obtained the Alvogen Midazolam Product in an unlawful manner for the reasons explained in Counts VI through VIII, as Defendants' acquisition of the Alvogen Midazolam Product is in derogation of, and violates, Alvogen's property rights.

70. Further, Defendants obtained the Alvogen Midazolam Product in an unlawful manner for the reasons explained in Counts IV and V, as Defendants' acquisition of the Alvogen Midazolam Product 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.

71. Because of Defendants' wrongdoing, Alvogen 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 (iii) other irreparable harm to be proven at trial.

COUNT IV: ADMINISTRATION OF A CONTROLLED SUBSTANCE FOR AN ILLEGITIMATE PURPOSE

72. Alvogen incorporates paragraphs 1 through 71 above as if fully set forth herein

73. 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.

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74. 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 Sec. 110.02 – Execution of Condemned Inmate* (Effective Date: June 11, 2018).

75. 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 that patient. *See, e.g.*, Center for Medicare and Medicaid Services, *Glossary* (accessed on July 8, 2018), *available* at 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 (accessed on July 8, 2018), *available* at 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").

76. 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 "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").

77. Defendants threaten to imminently – by July 11, 2018 at 8 p.m. Nevada time – have a physician administer and/or direct and supervise the administration of the Alvogen Midazolam Product 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 the Alvogen Midazolam Product 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.

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

79. To the extent that Defendants intend to employ non-physicians to administer the Alvogen Midazolam Product, John Doe I would again be acting in violation of Nevada law, the attending physician is ultimately responsible for the administration of anesthetic agents like the Alvogen Midazolam Product. *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").

80. Unless enjoined, Defendants' threatened and imminent wrongdoing will cause Alvogen 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 (iii) other irreparable harm to be proven at trial.

COUNT V: UNLAWFUL FURNISHING OF A CONTROLLED SUBSTANCE

81. Alvogen incorporates paragraphs 1 through 80 above as if fully set forth herein.

82. 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).

83. Defendants' furnishing of the Alvogen Midazolam Product to John Doe I and/or non-physician administrators is unlawful because, *inter alia*, it was obtained from Alvogen and/or Cardinal Health by way of deception, evasion, deceit, and/or subterfuge, in violation of NRS § 453.331(1)(d); NAC § 630.230(d).

84. Further, Defendants' furnishing of the Alvogen Midazolam Product to John Doe I and/or non-physician administrators is unlawful for the reasons set forth in Counts VI - VIII, as

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LAS VEGAS, NEVADA 89101

Defendants' acquisition of the Alvogen Midazolam Product is in derogation of, and violates, Alvogen's property rights.

85. Further, Defendants' furnishing of the Alvogen Midazolam Product to John Doe I and/or non-physician administrators is unlawful because Defendants' acquisition of the Alvogen Midazolam Product 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.

86. Under Nevada law, a person who "knowingly allows another person to use a controlled substance in an unlawful manner on premises or in a conveyance bellowing 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).

87. Defendants intend to imminently allow another person – John Doe I and/or non-physician administrators – to use a controlled substance (the Alvogen Midazolam Product) on their premises. Defendants' proposed conduct is unlawful for the reasons set forth *supra*. Defendant's imminently threatened wrongdoing will be in violation of Nevada law for this independent reason.

88. Unless enjoined, Defendants' threatened and imminent wrongdoing will cause Alvogen 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 (iii) other irreparable harm to be proven at trial.

COUNT VI: REPLEVIN

89. Alvogen incorporates paragraphs 1 through 88 above as if fully set forth herein.

90. On information and belief, Defendants sought to circumvent Alvogen's controls by issuing purchase orders for the Alvogen Midazolam Product for completion in June 2018 with an unsuspecting distributor, Cardinal Health. Based on those purchase orders to be completed in June 2018, Cardinal Health shipped to Defendants a total of 60 10ml vials of 5mg/ml midazolam and 30 5ml vials of 5mg/ml.

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91. As set forth above, Defendants knew or should have known that the distributor was not permitted, allowed, or authorized to sell the Alvogen Midazolam Products to NDOC and the remaining Defendants, let alone for the purpose of an execution. Indeed, Alvogen had written to Defendants in April of 2018 – prior to their illicit acquisition of the Midazolam products – to warn them that Alvogen has various controls in place to "ensure our products are not purchased for use in lethal injection executions," including its refusal to "accept orders from any state departments of corrections" as well as various "controls in place [to] direct[] its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions."

92. On information and belief, NDOC wrongfully took possession of the Alvogen Midazolam Product by tacitly misrepresenting that it would be used for a legitimate medical purpose.

93. As set forth in its April 2018 letters to Defendants, in light of its clear and unambiguous communications and restrictions regarding the sale of its Midazolam Product, Alvogen is the rightful owner of the Midazolam Product and has a present and immediate right of possession to said property.

94. Given the unambiguous contents of the April Alvogen Letters, Defendants were on actual and/or constructive notice that they could not purchase the Alvogen Midazolam Product directly from Alvogen and that Alvogen's distributors were not authorized to transfer the Alvogen Midazolam Product 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 the Alvogen Midazolam Product. Hence, the Alvogen Midazolam Product is neither the property of NDOC nor the State of Nevada.

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

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96. In its April 2018 letter, Alvogen specifically demanded that should Defendants somehow circumvent Alvogen's controls, intentions, and property rights to illicitly obtain any of Alvogen's Midazolam product, Defendants should immediately return said Midazolam products in exchange for a full refund.

97. In spite of said demand, Defendants have refused to return the Midazolam products that they illicitly and improperly obtained.

98. Alvogen's Midazolam Product is approved by the FDA solely for the following therapeutic uses: intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia; intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures either alone or in combination with other CNS depressants; intravenously for induction of general anesthesia, before administration of other anesthetic agents; and for continuous intravenous infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

99. Defendants have announced plans to utilize Alvogen's Midazolam Product for a purpose for which it is neither indicated nor intended to be used – to wit, to intentionally cause death. Defendants' proposed use for Alvogen's Midazolam Product clearly runs counter to the FDA-approved indications for this product. While Alvogen takes no position on the death penalty itself, Alvogen's products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

100. Alvogen has a property right in both its Midazolam product 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). Alvogen has exercised those rights both generally in its statements to the public and to prison

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officials and specifically in communications with Defendants. Thus, as set forth *supra*, Alvogen specifically wrote to the Nevada Department of Corrections (through the Warden at the prison at which the Execution is to take place) and the Nevada Attorney General to specifically warn them that they were customers with whom Alvogen refused to deal – both directly and indirectly – with regard to the acquisition of its Midazolam Product.

101. Defendants' actions are wrongful vis-à-vis Alvogen because, *inter alia*, they are inconsistent with Alvogen's property rights, they do not constitute the appropriate and therapeutic use for the Midazolam Product 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 Alvogen's reputation and goodwill.

102. Because of Defendants' wrongdoing, Alvogen 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 (iii) other irreparable harm to be proven at trial.

COUNT VII: CONVERSION

103. Alvogen incorporates paragraphs 1 through 102 above as if fully set forth herein.

104. NDOC has undertaken a distinct act of dominion wrongfully exerted over Alvogen's personal property, the Midazolam product, in denial of, or inconsistent with his title or rights therein or in derogation, exclusion, or defiance of such title or rights.

105. NDOC has dominion over the Midazolam product because NDOC is currently in possession of the Alvogen Midazolam Product.

106. Given the unambiguous contents of the April Alvogen Letters, Defendants were on actual and/or constructive notice that they could not purchase the Alvogen Midazolam Product directly from Alvogen and that Alvogen's distributors were not authorized to transfer the Alvogen Midazolam Product 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 the Alvogen Midazolam Product.

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107. Alvogen has true right or title to the Midazolam Product because, *inter alia*, they were sold without authorization, in direct contravention of Alvogen's stated policy of not selling midazolam to prisons and not allowing its distributors to sell midazolam to prisoners, in violation of Alvogen's fundamental property right to refuse to sell to Defendants (either directly or indirectly), and because Defendants' obtained possession of said product by way of deceit, subterfuge, evasion, and/or fraud by omission.

108. NDOC's dominion is wrongfully exerted because, according to the press report attached as Exhibit 1, NDOC was aware of Alvogen's policy of not selling midazolam to prisoners. Indeed on April 20, 2018, Alvogen sent a letter to NDOC informing them "in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment." As described in Paragraph 9 above, the NDOC's own statements in other litigation related to this 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.

109. NDOC's dominion is wrongfully exerted for the additional reasons set forth *supra*, in Counts I through V.

110. On information and belief, following their receipt of the April Alvogen Letters, Defendants thereafter sought to circumvent Alvogen's policy by purchasing the Alvogen Midazolam Product through an unsuspecting intermediary and without disclosing to said intermediary the contents of the April Alvogen Letters and/or the fact that they sought to obtain the Alvogen Midazolam Product for purposes of a non-therapeutic use (i.e., an execution). Defendants were thus able to illicitly and through subterfuge obtain the Alvogen Midazolam Product 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 the Alvogen Midazolam Product to the intermediary.

111. In its April 2018 letter, Alvogen specifically demanded that should Defendants somehow circumvent Alvogen's controls, intentions, and property rights to illicitly obtain any of Alvogen's Midazolam Product, Defendants should immediately return said Midazolam products

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in exchange for a full refund. In spite of said demand, Defendants have refused to return the Midazolam products that they illicitly and improperly obtained.

112. Defendants have announced plans to utilize Alvogen's Midazolam Product for a purpose for which it is neither indicated nor intended to be used – to wit, to intentionally cause death. Defendants' proposed use for Alvogen's Midazolam Product clearly runs counter to the FDA-approved indications for this product. While Alvogen takes no position on the death penalty itself, Alvogen's products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

113. Alvogen has a property right in both its Midazolam Product 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). Alvogen 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*, Alvogen specifically wrote to the Nevada Department of Corrections (through the Warden at the prison at which the Execution is to take place) and the Attorney General to specifically warn them that they were customers with whom Alvogen refused to deal – both directly and indirectly – with regard to the acquisition of its Midazolam Product.

114. Defendants' actions are wrongful vis-à-vis Alvogen because, *inter alia*, they are inconsistent with Alvogen's property rights, they do not constitute the appropriate and therapeutic use for the Midazolam product 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 Alvogen's reputation and goodwill.

115. Because of Defendants' wrongdoing, Alvogen has suffered and continues to suffer injuries, including, but not limited to reputational injury arising out of (i) association with the

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manufacture of drugs used for executions, (ii) the corresponding damage to business and investor relationships, (iii) damage to goodwill, and (iii) other irreparable harm to be proven at trial.

COUNT VIII: FALSE PRETENSES

116. Alvogen incorporates paragraphs 1 through 115 above as if fully set forth herein.

117. Defendants were aware from the April 2018 letter "that Alvogen strongly objects to the use of its products in capital punishment." The April 2018 letter went on to explain that "Alvogen does not accept orders from any state departments of corrections. Further, Alvogen has controls in place and directs its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions."

118. Despite this awareness, Defendants intentionally defrauded Alvogen's distributor by, on information and belief, concealing the April 2018 letter from the distributor and/or the fact that Defendants intended to use the Alvogen Midazolam Product for purposes of an execution. In failing to disclose the April 2018 letter and/or their intent to use the Alvogen Midazolam Product for purposes of an execution and proceeding to order the Midazolam product, Defendants omitted relevant information and implicitly made the false representation that they had legitimate therapeutic rationale to purchase the Alvogen Midazolam Product.

119. Alvogen's distributor justifiably relied on the false pretense(s) because they had no reason to suspect that Defendants were not authorized to purchase the Midazolam product or that the Midazolam product would not be used for a legitimate medical purpose.

120. Defendants were thus able to illicitly and through subterfuge obtain the Alvogen Midazolam Product by defrauding the intermediary, and in doing so, causing grave reputational harm to Alvogen.

121. Defendants have announced plans to utilize the Alvogen Midazolam Product for a purpose for which it is neither indicated nor intended to be used – to wit, to intentionally cause death. Defendants' proposed use for Alvogen's Midazolam Product clearly runs counter to the FDA-approved indications for this product. While Alvogen takes no position on the death penalty itself, Alvogen's products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

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122. Defendants' actions are wrongful vis-à-vis Alvogen because, *inter alia*, they are inconsistent with Alvogen's property rights insofar as Defendants obtained Alvogen's products by defrauding Alvogen's distributor, they do not constitute the appropriate and therapeutic use for the Midazolam product, they are contrary to the therapeutic uses for which the drug can be utilized, and they risk grave harm to Alvogen's reputation and goodwill.

123. Because of Defendants' wrongdoing, Alvogen 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 (iii) other irreparable harm to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

1. Alvogen requests a temporary restraining order and preliminary/permanent injunctive relief precluding the use of any Alvogen drug, including Midazolam, in carrying out any capital punishment and further ordering NDOC to return immediately all of the Midazolam product to Alvogen, as well as requiring an impoundment of the 90 vials of midazolam 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 10th day of July, 2018.

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EXHIBIT 1

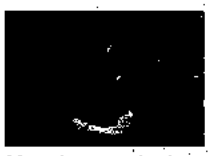
REVIEW-JOURNAL

Nevada's new $860,000 execution chamber is finished but gathering dust

A view of the gurney inside the newly completed execution chamber at Ely State Prison on Nov. 10, 2016. Courtesy the Nevada Department of Corrections

By SEAN WHALEY LAS VEGAS REVIEW-JOURNAL

More in Crime

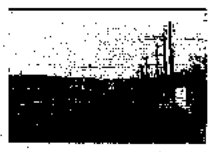


Henderson judge orders 2 teens to stand trial in shooting death

Henderson woman shot in head, left in burning apartment

Adult, not teen was victim of sex assault in Las Vegas underpass

Las Vegas lawyer linked to death of drug informant



Man, 39, fatally shot in North Las Vegas

Nevada has the death penalty and is required by law to use lethal injection for executions, but its supply of one of the drugs has expired and drug companies will no longer provide the chemicals to the state for such purposes.

The new execution chamber and related facilities take up 1,900 square feet of the administration wing at the Ely State Prison, the state's maximum security prison where Nevada's death row population of 81 men is housed.

There are no pending executions because of legal appeals in progress by the inmates. The execution space at the prison will be used for other purposes in the meantime.

State Senate Judiciary Chairman Tick Segerblom, D-Las Vegas, said he does not plan to propose legislation to do away with the death penalty given the de facto moratorium on the process. While there might be support to abolish the death penalty in the Legislature, any bill would likely be vetoed by Gov. Brian Sandoval, he said.

Sandoval supports the death penalty.

Segerblom said he has no interest in pursuing legislation to change the method of execution, either.

VOTERS MAY WEIGH IN

But Assemblyman James Ohrenschall, D-Las Vegas, named last week as chairman of the Corrections, Probation and Parole Committee, said he plans to ask voters to weigh in on whether to repeal capital punishment.

"Given the state audit that documented the high financial costs of having capital punishment as a penalty in Nevada along with the practical matter of the lack of availability of the lethal chemical cocktail used to carry out the executions, I think it's time that Nevadans are asked to weigh in on whether they still want capital punishment on the books," he said.

Ohrenschall said he will introduce legislation to amend the state Constitution to abolish capital punishment and make life without parole the maximum sentence. The measure would have to pass the Legislature in both 2017 and 2019 and then go to the voters in 2020.

He will also propose legislation for a moratorium on capital punishment until voters can have the final say on the issue.

The 105-page audit cited by Ohrenschall, presented to lawmakers in 2014, showed that the cost to prosecute and litigate death penalty cases is higher than if convicted murderers were given life in prison.

Death penalty cases cost the public on average $1.03 million to $1.31 million, according to the audit. In a murder case in which capital punishment is not sought, the average cost is $775,000. In those cases, prosecutors typically seek life in prison without parole.

The 2013 Legislature ordered auditors to review the costs of capital punishment. The audit, which took 18 months, looked at the price of trials, appeals and jail time for 28 Nevada cases.

DRUG COMPANIES SIT OUT

Nevada prison officials said last month that the state will have to explore its options to carry out executions after it received no bids from pharmaceutical companies to supply drugs for lethal injections.

The state issued 247 requests for proposals on Sept. 2 after its stockpile of at least one drug used in executions expired. Not one response was received.

Nevada has used the drugs midazolam and hydromorphone to administer a lethal injection. Both are manufactured by Pfizer.

Nevada's last execution, by lethal injection, occurred at the Nevada State Prison on April 26, 2006, when Daryl Mack was put to death. Mack was executed for the rape and murder of a Reno woman, Betty Jane May, in 1988.

Nevada has executed 12 inmates since capital punishment was reinstated by the state Legislature in 1977. All but one have been "volunteers," or inmates who have voluntarily given up their appeals.

Contact Sean Whaley at swhaley@reviewjournal.com or 775-461-3820. Follow @seanw801 on Twitter.

RELATED

Architecture contract OK'd for Nevada execution chamber

Nevada pursues death chamber, controversial drug

Nevada has 80 on death row, but no place to execute

Nevada legislators question need for new death chamber

News

EXHIBIT 2

DAILYMED

LABEL: MIDAZOLAM- midazolam hydrochloride injection, solution

VIEW PACKAGE PHOTOS

NDC Code(s): 47781-589-17, 47781-589-20, 47781-589-22, 47781-589-91
Packager: Alvogen Inc.

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: CIV
Marketing Status: Abbreviated New Drug Application

DRUG LABEL INFORMATION

Updated May 31, 2017

If you are a consumer or patient please visit this version.

VIEW ALL SECTIONS

BOXED WARNING (WHAT IS THIS?)

Personnel and Equipment for Monitoring and Resuscitation Adults and Pediatrics: Intravenous midazolam hydrochloride has been associated with respiratory depression and ...

WARNINGS

Personnel and Equipment for Monitoring and Resuscitation

Adults and Pediatrics: Intravenous midazolam hydrochloride has been associated with respiratory depression and respiratory arrest, especially when used for sedation in noncritical care settings. In some cases, where this was not recognized promptly and treated effectively, death or hypoxic encephalopathy has resulted. Intravenous midazolam hydrochloride should be used only in hospital or ambulatory care settings, including physicians' and dental offices, that provide for continuous monitoring of respiratory and cardiac function, e.g., pulse oximetry. Immediate availability of resuscitative drugs and age- and

size-appropriate equipment for bag/valve/mask ventilation and intubation, and personnel trained in their use and skilled in airway management should be assured (see WARNINGS). For deeply sedated pediatric patients, a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.

Risks From Concomitant Use With Opioids

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Monitor patients for respiratory depression and sedation (see WARNINGS and PRECAUTIONS, DRUG INTERACTIONS).

Individualization of Dosage

Midazolam hydrochloride must never be used without individualization of dosage. The initial intravenous dose for sedation in adult patients may be as little as 1 mg, but should not exceed 2.5 mg in a normal healthy adult. Lower doses are necessary for older (over 60 years) or debilitated patients and in patients receiving concomitant narcotics or other central nervous system (CNS) depressants. The initial dose and all subsequent doses should always be titrated slowly; administer over at least 2 minutes and allow an additional 2 or more minutes to fully evaluate the sedative effect. The use of the 1 mg/mL formulation or dilution of the 1 mg/mL or 5 mg/mL formulation is recommended to facilitate slower injection. Doses of sedative medications in pediatric patients must be calculated on a mg/kg basis, and initial doses and all subsequent doses should always be titrated slowly. The initial pediatric dose of midazolam for sedation/anxiolysis/amnesia is age, procedure, and route dependent (see DOSAGE AND ADMINISTRATION for complete dosing information).

Neonates: Midazolam should not be administered by rapid injection in the neonatal population. Severe hypotension and seizures have been reported following rapid IV administration, particularly with concomitant use of fentanyl (see DOSAGE AND ADMINISTRATION for complete information).

CLOSE

SPL UNCLASSIFIED SECTION

NOT FOR USE IN NEONATES

CONTAINS BENZYL ALCOHOL

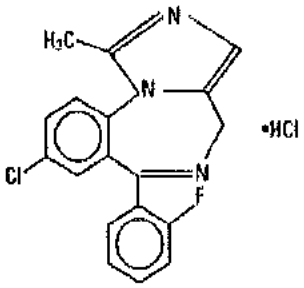
Rx only

CLOSE

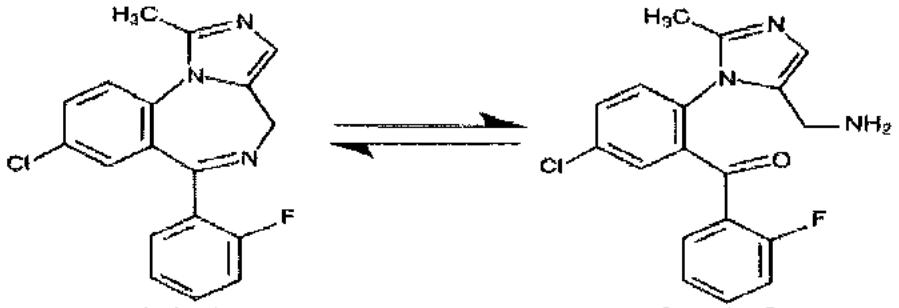
DESCRIPTION

Midazolam hydrochloride is a water-soluble benzodiazepine available as a sterile, nonpyrogenic parenteral dosage form for intravenous or intramuscular injection. Each mL contains midazolam hydrochloride equivalent to 5 mg midazolam compounded with 0.8% sodium chloride and 0.01% edetate disodium, with 1% benzyl alcohol as preservative; the pH is adjusted to 2.9 to 3.5 with hydrochloric acid and, if necessary, sodium hydroxide.

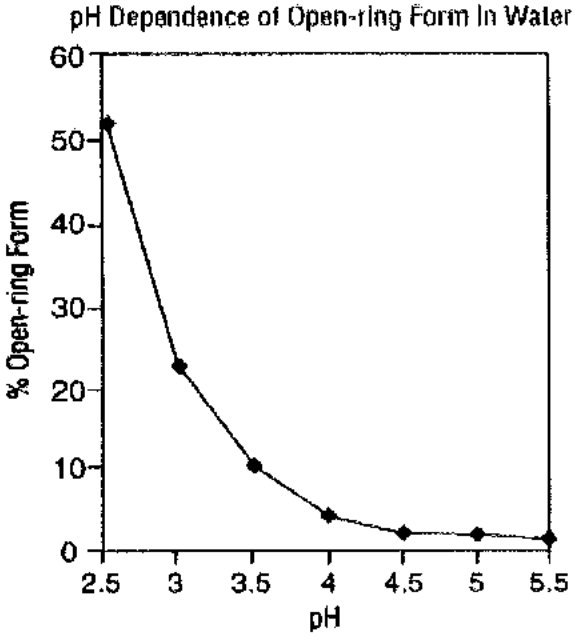
Midazolam is a white or yellowish crystalline powder, insoluble in water. The hydrochloride salt of midazolam, which is formed *in situ*, is soluble in aqueous solutions. Chemically, midazolam HCl is 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-imidazo[1,5-a][1,4]benzodiazepine hydrochloride. Midazolam hydrochloride has the empirical formula C18H13ClFN3•HCl, a calculated molecular weight of 362.25 and the following structural formula:



Under the acidic conditions required to solubilize midazolam in the product, midazolam is present as an equilibrium mixture (shown below) of the closed ring form shown above and an open-ring structure formed by the acid-catalyzed ring opening of the 4,5-double bond of the diazepine ring. The amount of open-ring form is dependent upon the pH of the solution. At the specified pH of the product, the solution may contain up to about 25% of the open-ring compound. At the physiologic conditions under which the product is absorbed (pH of 5 to 8) into the systemic circulation, any open-ring form present reverts to the physiologically active, lipophilic, closed-ring form (midazolam) and is absorbed as such.



The following chart plots the percentage of midazolam present as the open-ring form as a function of pH in aqueous solutions. As indicated in the graph, the amount of open-ring compound present in solution is sensitive to changes in pH over the pH range specified for the product: 3.0 to 3.6 for the 5 mg/mL concentration. Above pH 5, at least 99% of the mixture is present in the closed-ring form.



CLOSE

CLINICAL PHARMACOLOGY

Midazolam is a short-acting benzodiazepine central nervous system (CNS) depressant.

Pharmacodynamics

The effects of midazolam hydrochloride on the CNS are dependent on the dose administered, the route of administration, and the presence or absence of other medications. Onset time of sedative effects after IM administration in adults is 15 minutes, with peak sedation occurring 30 to 60 minutes following injection. In one adult study, when tested the following day, 73% of the patients who received midazolam hydrochloride intramuscularly had no recall of memory cards shown 30 minutes following drug administration; 40% had no recall of the memory cards shown 60 minutes following drug administration. Onset time of sedative effects in the pediatric population begins within 5 minutes and peaks at 15 to 30 minutes depending upon the dose administered. In pediatric patients, up to 85% had no recall of pictures shown after receiving intramuscular midazolam compared with 5% of the placebo controls.

Sedation in adult and pediatric patients is achieved within 3 to 5 minutes after intravenous (IV) injection; the time of onset is affected by total dose administered and the concurrent administration of narcotic premedication. Seventy-one percent of the adult patients in endoscopy studies had no recall of introduction of the endoscope; 82% of the patients had no recall of withdrawal of the endoscope. In one study of pediatric patients undergoing lumbar puncture or bone marrow aspiration, 88% of patients had impaired recall vs 9% of the placebo controls. In another pediatric oncology study, 91% of midazolam treated patients were amnestic compared with 35% of patients who had received fentanyl alone.

When midazolam hydrochloride is given IV as an anesthetic induction agent, induction of anesthesia occurs in approximately 1.5 minutes when narcotic premedication has been administered and in 2 to 2.5 minutes without narcotic premedication or other sedative premedication. Some impairment in a test of memory was noted in 90% of the patients studied. A dose response study of pediatric patients premedicated with 1 mg/kg intramuscular (IM) meperidine found that only 4 out of 6 pediatric patients who received 600 mcg/kg IV midazolam lost consciousness, with eye closing at 108 to 140 seconds. This

group was compared with pediatric patients who were given thiopental 5 mg/kg IV; 6 out of 6 closed their eyes at 20 ± 3.2 seconds. Midazolam did not dependably induce anesthesia at this dose despite concomitant opioid administration in pediatric patients.

Midazolam, used as directed, does not delay awakening from general anesthesia in adults. Gross tests of recovery after awakening (orientation, ability to stand and walk, suitability for discharge from the recovery room, return to baseline Trieger competency) usually indicate recovery within 2 hours but recovery may take up to 6 hours in some cases. When compared with patients who received thiopental, patients who received midazolam generally recovered at a slightly slower rate. Recovery from anesthesia or sedation for procedures in pediatric patients depends on the dose of midazolam administered, coadministration of other medications causing CNS depression and duration of the procedure.

In patients without intracranial lesions, induction of general anesthesia with IV midazolam hydrochloride is associated with a moderate decrease in cerebrospinal fluid pressure (lumbar puncture measurements), similar to that observed following IV thiopental. Preliminary data in neurosurgical patients with normal intracranial pressure but decreased compliance (subarachnoid screw measurements) show comparable elevations of intracranial pressure with midazolam and with thiopental during intubation. No similar studies have been reported in pediatric patients.

The usual recommended intramuscular premedicating doses of midazolam hydrochloride do not depress the ventilatory response to carbon dioxide stimulation to a clinically significant extent in adults. Intravenous induction doses of midazolam hydrochloride depress the ventilatory response to carbon dioxide stimulation for 15 minutes or more beyond the duration of ventilatory depression following administration of thiopental in adults. Impairment of ventilatory response to carbon dioxide is more marked in adult patients with chronic obstructive pulmonary disease (COPD). Sedation with IV midazolam does not adversely affect the mechanics of respiration (resistance, static recoil, most lung volume measurements); total lung capacity and peak expiratory flow decrease significantly but static compliance and maximum expiratory flow at 50% of awake total lung capacity (Vmax) increase. In one study of pediatric patients under general anesthesia, intramuscular midazolam (100 mcg/kg or 200 mcg/kg) was shown to depress the response to carbon dioxide in a dose-related manner.

In cardiac hemodynamic studies in adults, IV induction of general anesthesia with midazolam hydrochloride was associated with a slight to moderate decrease in mean arterial pressure, cardiac output, stroke volume and systemic vascular resistance. Slow heart rates (less than 65/minute), particularly in patients taking propranolol for angina, tended to rise slightly; faster heart rates (e.g., 85/minute) tended to slow slightly. In pediatric patients, a comparison of IV midazolam hydrochloride (500 mcg/kg) with propofol (2.5 mg/kg) revealed a mean 15% decrease in systolic blood pressure in patients who had received IV midazolam vs a mean 25% decrease in systolic blood pressure following propofol.

Pharmacokinetics

Midazolam's activity is primarily due to the parent drug. Elimination of the parent drug takes place via hepatic metabolism of midazolam to hydroxylated metabolites that are conjugated and excreted in the urine. Six single-dose pharmacokinetic studies involving healthy adults yield pharmacokinetic parameters for midazolam in the following ranges: volume of distribution (Vd), 1.0 to 3.1 L/kg; elimination half-life, 1.8 to 6.4 hours (mean approximately 3 hours); total clearance (Cl), 0.25 to 0.54 L/hr/kg. In a parallel group study, there was no difference in the clearance, in subjects administered 0.15 mg/kg (n=4) and 0.30 mg/kg

(n=4) IV doses indicating linear kinetics. The clearance was successively reduced by approximately 30% at doses of 0.45 mg/kg (n=4) and 0.6 mg/kg (n=5) indicating non-linear kinetics in this dose range.

Absorption

The absolute bioavailability of the intramuscular route was greater than 90% in a crossover study in which healthy subjects (n=17) were administered a 7.5 mg IV or IM dose. The mean peak concentration (Cmax) and time to peak (Tmax) following the IM dose was 90 ng/mL (20% CV) and 0.5 hour (50% CV). Cmax for the 1-hydroxy metabolite following the IM dose was 8 ng/mL (Tmax=1.0 hour).

Following IM administration, Cmax for midazolam and its 1-hydroxy metabolite were approximately one-half of those achieved after intravenous injection.

Distribution

The volume of distribution (Vd) determined from six single-dose pharmacokinetic studies involving healthy adults ranged from 1.0 to 3.1 L/kg. Female gender, old age, and obesity are associated with increased values of midazolam Vd. In humans, midazolam has been shown to cross the placenta and enter into fetal circulation and has been detected in human milk and CSF (see SPECIAL POPULATIONS).

In adults and pediatric patients older than 1 year, midazolam is approximately 97% bound to plasma protein, principally albumin and that for 1-hydroxy metabolite is about 89%.

Metabolism

In vitro studies with human liver microsomes indicate that the biotransformation of midazolam is mediated by cytochrome P450-3A4. This cytochrome also appears to be present in gastrointestinal tract mucosa as well as liver. Sixty to seventy percent of the biotransformation products is 1-hydroxy-midazolam (also termed alpha-hydroxy-midazolam) while 4-hydroxy-midazolam constitutes 5% or less. Small amounts of a dihydroxy derivative have also been detected but not quantified. The principal urinary excretion products are glucuronide conjugates of the hydroxylated derivatives.

Drugs that inhibit the activity of cytochrome P450-3A4 may inhibit midazolam clearance and elevate steady-state midazolam concentrations.

Studies of the intravenous administration of 1-hydroxy-midazolam in humans suggest that 1-hydroxy-midazolam is at least as potent as the parent compound and may contribute to the net pharmacologic activity of midazolam. *In vitro* studies have demonstrated that the affinities of 1- and 4-hydroxy-midazolam for the benzodiazepine receptor are approximately 20% and 7%, respectively, relative to midazolam.

Excretion

Clearance of midazolam is reduced in association with old age, congestive heart failure, liver disease (cirrhosis) or conditions which diminish cardiac output and hepatic blood flow.

The principal urinary excretion product is 1-hydroxy-midazolam in the form of a glucuronide conjugate; smaller amounts of the glucuronide conjugates of 4-hydroxy- and dihydroxy-midazolam are detected as well. The amount of midazolam excreted unchanged in the urine after a single IV dose is less than 0.5% (n=5). Following a single IV infusion in 5 healthy volunteers, 45% to 57% of the dose was excreted in the urine as 1-hydroxymethyl midazolam conjugate.

Pharmacokinetics-Continuous Infusion

The pharmacokinetic profile of midazolam following continuous infusion, based on 282 adult subjects, has been shown to be similar to that following single-dose administration for subjects of comparable age, gender, body habitus and health status. However, midazolam can accumulate in peripheral tissues with continuous infusion. The effects of accumulation are greater after long-term infusions than after short-term infusions. The effects of accumulation can be reduced by maintaining the lowest midazolam infusion rate that produces satisfactory sedation.

Infrequent hypotensive episodes have occurred during continuous infusion; however, neither the time to onset nor the duration of the episode appeared to be related to plasma concentrations of midazolam or alpha-hydroxy-midazolam. Further, there does not appear to be an increased chance of occurrence of a hypotensive episode with increased loading doses.

Patients with renal impairment may have longer elimination half-lives for midazolam (see SPECIAL POPULATIONS, RENAL IMPAIRMENT).

Special Populations

Changes in the pharmacokinetic profile of midazolam due to drug interactions, physiological variables, etc., may result in changes in the plasma concentration-time profile and pharmacological response to midazolam in these patients. For example, patients with acute renal failure appear to have a longer elimination half-life for midazolam and may experience delayed recovery (see SPECIAL POPULATIONS, RENAL IMPAIRMENT). In other groups, the relationship between prolonged half-life and duration of effect has not been established.

Pediatrics and Neonates

In pediatric patients aged 1 year and older, the pharmacokinetic properties following a single dose of midazolam reported in 10 separate studies of midazolam are similar to those in adults. Weight-normalized clearance is similar or higher (0.19 to 0.80 L/hr/kg) than in adults and the terminal elimination half-life (0.78 to 3.3 hours) is similar to or shorter than in adults. The pharmacokinetic properties during and following continuous intravenous infusion in pediatric patients in the operating room as an adjunct to general anesthesia and in the intensive care environment are similar to those in adults.

In seriously ill neonates, however, the terminal elimination half-life of midazolam is substantially prolonged (6.5 to 12.0 hours) and the clearance reduced (0.07 to 0.12 L/hr/kg) compared to healthy adults or other groups of pediatric patients. It cannot be determined if these differences are due to age, immature organ function or metabolic pathways, underlying illness or debility.

Obese

In a study comparing normals (n=20) and obese patients (n=20) the mean half-life was greater in the obese group (5.9 vs 2.3 hours). This was due to an increase of approximately 50% in the Vd corrected for total body weight. The clearance was not significantly different between groups.

Geriatric

In three parallel group studies, the pharmacokinetics of midazolam administered IV or IM were compared in young (mean age 29, n=52) and healthy elderly subjects (mean age 73, n=53). Plasma half-life was approximately two-fold higher in the elderly. The mean Vd based on total body weight increased

consistently between 15% to 100% in the elderly. The mean Cl decreased approximately 25% in the elderly in two studies and was similar to that of the younger patients in the other.

Congestive Heart Failure

In patients suffering from congestive heart failure, there appeared to be a two-fold increase in the elimination half-life, a 25% decrease in the plasma clearance and a 40% increase in the volume of distribution of midazolam.

Hepatic Impairment

Midazolam pharmacokinetics were studied after an IV single dose (0.075 mg/kg) was administered to 7 patients with biopsy proven alcoholic cirrhosis and 8 control patients. The mean half-life of midazolam increased 2.5-fold in the alcoholic patients. Clearance was reduced by 50% and the Vd increased by 20%. In another study in 21 male patients with cirrhosis, without ascites and with normal kidney function as determined by creatinine clearance, no changes in the pharmacokinetics of midazolam or 1-hydroxy-midazolam were observed when compared to healthy individuals.

Renal Impairment

Patients with renal impairment may have longer elimination half-lives for midazolam and its metabolites which may result in slower recovery.

Midazolam and 1-hydroxy-midazolam pharmacokinetics in 6 ICU patients who developed acute renal failure (ARF) were compared with a normal renal function control group. Midazolam was administered as an infusion (5 to 15 mg/hr). Midazolam clearance was reduced (1.9 vs 2.8 mL/min/kg) and the half-life was prolonged (7.6 vs 13 hours) in the ARF patients. The renal clearance of the 1-hydroxy-midazolam glucuronide was prolonged in the ARF group (4 vs 136 mL/min) and the half-life was prolonged (12 vs >25 hours). Plasma levels accumulated in all ARF patients to about ten times that of the parent drug. The relationship between accumulating metabolite levels and prolonged sedation is unclear.

In a study of chronic renal failure patients (n=15) receiving a single IV dose, there was a two-fold increase in the clearance and volume of distribution but the half-life remained unchanged. Metabolite levels were not studied.

Plasma Concentration-Effect Relationship

Concentration-effect relationships (after an IV dose) have been demonstrated for a variety of pharmacodynamic measures (e.g., reaction time, eye movement, sedation) and are associated with extensive intersubject variability. Logistic regression analysis of sedation scores and steady-state plasma concentration indicated that at plasma concentrations greater than 100 ng/mL there was at least a 50% probability that patients would be sedated, but respond to verbal commands (sedation score = 3). At 200 ng/mL there was at least a 50% probability that patients would be asleep, but respond to glabellar tap (sedation score = 4).

Drug Interactions

For information concerning pharmacokinetic drug interactions with midazolam (see PRECAUTIONS).

CLOSE

INDICATIONS AND USAGE

Midazolam Injection, USP is indicated:

intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia;

intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures either alone or in combination with other CNS depressants;

intravenously for induction of general anesthesia, before administration of other anesthetic agents. With the use of narcotic premedication, induction of anesthesia can be attained within a relatively narrow dose range and in a short period of time. Intravenous midazolam can also be used as a component of intravenous supplementation of nitrous oxide and oxygen (balanced anesthesia);

continuous intravenous infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

CLOSE

CONTRAINDICATIONS

Injectable midazolam hydrochloride is contraindicated in patients with a known hypersensitivity to the drug. Benzodiazepines are contraindicated in patients with acute narrow-angle glaucoma. Benzodiazepines may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. Measurements of intraocular pressure in patients without eye disease show a moderate lowering following induction with midazolam hydrochloride; patients with glaucoma have not been studied.

Midazolam hydrochloride is not intended for intrathecal or epidural administration due to the presence of the preservative benzyl alcohol in the dosage form. Midazolam hydrochloride is contraindicated for use in premature infants because the formulation contains benzyl alcohol (see WARNINGS and PRECAUTIONS, PEDIATRIC USE).

CLOSE

WARNINGS

Personnel and Equipment for Monitoring and Resuscitation

Prior to the intravenous administration of midazolam hydrochloride in any dose, the immediate availability of oxygen, resuscitative drugs, age- and size-appropriate equipment for bag/valve/mask ventilation and intubation, and skilled personnel for the maintenance of a patent airway and support of ventilation should be ensured. Patients should be continuously monitored for early signs of hypoventilation, airway obstruction, or apnea with means readily available (e.g., pulse oximetry). Hypoventilation, airway obstruction, and apnea can lead to hypoxia and/or cardiac arrest unless effective countermeasures are taken immediately. The immediate availability of specific reversal agents (flumazenil) is highly recommended. Vital signs should continue to be monitored during the recovery period. Because intravenous midazolam can depress respiration (see CLINICAL PHARMACOLOGY), especially when used concomitantly with opioid agonists and other sedatives (see DOSAGE AND ADMINISTRATION), it should be used for sedation/anxiolysis/amnesia only in the presence of personnel skilled in early detection of hypoventilation, maintaining a patent airway, and supporting ventilation. When used for

sedation/anxiolysis/amnesia, midazolam should always be titrated slowly in adult or pediatric patients. Adverse hemodynamic events have been reported in pediatric patients with cardiovascular instability; rapid intravenous administration should also be avoided in this population (see DOSAGE AND ADMINISTRATION for complete information).

Risks From Concomitant Use With Opioids

Concomitant use of benzodiazepines, including midazolam, and opioids may result in profound sedation, respiratory depression, coma, and death. If a decision is made to use midazolam concomitantly with opioids, monitor patients closely for respiratory depression and sedation (see PRECAUTIONS, DRUG INTERACTIONS).

Risk of Respiratory Adverse Events

Serious cardiorespiratory adverse events have occurred after administration of midazolam. These have included respiratory depression, airway obstruction, oxygen desaturation, apnea, respiratory arrest and/or cardiac arrest, sometimes resulting in death or permanent neurologic injury. There have also been rare reports of hypotensive episodes requiring treatment during or after diagnostic or surgical manipulations particularly in adult or pediatric patients with hemodynamic instability. Hypotension occurred more frequently in the sedation studies in patients premedicated with a narcotic.

Individualization of Dosage

Midazolam hydrochloride must never be used without individualization of dosage particularly when used with other medications capable of producing central nervous system depression (see DOSAGE AND ADMINISTRATION for complete information).

Other Adverse Events

Reactions such as agitation, involuntary movements (including tonic/clonic movements and muscle tremor), hyperactivity and combativeness have been reported in both adult and pediatric patients. These reactions may be due to inadequate or excessive dosing or improper administration of midazolam hydrochloride; however, consideration should be given to the possibility of cerebral hypoxia or true paradoxical reactions. Should such reactions occur, the response to each dose of midazolam hydrochloride and all other drugs, including local anesthetics, should be evaluated before proceeding. Reversal of such responses with flumazenil has been reported in pediatric patients.

Concomitant Use of Central Nervous System Depressants

Concomitant use of barbiturates, alcohol or other central nervous system depressants may increase the risk of hypoventilation, airway obstruction, desaturation, or apnea and may contribute to profound and/or prolonged drug effect. Narcotic premedication also depresses the ventilatory response to carbon dioxide stimulation.

Debilitation and Comorbid Considerations

Higher risk adult and pediatric surgical patients, elderly patients and debilitated adult and pediatric patients require lower dosages, whether or not concomitant sedating medications have been administered. Adult or pediatric patients with COPD are unusually sensitive to the respiratory depressant effect of midazolam hydrochloride. Pediatric and adult patients undergoing procedures involving the upper airway such as upper endoscopy or dental care, are particularly vulnerable to episodes of desaturation and hypoventilation due to partial airway obstruction. Adult and pediatric patients with chronic renal failure and patients with congestive heart failure eliminate midazolam more slowly (see CLINICAL PHARMACOLOGY). Because elderly patients frequently have inefficient function of one or more

organ systems and because dosage requirements have been shown to decrease with age, reduced initial dosage of midazolam hydrochloride is recommended, and the possibility of profound and/or prolonged effect should be considered.

Injectable midazolam should not be administered to adult or pediatric patients in shock or coma, or in acute alcohol intoxication with depression of vital signs. Particular care should be exercised in the use of intravenous midazolam in adult or pediatric patients with uncompensated acute illnesses, such as severe fluid or electrolyte disturbances.

Risk of Intra-Arterial Injection

There have been limited reports of intra-arterial injection of midazolam hydrochloride. Adverse events have included local reactions, as well as isolated reports of seizure activity in which no clear causal relationship was established. Precautions against unintended intra-arterial injection should be taken. Extravasation should also be avoided.

The safety and efficacy of midazolam following non-intravenous and non-intramuscular routes of administration have not been established. Midazolam hydrochloride should only be administered intramuscularly or intravenously.

Return to Full Cognitive Function

Midazolam is associated with a high incidence of partial or complete impairment of recall for the next several hours. The decision as to when patients who have received injectable midazolam, particularly on an outpatient basis, may again engage in activities requiring complete mental alertness, operate hazardous machinery or drive a motor vehicle must be individualized. Gross tests of recovery from the effects of midazolam (see CLINICAL PHARMACOLOGY) cannot be relied upon to predict reaction time under stress. It is recommended that no patient operate hazardous machinery or a motor vehicle until the effects of the drug, such as drowsiness, have subsided or until 1 full day after anesthesia and surgery, whichever is longer. For pediatric patients, particular care should be taken to assure safe ambulation.

Usage in Pregnancy

An increased risk of congenital malformations associated with the use of benzodiazepine drugs (diazepam and chlordiazepoxide) has been suggested in several studies. If this drug is used during pregnancy, the patient should be apprised of the potential hazard to the fetus.

Withdrawal symptoms of the barbiturate type have occurred after the discontinuation of benzodiazepines (see DRUG ABUSE AND DEPENDENCE).

Usage in Preterm Infants and Neonates

Rapid injection should be avoided in the neonatal population. Midazolam hydrochloride administered rapidly as an intravenous injection (less than 2 minutes) has been associated with severe hypotension in neonates, particularly when the patient has also received fentanyl. Likewise, severe hypotension has been observed in neonates receiving a continuous infusion of midazolam who then receive a rapid intravenous injection of fentanyl. Seizures have been reported in several neonates following rapid intravenous administration.

The neonate also has reduced and/or immature organ function and is also vulnerable to profound and/or prolonged respiratory effects of midazolam.

Exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates, and an increased incidence of kernicterus, particularly in small preterm infants. There have been rare reports of deaths, primarily in preterm infants, associated with exposure to excessive amounts of benzyl alcohol. The amount of benzyl alcohol from medications is usually considered negligible compared to that received in flush solutions containing benzyl alcohol. Administration of high dosages of medications (including midazolam hydrochloride) containing this preservative must take into account the total amount of benzyl alcohol administered. The recommended dosage range of midazolam hydrochloride for preterm and term infants includes amounts of benzyl alcohol well below that associated with toxicity; however, the amount of benzyl alcohol at which toxicity may occur is not known. If the patient requires more than the recommended dosages or other medications containing this preservative, the practitioner must consider the daily metabolic load of benzyl alcohol from these combined sources (see WARNINGS and PRECAUTIONS, PEDIATRIC USE).

Pediatric Neurotoxicity

Published animal studies demonstrate that the administration of anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of these findings is not clear. However, based on the available data, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but may extend out to approximately three years of age in humans (see PRECAUTIONS, PREGNANCY and PEDIATRIC USE, and ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY).

Some published studies in children suggest that similar deficits may occur after repeated or prolonged exposures to anesthetic agents early in life and may result in adverse cognitive or behavioral effects. These studies have substantial limitations, and it is not clear if the observed effects are due to the anesthetic/sedation drug administration or other factors such as the surgery or underlying illness.

Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

CLOSE

PRECAUTIONS

General

Intravenous doses of midazolam hydrochloride should be decreased for elderly and for debilitated patients (see WARNINGS and DOSAGE AND ADMINISTRATION). These patients will also probably take longer to recover completely after midazolam administration for the induction of anesthesia.

Midazolam does not protect against the increase in intracranial pressure or against the heart rate rise and/or blood pressure rise associated with endotracheal intubation under light general anesthesia.

The efficacy and safety of midazolam in clinical use are functions of the dose administered, the clinical status of the individual patient, and the use of concomitant medications capable of depressing the CNS. Anticipated effects range from mild sedation to deep levels of sedation virtually equivalent to a state of general anesthesia where the patient may require external support of vital functions. Care must be taken

to individualize and carefully titrate the dose of midazolam hydrochloride to the patient's underlying medical/surgical conditions, administer to the desired effect being certain to wait an adequate time for peak CNS effects of both midazolam hydrochloride and concomitant medications, and have the personnel and size-appropriate equipment and facilities available for monitoring and intervention (see BOXED WARNING, WARNINGS and DOSAGE AND ADMINISTRATION). Practitioners administering midazolam hydrochloride must have the skills necessary to manage reasonably foreseeable adverse effects, particularly skills in airway management. For information regarding withdrawal (see DRUG ABUSE AND DEPENDENCE).

Information for Patients

To assure safe and effective use of benzodiazepines, the following information and instructions should be communicated to the patient when appropriate:

Inform your physician about any alcohol consumption and medicine you are now taking, especially blood pressure medication and antibiotics, including drugs you buy without a prescription. Alcohol has an increased effect when consumed with benzodiazepines; therefore, caution should be exercised regarding simultaneous ingestion of alcohol during benzodiazepine treatment.

Inform your physician if you are pregnant or are planning to become pregnant.

Inform your physician if you are nursing.

Patients should be informed of the pharmacological effects of midazolam, such as sedation and amnesia, which in some patients may be profound. The decision as to when patients who have received injectable midazolam hydrochloride, particularly on an outpatient basis, may again engage in activities requiring complete mental alertness, operate hazardous machinery or drive a motor vehicle must be individualized.

Patients receiving continuous infusion of midazolam in critical care settings over an extended period of time, may experience symptoms of withdrawal following abrupt discontinuation.

Effect of anesthetic and sedation drugs on early brain development

Studies conducted in young animals and children suggest repeated or prolonged use of general anesthetic or sedation drugs in children younger than 3 years may have negative effects on their developing brains. Discuss with parents and caregivers the benefits, risks, and timing and duration of surgery or procedures requiring anesthetic and sedation drugs.

Drug Interactions

Effect of Concomitant Use of Benzodiazepines and Opioids

The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration. Benzodiazepines interact at GABAA sites and opioids interact primarily at mu receptors. When benzodiazepines and opioids are

combined, the potential for benzodiazepines to significantly worsen opioid-related respiratory depression exists. Monitor patients closely for respiratory depression and sedation.

Other CNS Depressants

The sedative effect of intravenous midazolam is accentuated by any concomitantly administered medication which depresses the central nervous system, particularly opioids (e.g., morphine, meperidine and fentanyl) and also secobarbital and droperidol. Consequently, the dosage of midazolam should be adjusted according to the type and amount of concomitant medications administered and the desired clinical response (see DOSAGE AND ADMINISTRATION).

Other Drug Interactions

Caution is advised when midazolam is administered concomitantly with drugs that are known to inhibit the P450-3A4 enzyme system such as cimetidine (not ranitidine), erythromycin, diltiazem, verapamil, ketoconazole and itraconazole. These drug interactions may result in prolonged sedation due to a decrease in plasma clearance of midazolam.

The effect of single oral doses of 800 mg cimetidine and 300 mg ranitidine on steady-state concentrations of oral midazolam was examined in a randomized crossover study (n=8). Cimetidine increased the mean midazolam steady-state concentration from 57 to 71 ng/mL. Ranitidine increased the mean steady-state concentration to 62 ng/mL. No change in choice reaction time or sedation index was detected after dosing with the H2 receptor antagonists.

In a placebo-controlled study, erythromycin administered as a 500 mg dose, three times a day, for 1 week (n=6), reduced the clearance of midazolam following a single 0.5 mg/kg IV dose. The half-life was approximately doubled.

Caution is advised when midazolam is administered to patients receiving erythromycin since this may result in a decrease in the plasma clearance of midazolam.

The effects of diltiazem (60 mg three times a day) and verapamil (80 mg three times a day) on the pharmacokinetics and pharmacodynamics of oral midazolam were investigated in a three-way crossover study (n=9).

The half-life of midazolam increased from 5 to 7 hours when midazolam was taken in conjunction with verapamil or diltiazem. No interaction was observed in healthy subjects between midazolam and nifedipine.

In a placebo-controlled study where saquinavir or placebo was administered orally as a 1200 mg dose, three times a day, for 5 days (n=12), a 56% reduction in the clearance of midazolam following a single 0.05 mg/kg IV dose was observed. The half-life was approximately doubled.

A moderate reduction in induction dosage requirements of thiopental (about 15%) has been noted following use of intramuscular midazolam hydrochloride for premedication in adults.

The intravenous administration of midazolam hydrochloride decreases the minimum alveolar concentration (MAC) of halothane required for general anesthesia. This decrease correlates with the dose of midazolam hydrochloride administered; no similar studies have been carried out in pediatric patients but there is no scientific reason to expect that pediatric patients would respond differently than adults.

Although the possibility of minor interactive effects has not been fully studied, midazolam and pancuronium have been used together in patients without noting clinically significant changes in dosage, onset or duration in adults. Midazolam hydrochloride does not protect against the characteristic circulatory changes noted after administration of succinylcholine or pancuronium and does not protect against the increased intracranial pressure noted following administration of succinylcholine. Midazolam does not cause a clinically significant change in dosage, onset or duration of a single intubating dose of succinylcholine; no similar studies have been carried out in pediatric patients but there is no scientific reason to expect that pediatric patients would respond differently than adults.

No significant adverse interactions with commonly used premedications or drugs used during anesthesia and surgery (including atropine, scopolamine, glycopyrrolate, diazepam, hydroxyzine, d-tubocurarine, succinylcholine and other nondepolarizing muscle relaxants) or topical local anesthetics (including lidocaine, dyclonine HCl and Cetacaine) have been observed in adults or pediatric patients. In neonates, however, severe hypotension has been reported with concomitant administration of fentanyl. This effect has been observed in neonates on an infusion of midazolam who received a rapid injection of fentanyl and in patients on an infusion of fentanyl who have received a rapid injection of midazolam.

Drug/Laboratory Test Interactions
Midazolam has not been shown to interfere with results obtained in clinical laboratory tests.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Midazolam maleate was administered with diet in mice and rats for 2 years at dosages of 1, 9 and 80 mg/kg/day. In female mice in the highest dose group there was a marked increase in the incidence of hepatic tumors. In high-dose male rats there was a small but statistically significant increase in benign thyroid follicular cell tumors. Dosages of 9 mg/kg/day of midazolam maleate (4 times a human induction dose of 0.35 mg/kg based on body surface area comparison) do not increase the incidence of tumors. The pathogenesis of induction of these tumors is not known. These tumors were found after chronic administration, whereas human use will ordinarily be of single or several doses.

Mutagenesis

Midazolam did not have mutagenic activity in *Salmonella typhimurium* (5 bacterial strains), Chinese hamster lung cells (V79), human lymphocytes or in the micronucleus test in mice.

Impairment of Fertility

Male rats were treated orally with 1, 4, or 16 mg/kg midazolam beginning 62 days prior to mating with female rats treated with the same doses for 14 days prior to mating to Gestation Day 13 or Lactation Day 21. The high dose produced an equivalent exposure (AUC) as 4 mg/kg intravenous midazolam (1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparison). There were no adverse effects on either male or female fertility noted.

Pregnancy

Teratogenic Effects: Pregnancy Category D (see WARNINGS).

Published studies in pregnant primates demonstrate that the administration of anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity during the period of peak brain

development increases neuronal apoptosis in the developing brain of the offspring when used for longer than 3 hours. There are no data on pregnancy exposures in primates corresponding to periods prior to the third trimester in humans (see DATA).

Data

Animal Data

Pregnant rats were treated with midazolam using intravenous doses of 0.2, 1, and 4 mg/kg/day (0.09, 0.46, and 1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparisons) during the period of organogenesis (Gestation Day 7 through 15). Midazolam did not cause adverse effects to the fetus at doses of up to 1.85 times the human induction dose. All doses produced slight to moderate ataxia. The high dose produced a 5% decrease in maternal body weight gain compared to control.

Pregnant rabbits were treated with midazolam using intravenous doses of 0.2, 0.6, and 2 mg/kg/day (0.09, 0.46, and 1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparisons) during the period of organogenesis (Gestation Day 7 to 18). Midazolam did not cause adverse effects to the fetus at doses of up to 1.85 times the human induction dose. The high dose was associated with findings of ataxia and sedation but no evidence of maternal toxicity.

Pregnant rats were administered midazolam using intravenous doses of 0.2, 1, and 4 mg/kg/day (0.09, 0.46, and 1.85 times the human induction dose of 0.35 mg/kg based on body surface area comparisons) during late gestation and through lactation (Gestation Day 15 through Lactation Day 21). All doses produced ataxia. The high dose produced a slight decrease in maternal body weight gain compared to control. There were no clear adverse effects noted in the offspring. The study included no functional assessments of the pups, such as learning and memory testing or reproductive capacity.

In a published study in primates, administration of an anesthetic dose of ketamine for 24 hours on Gestation Day 122 increased neuronal apoptosis in the developing brain of the fetus. In other published studies, administration of either isoflurane or propofol for 5 hours on Gestation Day 120 resulted in increased neuronal and oligodendrocyte apoptosis in the developing brain of the offspring. With respect to brain development, this time period corresponds to the third trimester of gestation in the human. The clinical significance of these findings is not clear; however, studies in juvenile animals suggest neuroapoptosis correlates with long-term cognitive deficits (see WARNINGS, PEDIATRIC NEUROTOXICITY, PRECAUTIONS, PEDIATRIC USE, and ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY).

Labor and Delivery

In humans, measurable levels of midazolam were found in maternal venous serum, umbilical venous and arterial serum and amniotic fluid, indicating placental transfer of the drug. Following intramuscular administration of 0.05 mg/kg of midazolam, both the venous and the umbilical arterial serum concentrations were lower than maternal concentrations.

The use of injectable midazolam in obstetrics has not been evaluated in clinical studies. Because midazolam is transferred transplacentally and because other benzodiazepines given in the last weeks of pregnancy have resulted in neonatal CNS depression, midazolam is not recommended for obstetrical use.

Nursing Mothers

Midazolam is excreted in human milk. Caution should be exercised when midazolam hydrochloride is administered to a nursing woman.

Pediatric Use

The safety and efficacy of midazolam for sedation/anxiolysis/amnesia following single dose intramuscular administration, intravenously by intermittent injections and continuous infusion have been established in pediatric and neonatal patients. For specific safety monitoring and dosage guidelines (see BOXED WARNING, CLINICAL PHARMACOLOGY, INDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE and DOSAGE AND ADMINISTRATION). UNLIKE ADULT PATIENTS, PEDIATRIC PATIENTS GENERALLY RECEIVE INCREMENTS OF MIDAZOLAM ON A MG/KG BASIS. As a group, pediatric patients generally require higher dosages of midazolam (mg/kg) than do adults. Younger (less than six years) pediatric patients may require higher dosages (mg/kg) than older pediatric patients, and may require closer monitoring. In obese PEDIATRIC PATIENTS, the dose should be calculated based on ideal body weight. When midazolam is given in conjunction with opioids or other sedatives, the potential for respiratory depression, airway obstruction, or hypoventilation is increased. The health care practitioner who uses this medication in pediatric patients should be aware of and follow accepted professional guidelines for pediatric sedation appropriate to their situation.

Midazolam hydrochloride should not be administered by rapid injection in the neonatal population. Severe hypotension and seizures have been reported following rapid IV administration, particularly, with concomitant use of fentanyl.

Midazolam contain benzyl alcohol as a preservative. Benzyl alcohol, a component of this product, has been associated with serious adverse events and death, particularly in pediatric patients. The "gasping syndrome", (characterized by central nervous system depression, metabolic acidosis, gasping respirations, and high levels of benzyl alcohol and its metabolites found in the blood and urine) has been associated with benzyl alcohol dosages greater than 99 mg/kg/day in neonates and low-birth-weight neonates. Additional symptoms may include gradual neurological deterioration, seizures, intracranial hemorrhage, hematologic abnormalities, skin breakdown, hepatic and renal failure, hypotension, bradycardia, and cardiovascular collapse. Although normal therapeutic doses of this product deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birth-weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity. Practitioners administering this and other medications containing benzyl alcohol should consider the combined daily metabolic load of benzyl alcohol from all sources.

Animal Data

Published juvenile animal studies demonstrate that the administration of anesthetic and sedation drugs, such as Midazolam Injection USP, that either block NMDA receptors or potentiate the activity of GABA during the period of rapid brain growth or synaptogenesis, results in widespread neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis. Based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but may extend out to approximately 3 years of age in humans.

In primates, exposure to 3 hours of ketamine that produced a light surgical plane of anesthesia did not increase neuronal cell loss, however, treatment regimens of 5 hours or longer of isoflurane increased neuronal cell loss. Data from isoflurane-treated rodents and ketamine-treated primates suggest that the neuronal and oligodendrocyte cell losses are associated with prolonged cognitive deficits in learning and memory. The clinical significance of these nonclinical findings is not known, and healthcare providers

should balance the benefits of appropriate anesthesia in pregnant women, neonates, and young children who require procedures with the potential risks suggested by the nonclinical data (see WARNINGS, PEDIATRIC NEUROTOXICITY, PRECAUTIONS, PREGNANCY, and ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY).

Geriatric Use

Because geriatric patients may have altered drug distribution and diminished hepatic and/or renal function, reduced doses of midazolam are recommended. Intravenous and intramuscular doses of midazolam should be decreased for elderly and for debilitated patients (see WARNINGS and DOSAGE AND ADMINISTRATION) and subjects over 70 years of age may be particularly sensitive. These patients will also probably take longer to recover completely after midazolam administration for the induction of anesthesia. Administration of IM and IV midazolam to elderly and/or high-risk surgical patients has been associated with rare reports of death under circumstances compatible with cardiorespiratory depression. In most of these cases, the patients also received other central nervous system depressants capable of depressing respiration, especially narcotics (see DOSAGE AND ADMINISTRATION).

Specific dosing and monitoring guidelines for geriatric patients are provided in the DOSAGE AND ADMINISTRATION section for premedicated patients for sedation/anxiolysis/amnesia following IV and IM administration, for induction of anesthesia following IV administration and for continuous infusion.

CLOSE

ADVERSE REACTIONS

See WARNINGS concerning serious cardiorespiratory events and possible paradoxical reactions. Fluctuations in vital signs were the most frequently seen findings following parenteral administration of midazolam in adults and included decreased tidal volume and/or respiratory rate decrease (23.3% of patients following IV and 10.8% of patients following IM administration) and apnea (15.4% of patients following IV administration), as well as variations in blood pressure and pulse rate. The majority of serious adverse effects, particularly those associated with oxygenation and ventilation, have been reported when midazolam hydrochloride is administered with other medications capable of depressing the central nervous system. The incidence of such events is higher in patients undergoing procedures involving the airway without the protective effect of an endotracheal tube (e.g., upper endoscopy and dental procedures).

Adults

The following additional adverse reactions were reported after intramuscular administration:

headache (1.3%)	*Local effects at IM Injection site*
	pain (3.7%)
	induration (0.5%)
	redness (0.5%)
	muscle stiffness (0.3%)

Administration of IM midazolam hydrochloride to elderly and/or higher risk surgical patients has been associated with rare reports of death under circumstances compatible with cardiorespiratory depression. In most of these cases, the patients also received other central nervous system depressants capable of depressing respiration, especially narcotics (see DOSAGE AND ADMINISTRATION). The following additional adverse reactions were reported subsequent to intravenous administration as a single sedative/anxiolytic/amnestic agent in adult patients:

hiccoughs (3.9%)	*Local effects at the IV site*
nausea (2.8%)	tenderness (5.6%)
vomiting (2.6%)	pain during injection (5.0%)
coughing (1.3%)	redness (2.6%)
"oversedation" (1.6%)	induration (1.7%)
headache (1.5%)	phlebitis (0.4%)
drowsiness (1.2%)	

Pediatric Patients

The following adverse events related to the use of IV midazolam hydrochloride in pediatric patients were reported in the medical literature: desaturation 4.6%, apnea 2.8%, hypotension 2.7%, paradoxical reactions 2.0%, hiccough 1.2%, seizure-like activity 1.1% and nystagmus 1.1%. The majority of airway-related events occurred in patients receiving other CNS depressing medications and in patients where midazolam was not used as a single sedating agent.

Neonates

For information concerning hypotensive episodes and seizures following the administration of midazolam hydrochloride to neonates (see BOXED WARNING, CONTRAINDICATIONS, WARNINGS and PRECAUTIONS).

Other adverse experiences, observed mainly following IV injection as a single sedative/anxiolytic/amnesia agent and occurring at an incidence of 1.0% in adult and pediatric patients, are as follows:

Respiratory: Laryngospasm, bronchospasm, dyspnea, hyperventilation, wheezing, shallow respirations, airway obstruction, tachypnea

Cardiovascular: Bigeminy, premature ventricular contractions, vasovagal episode, bradycardia, tachycardia, nodal rhythm

Gastrointestinal: Acid taste, excessive salivation, retching

CNS/Neuromuscular: Retrograde amnesia, euphoria, hallucination, confusion, argumentativeness, nervousness, anxiety, grogginess, restlessness, emergence delirium or agitation, prolonged emergence from anesthesia, dreaming during emergence, sleep disturbance, insomnia, nightmares, athetoid movements, seizure-like activity, ataxia, dizziness, dysphoria, slurred speech, dysphonia, paresthesia

Special Senses: Blurred vision, diplopia, nystagmus, pinpoint pupils, cyclic movements of eyelids, visual disturbance, difficulty focusing eyes, ears blocked, loss of balance, light-headedness

Integumentary: Hive-like elevation at injection site, swelling or feeling of burning, warmth or coldness at injection site

Hypersensitivity: Allergic reactions including anaphylactoid reactions, hives, rash, pruritus

Miscellaneous: Yawning, lethargy, chills, weakness, toothache, faint feeling, hematoma

To report SUSPECTED ADVERSE REACTIONS, contact Alvogen at 1-866-770-3024 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

CLOSE

DRUG ABUSE AND DEPENDENCE

Midazolam hydrochloride contains midazolam, a Schedule IV control substance.

Midazolam was actively self-administered in primate models used to assess the positive reinforcing effects of psychoactive drugs.

Midazolam produced physical dependence of a mild to moderate intensity in cynomolgus monkeys after 5 to 10 weeks of administration. Available data concerning the drug abuse and dependence potential of midazolam suggest that its abuse potential is at least equivalent to that of diazepam.

Withdrawal symptoms, similar in character to those noted with barbiturates and alcohol (convulsions, hallucinations, tremor, abdominal and muscle cramps, vomiting and sweating), have occurred following abrupt discontinuation of benzodiazepines, including midazolam. Abdominal distention, nausea, vomiting, and tachycardia are prominent symptoms of withdrawal in infants. The more severe withdrawal symptoms have usually been limited to those patients who had received excessive doses over an extended period of time. Generally milder withdrawal symptoms (e.g., dysphoria and insomnia) have been reported following abrupt discontinuance of benzodiazepines taken continuously at therapeutic levels for several months. Consequently, after extended therapy, abrupt discontinuation should generally be avoided and a gradual dosage tapering schedule followed. There is no consensus in the medical literature regarding tapering schedules; therefore, practitioners are advised to individualize therapy to meet patient's needs. In some case reports, patients who have had severe withdrawal reactions due to abrupt discontinuation of high-dose long-term midazolam, have been successfully weaned off of midazolam over a period of several days.

CLOSE

OVERDOSAGE

Symptoms

The manifestations of midazolam overdosage reported are similar to those observed with other benzodiazepines, including sedation, somnolence, confusion, impaired coordination, diminished reflexes, coma and untoward effects on vital signs. No evidence of specific organ toxicity from midazolam hydrochloride overdosage has been reported.

Treatment

Treatment of injectable midazolam overdosage is the same as that followed for overdosage with other benzodiazepines. Respiration, pulse rate and blood pressure should be monitored and general supportive measures should be employed. Attention should be given to the maintenance of a patent airway and support of ventilation, including administration of oxygen. An intravenous infusion should be started. Should hypotension develop, treatment may include intravenous fluid therapy, repositioning, judicious use of vasopressors appropriate to the clinical situation, if indicated, and other appropriate countermeasures. There is no information as to whether peritoneal dialysis, forced diuresis or hemodialysis are of any value in the treatment of midazolam overdosage.

Flumazenil, a specific benzodiazepine-receptor antagonist, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines and may be used in situations when an overdose with a benzodiazepine is known or suspected. There are anecdotal reports of reversal of adverse hemodynamic responses associated with midazolam hydrochloride following administration of flumazenil to pediatric patients. Prior to the administration of flumazenil, necessary measures should be instituted to secure the airway, assure adequate ventilation, and establish adequate intravenous access. Flumazenil is intended as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. Patients treated with flumazenil should be monitored for resedation, respiratory depression and other residual benzodiazepine effects for an appropriate period after treatment. Flumazenil will only reverse benzodiazepine-induced effects but will not reverse the effects of other concomitant medications. The reversal of benzodiazepine effects may be associated with the onset of seizures in certain high-risk patients. The prescriber should be aware of a risk of seizure in association with flumazenil treatment, particularly in long-term benzodiazepine users and in cyclic antidepressant overdose. The complete flumazenil package insert, including CONTRAINDICATIONS, WARNINGS and PRECAUTIONS, should be consulted prior to use.

CLOSE

DOSAGE AND ADMINSTRATION

NOTE: CONTAINS BENZYL ALCOHOL (see WARNINGS and PRECAUTIONS, PEDIATRIC USE).

Midazolam injection is a potent sedative agent that requires slow administration and individualization of dosage. Clinical experience has shown midazolam hydrochloride to be 3 to 4 times as potent per mg as diazepam. BECAUSE SERIOUS AND LIFE-THREATENING CARDIORESPIRATORY ADVERSE EVENTS HAVE BEEN REPORTED, PROVISION FOR MONITORING, DETECTION AND CORRECTION OF THESE REACTIONS MUST BE MADE FOR EVERY PATIENT TO WHOM MIDAZOLAM INJECTION IS ADMINISTERED, REGARDLESS OF AGE OR HEALTH STATUS. Excessive single doses or rapid intravenous administration may result in respiratory depression, airway obstruction and/or arrest. The potential for these latter effects is increased in debilitated patients, those receiving concomitant medications capable of depressing the CNS, and patients without an endotracheal tube but undergoing a procedure involving the upper airway such as endoscopy or dental (see BOXED WARNING and WARNINGS).

Reactions such as agitation, involuntary movements, hyperactivity and combativeness have been reported in adult and pediatric patients. Should such reactions occur, caution should be exercised before continuing administration of midazolam hydrochloride (see WARNINGS).

Midazolam injection should only be administered IM or IV (see WARNINGS).

Care should be taken to avoid intra-arterial injection or extravasation (see WARNINGS).

Midazolam injection may be mixed in the same syringe with the following frequently used premedications: morphine sulfate, meperidine, atropine sulfate or scopolamine. Midazolam, at a concentration of 0.5 mg/mL, is compatible with 5% dextrose in water and 0.9% sodium chloride for up to 24 hours and with lactated Ringer's solution for up to 4 hours. The 5 mg/mL formulation of midazolam may be diluted with 0.9% sodium chloride or 5% dextrose in water.

Monitoring

Patient response to sedative agents, and resultant respiratory status, is variable. Regardless of the intended level of sedation or route of administration, sedation is a continuum; a patient may move easily from light to deep sedation, with potential loss of protective reflexes. This is especially true in pediatric patients. Sedative doses should be individually titrated, taking into account patient age, clinical status and concomitant use of other CNS depressants. Continuous monitoring of respiratory and cardiac function is required (i.e., pulse oximetry).

Adults and Pediatrics

Sedation guidelines recommend a careful presedation history to determine how a patient's underlying medical conditions or concomitant medications might affect their response to sedation/analgesia as well as a physical examination including a focused examination of the airway for abnormalities. Further recommendations include appropriate presedation fasting.

Titration to effect with multiple small doses is essential for safe administration. It should be noted that adequate time to achieve peak central nervous system effect (3 to 5 minutes) for midazolam should be allowed between doses to minimize the potential for oversedation. Sufficient time must elapse between doses of concomitant sedative medications to allow the effect of each dose to be assessed before subsequent drug administration. This is an important consideration for all patients who receive intravenous midazolam.

Immediate availability of resuscitative drugs and *age- and size-appropriate* equipment and personnel trained in their use and skilled in airway management should be assured (see WARNINGS).

Pediatrics

For deeply sedated pediatric patients a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.

Intravenous access is not thought to be necessary for all pediatric patients sedated for a diagnostic or therapeutic procedure because in some cases the difficulty of gaining IV access would defeat the purpose of sedating the child; rather, emphasis should be placed upon having the intravenous equipment available and a practitioner skilled in establishing vascular access in pediatric patients immediately available.

USUAL ADULT DOSE INTRAMUSCULARLY FOR PREOPERATIVE SEDATION/ANXIOLYSIS/AMNESIA	THE RECOMMENDED PREMEDICATION DOSE OF MIDAZOLAM FOR GOOD RISK (ASA PHYSICAL STATUS

(INDUCTION OF SLEEPINESS OR DROWSINESS AND RELIEF OF APPREHENSION AND TO IMPAIR MEMORY OF PERIOPERATIVE EVENTS). FOR INTRAMUSCULAR USE, MIDAZOLAM HYDROCHLORIDE SHOULD BE INJECTED DEEP IN A LARGE MUSCLE MASS.	I & II) ADULT PATIENTS BELOW THE AGE OF 60 YEARS IS 0.07 TO 0.08 MG/KG IM (APPROXIMATELY 5 MG IM) ADMINISTERED UP TO 1 HOUR BEFORE SURGERY. THE DOSE MUST BE INDIVIDUALIZED AND REDUCED WHEN IM MIDAZOLAM IS ADMINISTERED TO PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE, OTHER HIGHER RISK SURGICAL PATIENTS, PATIENTS 60 OR MORE YEARS OF AGE, AND PATIENTS WHO HAVE RECEIVED
INTRAVENOUSLY Sedation/anxiolysis/amnesia for procedures (see INDICATIONS): Narcotic premedication results in less variability in patient response and a reduction in dosage of midazolam. For peroral procedures, the use of an appropriate topical anesthetic is recommended. For bronchoscopic procedures, the use of narcotic premedication is recommended.	CONCOMITANT NARCOTICS OR OTHER CNS DEPRESSANTS (SEE ADVERSE REACTIONS). IN A STUDY OF PATIENTS 60 YEARS OR OLDER, WHO DID NOT RECEIVE CONCOMITANT ADMINISTRATION OF NARCOTICS, 2 TO 3 MG (0.02 TO 0.05 MG/KG) OF MIDAZOLAM PRODUCED ADEQUATE SEDATION DURING THE PREOPERATIVE PERIOD. THE DOSE OF 1 MG IM MIDAZOLAM HYDROCHLORIDE MAY SUFFICE FOR SOME OLDER PATIENTS IF THE ANTICIPATED INTENSITY AND DURATION OF SEDATION IS LESS CRITICAL. AS WITH ANY POTENTIAL RESPIRATORY DEPRESSANT, THESE PATIENTS REQUIRE OBSERVATION FOR SIGNS OF CARDIORESPIRATORY DEPRESSION AFTER RECEIVING IM MIDAZOLAM. When used for sedation/anxiolysis/amnesia for a procedure, dosage must be individualized and titrated. Midazolam hydrochloride should always be titrated slowly; administer over at least 2 minutes and allow an additional 2 or more minutes to fully evaluate the sedative effect. Individual response will vary with age, physical status and concomitant medications, but may also vary independent of these factors (see WARNINGS concerning cardiac/respiratory arrest/airway obstruction/hypoventilation.)
Midazolam hydrochloride 1 mg/mL formulation is recommended for sedation/anxiolysis/amnesia for procedures to facilitate slower injection. The 5 mg/mL formulation may be diluted with 0.9% sodium chloride or 5% dextrose in water.	ONSET IS WITHIN 15 MINUTES, PEAKING AT 30 TO 60 MINUTES. IT CAN BE ADMINISTERED CONCOMITANTLY WITH ATROPINE SULFATE OR SCOPOLAMINE HYDROCHLORIDE AND REDUCED DOSES OF NARCOTICS. *Healthy Adults Below the Age of 60:* Titrate slowly to the desired effect (e.g., the initiation of slurred speech). Some patients may respond to as little as 1 mg. No more than 2.5 mg should be given over a period of at least 2 minutes. Wait an additional 2 or more minutes to fully evaluate the sedative effect. If further titration is necessary, continue to titrate, using small increments, to the appropriate level of sedation. Wait an additional 2 or more minutes after each increment to fully evaluate the sedative effect. A total dose greater than 5 mg is not usually necessary to reach the desired endpoint. If narcotic premedication or other CNS depressants are used, patients will require approximately 30% less midazolam than unpremedicated patients. *Patients Age 60 or Older, and Debilitated or Chronically Ill Patients:* Because the danger of

	hypoventilation, airway obstruction, or apnea is greater in elderly patients and those with chronic disease states or decreased pulmonary reserve, and because the peak effect may take longer in these patients, increments should be smaller and the rate of injection slower. Titrate slowly to the desired effect (e.g., the initiation of slurred speech). Some patients may respond to as little as 1 mg. No more than 1.5 mg should be given over a period of no less than 2 minutes. Wait an additional 2 or more minutes to fully evaluate the sedative effect. If additional titration is necessary, it should be given at a rate of no more than 1 mg over a period of 2 minutes, waiting an additional 2 or more minutes each time to fully evaluate the sedative effect. Total doses greater than 3.5 mg are not usually necessary. If concomitant CNS depressant premedications are used in these patients, they will require at least 50% less midazolam than healthy young unpremedicated patients. *Maintenance Dose:* Additional doses to maintain the desired level of sedation may be given in increments of 25% of the dose used to first reach the sedative endpoint, but again only by slow titration, especially in the elderly and chronically ill or debilitated patient. These additional doses should be given only after a thorough clinical evaluation clearly indicates the need for additional sedation.
Induction of Anesthesia: For induction of general anesthesia, before administration of other anesthetic agents.	Individual response to the drug is variable, particularly when a narcotic premedication is not used. The dosage should be titrated to the desired effect according to the patient's age and clinical status. When midazolam is used before other intravenous agents for induction of anesthesia, the initial dose of each agent may be significantly reduced, at times to as low as 25% of the usual initial dose of the individual agents.

Unpremedicated Patients: In the absence of premedication, an average adult under the age of 55 years will usually require an initial dose of 0.3 to 0.35 mg/kg for induction, administered over 20 to 30 seconds and allowing 2 minutes for effect. If needed to complete induction, increments of approximately 25% of the patient's initial dose may be used; induction may instead be completed with inhalational anesthetics. In resistant cases, up to 0.6 mg/kg total dose may be used for induction, but such larger doses may prolong recovery.

Unpremedicated patients over the age of 55 years usually require less midazolam for induction; an initial dose of 0.3 mg/kg is recommended. Unpremedicated patients with severe systemic disease or other debilitation usually require less midazolam for induction. An initial dose of 0.2 to 0.25 mg/kg will usually suffice; in some cases, as little as 0.15 mg/kg may suffice.

Premedicated Patients: When the patient has received sedative or narcotic premedication, particularly narcotic premedication, the range of recommended doses is 0.15 to 0.35 mg/kg.

In average adults below the age of 55 years, a dose of 0.25 mg/kg, administered over 20 to 30 seconds and allowing 2 minutes for effect, will usually suffice.

The initial dose of 0.2 mg/kg is recommended for good risk (ASA I & II) surgical patients over the age of 55 years.

In some patients with severe systemic disease or debilitation, as little as 0.15 mg/kg may suffice.

Narcotic premedication frequently used during clinical trials included fentanyl (1.5 to 2 mcg/kg IV, administered 5 minutes before induction), morphine (dosage individualized, up to 0.15 mg/kg IM), and meperidine (dosage individualized, up to 1 mg/kg IM). Sedative premedications were hydroxyzine pamoate (100 mg orally) and sodium secobarbital (200 mg orally). Except for intravenous fentanyl, administered

	5 minutes before induction, all other premedications should be administered approximately 1 hour prior to the time anticipated for midazolam induction.
Injectable midazolam hydrochloride can also be used during maintenance of anesthesia, for surgical procedures, as a component of balanced anesthesia. Effective narcotic premedication is especially recommended in such cases.	Incremental injections of approximately 25% of the induction dose should be given in response to signs of lightening of anesthesia and repeated as necessary.
CONTINUOUS INFUSION For continuous infusion, midazolam hydrochloride 5 mg/mL formulation is recommended diluted to a concentration of 0.5 mg/mL with 0.9% sodium chloride or 5% dextrose in water.	*Usual Adult Dose:* If a loading dose is necessary to rapidly initiate sedation, 0.01 to 0.05 mg/kg (approximately 0.5 to 4.0 mg for a typical adult) may be given slowly or infused over several minutes. This dose may be repeated at 10 to 15 minute intervals until adequate sedation is achieved. For maintenance of sedation, the usual initial infusion rate is 0.02 to 0.10 mg/kg/hr (1 to 7 mg/hr). Higher loading or maintenance infusion rates may occasionally be required in some patients. The lowest recommended doses should be used in patients with residual effects from anesthetic drugs, or in those concurrently receiving other sedatives or opioids. Individual response to midazolam is variable. The infusion rate should be titrated to the desired level of sedation, taking into account the patient's age, clinical status and current medications. In general, midazolam should be infused at the lowest rate that produces the desired level of sedation. Assessment of sedation should be performed at regular intervals and the midazolam infusion rate adjusted up or down by 25% to 50% of the initial infusion rate so as to assure adequate titration of sedation level. Larger adjustments or even a small incremental dose may be necessary if rapid changes in the level of sedation are indicated. In addition, the infusion rate should be decreased by 10% to 25% every few hours to find the minimum effective infusion rate. Finding the minimum effective infusion rate decreases the potential accumulation of midazolam and provides for the most rapid recovery once the infusion is terminated.

	Patients who exhibit agitation, hypertension, or tachycardia in response to noxious stimulation, but who are otherwise adequately sedated, may benefit from concurrent administration of an opioid analgesic. Addition of an opioid will generally reduce the minimum effective midazolam hydrochloride infusion rate.
PEDIATRIC PATIENTS	UNLIKE ADULT PATIENTS, PEDIATRIC PATIENTS GENERALLY RECEIVE INCREMENTS OF MIDAZOLAM HYDROCHLORIDE ON A MG/KG BASIS. As a group, pediatric patients generally require higher dosages of midazolam hydrochloride (mg/kg) than do adults. Younger (less than six years) pediatric patients may require higher dosages (mg/kg) than older pediatric patients, and may require close monitoring (see tables below). In obese PEDIATRIC PATIENTS, the dose should be calculated based on ideal body weight. When midazolam is given in conjunction with opioids or other sedatives, the potential for respiratory depression, airway obstruction, or hypoventilation is increased. For appropriate patient monitoring, see BOXED WARNING, WARNINGS, MONITORING subsection of DOSAGE AND ADMINISTRATION. The health care practitioner who uses this medication in pediatric patients should be aware of and follow accepted professional guidelines for pediatric sedation appropriate to their situation.

OBSERVER'S ASSESSMENT OF ALERTNESS/SEDATION (OAA/S)				
Assessment Categories				
Responsiveness	Speech	Facial Expression	Eyes	Composite Score
Responds readily to name spoken in normal tone	normal	normal	clear, no ptosis	5 (alert)
Lethargic response to name spoken in normal tone	mild slowing or thickening	mild relaxation	glazed or mild ptosis (less than half the eye)	4

Responds only after name is called loudly and/or repeatedly	slurring or prominent slowing	marked relaxation (slack jaw)	glazed and marked ptosis (half the eye or more)	3
Responds only after mild prodding or shaking	few recognizable words	-	-	2
Does not respond to mild prodding or shaking	-	-	-	1 (deep sleep)

FREQUENCY OF OBSERVER'S ASSESSMENT OF ALERTNESS/SEDATION COMPOSITE SCORES IN ONE STUDY OF PEDIATRIC PATIENTS UNDERGOING PROCEDURES WITH INTRAVENOUS MIDAZOLAM FOR SEDATION

Age Range (years)	n	OAA/S Score				
		1 (deep sleep)	2	3	4	5 (alert)
1-2	16	6 (38%)	4 (25%)	3 (19%)	3 (19%)	0
>2-5	22	9 (41%)	5 (23%)	8 (36%)	0	0
>5-12	34	1 (3%)	6 (18%)	22 (65%)	5 (15%)	0
>12-17	18	0	4 (22%)	14 (78%)	0	0
Total (1-17)	90	16 (18%)	19 (21%)	47 (52%)	8 (9%)	0

INTRAMUSCULARLY	USUAL PEDIATRIC DOSE (NON-NEONATAL)
FOR SEDATION/ANXIOLYSIS/AMNESIA PRIOR TO ANESTHESIA OR FOR PROCEDURES, INTRAMUSCULAR	SEDATION AFTER INTRAMUSCULAR MIDAZOLAM IS AGE AND DOSE DEPENDENT: HIGHER DOSES MAY RESULT IN DEEPER AND MORE PROLONGED

MIDAZOLAM CAN BE USED TO SEDATE PEDIATRIC PATIENTS TO FACILITATE LESS TRAUMATIC INSERTION OF AN INTRAVENOUS CATHETER FOR TITRATION OF ADDITIONAL MEDICATION.	SEDATION. DOSES OF 0.1 TO 0.15 MG/KG ARE USUALLY EFFECTIVE AND DO NOT PROLONG EMERGENCE FROM GENERAL ANESTHESIA. FOR MORE ANXIOUS PATIENTS, DOSES UP TO 0.5 MG/KG HAVE BEEN USED. ALTHOUGH NOT SYSTEMATICALLY STUDIED, THE TOTAL DOSE USUALLY DOES NOT EXCEED 10 MG. IF MIDAZOLAM IS GIVEN WITH AN OPIOID, THE INITIAL DOSE OF EACH MUST BE REDUCED.
INTRAVENOUSLY BY INTERMITTENT INJECTION For sedation/anxiolysis/amnesia prior to and during procedures or prior to anesthesia.	USUAL PEDIATRIC DOSE (NON-NEONATAL) It should be recognized that the depth of sedation/anxiolysis needed for pediatric patients depends on the type of procedure to be performed. For example, simple light sedation/anxiolysis in the preoperative period is quite different from the deep sedation and analgesia required for an endoscopic procedure in a child. For this reason, there is a broad range of dosage. For all pediatric patients, regardless of the indications for sedation/anxiolysis, it is vital to titrate midazolam hydrochloride and other concomitant medications slowly to the desired clinical effect. The initial dose of midazolam should be administered over 2 to 3 minutes. Since midazolam hydrochloride is water soluble, it takes approximately three times longer than diazepam to achieve peak EEG effects, therefore one must wait an additional 2 to 3 minutes to fully evaluate the sedative effect before initiating a procedure or repeating a dose. If further sedation is necessary, continue to titrate with small increments until the appropriate level of sedation is achieved. If other medications capable of depressing the CNS are coadministered, the peak effect of those concomitant medications must be considered and the dose of midazolam adjusted. The importance of drug titration to effect is vital to the safe sedation/anxiolysis of the pediatric patient. The total dose of midazolam will depend on patient response, the type and duration of the procedure, as well as the type and dose of concomitant medications. *Pediatric Patients Less Than 6 Months of Age:* Limited information is available in non-intubated pediatric patients less than 6 months of age. It is uncertain

	when the patient transfers from neonatal physiology to pediatric physiology, therefore the dosing recommendations are unclear. Pediatric patients less than 6 months of age are particularly vulnerable to airway obstruction and hypoventilation, therefore titration with small increments to clinical effect and careful monitoring are essential. *Pediatric Patients 6 Months to 5 Years of Age:* Initial dose 0.05 to 0.1 mg/kg; a total dose up to 0.6 mg/kg may be necessary to reach the desired endpoint but usually does not exceed 6 mg. Prolonged sedation and risk of hypoventilation may be associated with the higher doses. *Pediatric Patients 6 to 12 Years of Age:* Initial dose 0.025 to 0.05 mg/kg; total dose up to 0.4 mg/kg may be needed to reach the desired endpoint but usually does not exceed 10 mg. Prolonged sedation and risk of hypoventilation may be associated with the higher doses. *Pediatric Patients 12 to 16 Years of Age:* Should be dosed as adults. Prolonged sedation may be associated with higher doses; some patients in this age range will require higher than recommended adult doses but the total dose usually does not exceed 10 mg. The dose of midazolam hydrochloride must be reduced in patients premedicated with opioid or other sedative agents including midazolam. Higher risk or debilitated patients may require lower dosages whether or not concomitant sedating medications have been administered (see WARNINGS).
CONTINUOUS INTRAVENOUS INFUSION For sedation/anxiolysis/amnesia in critical care settings.	USUAL PEDIATRIC DOSE (NON-NEONATAL) To initiate sedation, an intravenous loading dose of 0.05 to 0.2 mg/kg administered over at least 2 to 3 minutes can be used to establish the desired clinical effect IN PATIENTS WHOSE TRACHEA IS INTUBATED. (Midazolam should not be administered as a rapid intravenous dose.) This loading dose may be followed

	by a continuous intravenous infusion to maintain the effect. An infusion of midazolam injection has been used in patients whose trachea was intubated but who were allowed to breathe spontaneously. Assisted ventilation is recommended for pediatric patients who are receiving other central nervous system depressant medications such as opioids. Based on pharmacokinetic parameters and reported clinical experience, continuous intravenous infusions of midazolam should be initiated at a rate of 0.06 to 0.12 mg/kg/hr (1 to 2 mcg/kg/min). The rate of infusion can be increased or decreased (generally by 25% of the initial or subsequent infusion rate) as required, or supplemental intravenous doses of midazolam hydrochloride can be administered to increase or maintain the desired effect. Frequent assessment at regular intervals using standard pain/sedation scales is recommended. Drug elimination may be delayed in patients receiving erythromycin and/or other P450-3A4 enzyme inhibitors (see PRECAUTIONS, DRUG INTERACTIONS) and in patients with liver dysfunction, low cardiac output (especially those requiring inotropic support), and in neonates. Hypotension may be observed in patients who are critically ill, particularly those receiving opioids and/or when midazolam is rapidly administered. When initiating an infusion with midazolam in hemodynamically compromised patients, the usual loading dose of midazolam hydrochloride should be titrated in small increments and the patient monitored for hemodynamic instability (e.g., hypotension). These patients are also vulnerable to the respiratory depressant effects of midazolam and require careful monitoring of respiratory rate and oxygen saturation.
CONTINUOUS INTRAVENOUS INFUSION For sedation in critical care settings.	USUAL NEONATAL DOSE Based on pharmacokinetic parameters and reported clinical experience in preterm and term neonates WHOSE TRACHEA WAS INTUBATED, continuous intravenous infusions of midazolam injection should be initiated at a rate of 0.03 mg/kg/hr (0.5 mcg/kg/min) in neonates <32 weeks and 0.06

	mg/kg/hr (1 mcg/kg/min) in neonates >32 weeks. Intravenous loading doses should not be used in neonates, rather the infusion may be run more rapidly for the first several hours to establish therapeutic plasma levels. The rate of infusion should be carefully and frequently reassessed, particularly after the first 24 hours so as to administer the lowest possible effective dose and reduce the potential for drug accumulation. This is particularly important because of the potential for adverse effects related to metabolism of the benzyl alcohol (see WARNINGS, USAGE IN PRETERM INFANTS AND NEONATES). Hypotension may be observed in patients who are critically ill and in preterm and term infants, particularly those receiving fentanyl and/or when midazolam is administered rapidly. Due to an increased risk of apnea, extreme caution is advised when sedating preterm and former preterm patients whose trachea is not intubated.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

CLOSE

HOW SUPPLIED

Midazolam Injection, USP is supplied as follows:

NDC	Midazolam Injection, USP (5 mg per mL)	Package Factor
47781-589-17	25 mg per 5 mL Multi-Dose Vial	10 vials per carton
47781-589-91	50 mg per 10 mL Multi-Dose Vial	10 vials per carton

Storage Conditions
Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from light.

Sterile, Nonpyrogenic.

The container closure is not made with natural rubber latex.

CLOSE

ANIMAL TOXICOLOGY AND/OR PHARMACOLOGY

Published studies in animals demonstrate that the use of anesthetic agents during the period of rapid brain growth or synaptogenesis results in widespread neuronal and oligodendrocyte cell loss in the developing brain and alterations in synaptic morphology and neurogenesis. Based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester through the first several months of life, but may extend out to approximately 3 years of age in humans.

In primates, exposure to 3 hours of an anesthetic regimen that produced a light surgical plane of anesthesia did not increase neuronal cell loss, however, treatment regimens of 5 hours or longer increased neuronal cell loss. Data in rodents and in primates suggest that the neuronal and oligodendrocyte cell losses are associated with subtle but prolonged cognitive deficits in learning and memory. The clinical significance of these nonclinical findings is not known, and healthcare providers should balance the benefits of appropriate anesthesia in neonates and young children who require procedures against the potential risks suggested by the nonclinical data (see WARNINGS, PEDIATRIC NEUROTOXICITY and PRECAUTIONS, PREGNANCY and PEDIATRIC USE).

Manufactured by:
Gland Pharma Limited
D.P.Pally, Dundigal Post
Hyderabad-500 043, India

Product of India

Distributed by:
Alvogen, Inc.
Pine Brook, NJ07058 USA

Revised: May 2017
PI589-00

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PRINCIPAL DISPLAY PANEL

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – Carton

NDC 47781-589-17

Midazolam Injection, USP

C-IV

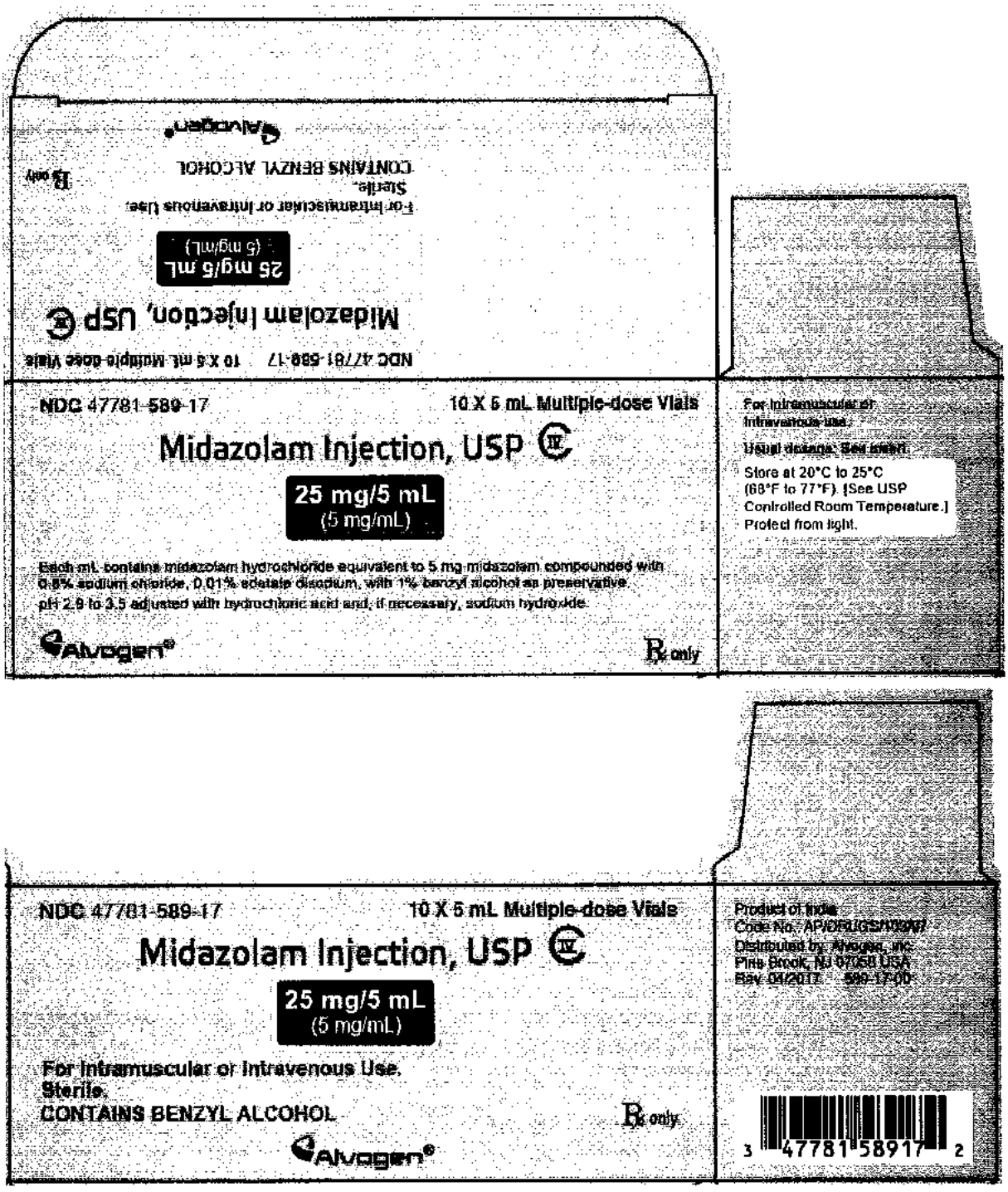
25 mg/5 mL

(5 mg/mL)

For Intramuscular or Intravenous Use. Sterile.

Rx only

CONTAINS BENZYL ALCOHOL



CLOSE

PRINCIPAL DISPLAY PANEL

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – Carton

NDC 47781-589-91

Midazolam Injection, USP

C-IV

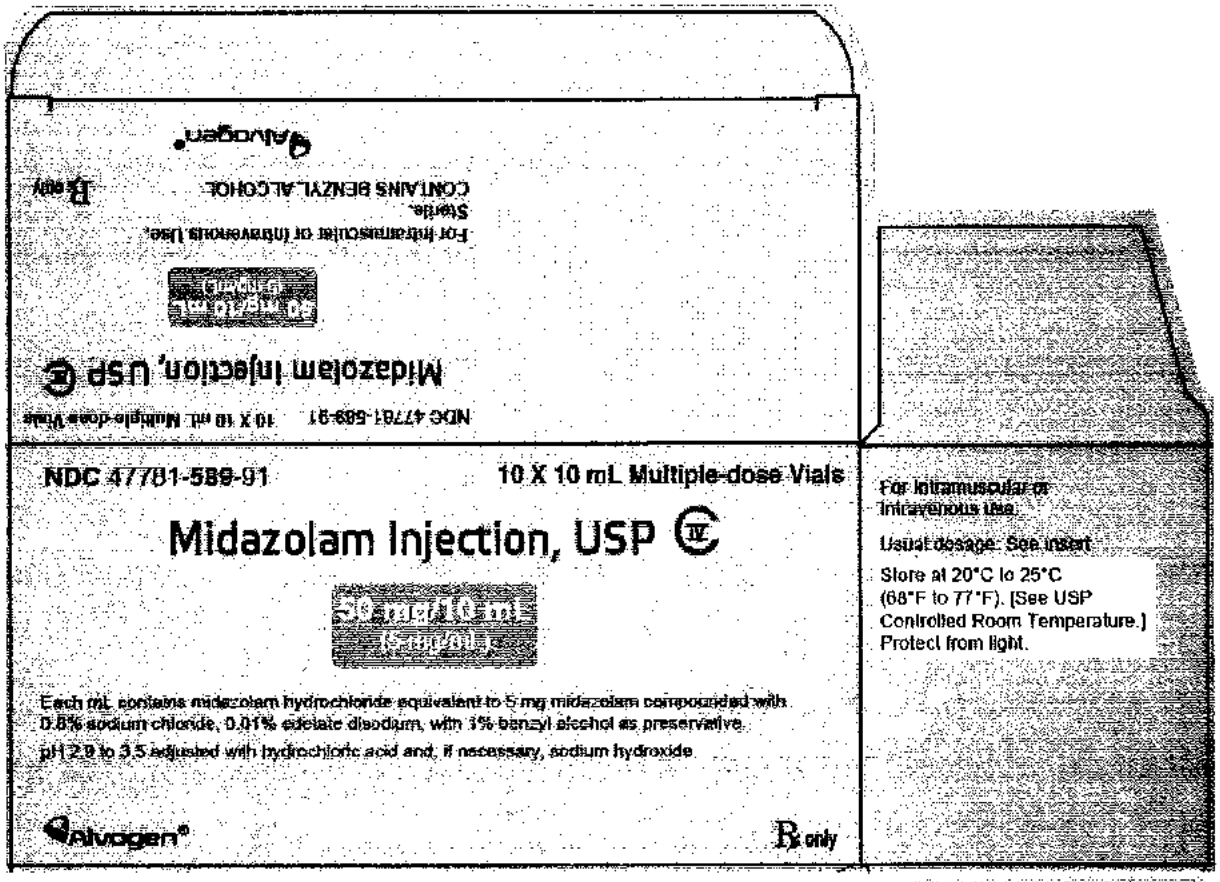
50 mg/10 mL

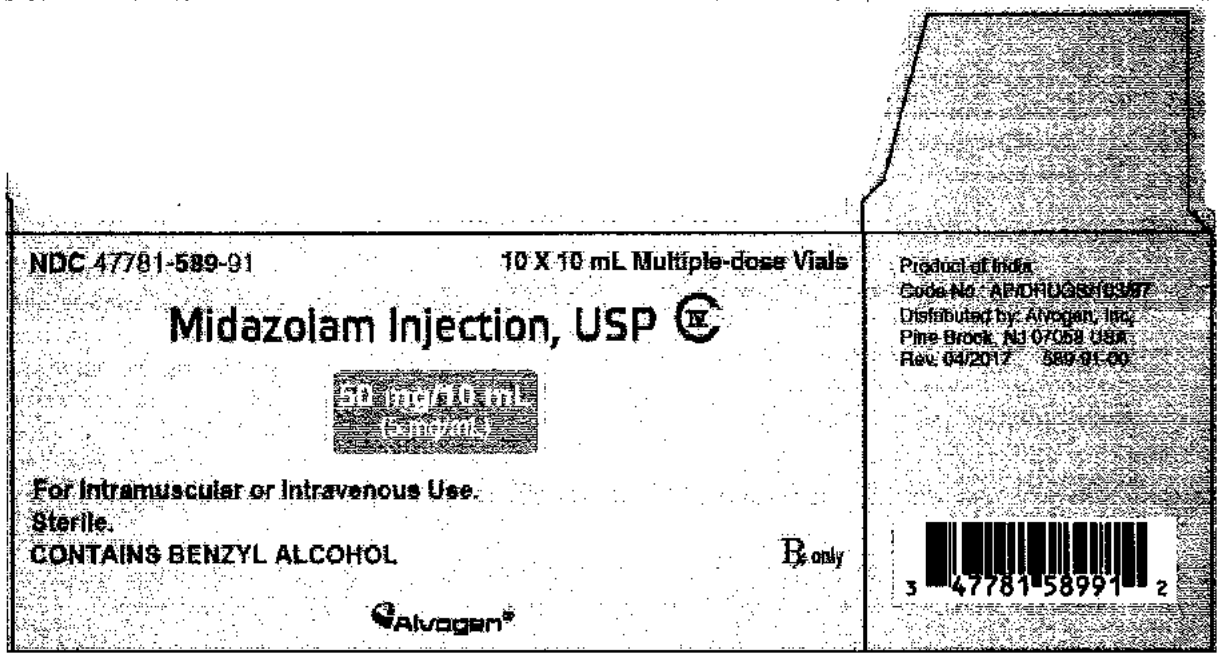
(5 mg/mL)

For Intramuscular or Intravenous Use. Sterile.

Rx only

CONTAINS BENZYL ALCOHOL





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INGREDIENTS AND APPEARANCE

MIDAZOLAM midazolam hydrochloride injection, solution

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:47781-589
Route of Administration	INTRAVENOUS, INTRAMUSCULAR	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	Basis of Strength	Strength
midazolam hydrochloride (UNII: W7TTW573JJ) (midazolam - UNII:R60L0SM5BC)	midazolam	5 mg in 1 mL

INACTIVE INGREDIENTS	
Ingredient Name	Strength
sodium chloride (UNII: 451W47IQ8X)	
edetate disodium (UNII: 7FLD91C86K)	
benzyl alcohol (UNII: LKG8494WBH)	
sodium hydroxide (UNII: 55X04QC32I)	
hydrochloric acid (UNII: QTT17582CB)	

PACKAGING				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47781-589-17	10 in 1 CARTON	08/11/2017	
1	NDC:47781-589-20	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
2	NDC:47781-589-91	10 in 1 CARTON	08/11/2017	
2	NDC:47781-589-22	10 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

MARKETING INFORMATION			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA090850	08/11/2017	

LABELER - ALVOGEN INC. (008057330)

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VIEW ALL SECTIONS

FIND ADDITIONAL RESOURCES (also available in the left menu)

SAFETY

Boxed Warnings, Report Adverse Events, FDA Safety Recalls, Presence in Breast Milk

RELATED RESOURCES

Medline Plus, Clinical Trials, PubMed, Biochemical Data Summary

MORE INFO ON THIS DRUG

View Label Archives, RxNorm, Get Label RSS Feed

NIH NLM

EXHIBIT 3

State Governor
State Attorney General
Director of the State Department of Corrections

April 20, 2018

Dear Warden Filson,

My name is Andrea Sweet and I am a Vice President, Legal Affairs at Alvogen, Inc.

Alvogen is aware that certain medicines we manufacture for specific healthcare applications are currently sought by some correctional facilities in the US for use in lethal injection executions.

I am writing to communicate in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment. While Alvogen takes no position on the death penalty itself, our products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

To ensure our products are not purchased for use in lethal injection executions, Alvogen does not accept orders from any state departments of corrections. Further, Alvogen has controls in place and directs its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions. These controls reflect our company's policy of ensuring the appropriate use of our medicines.

The use of Alvogen products, such as midazolam or rocuronium, in executions clearly runs counter to the FDA-approved indication for these products. If your state has purchased products manufactured by Alvogen for use in capital punishment procedures – either directly or indirectly – we ask that you immediately return our products in exchange for a full refund.

Finally, I have been informed that some states have implemented secrecy policies/laws" which they hope will enable them to bypass company control systems and purchase manufactured medicines for use in executions. Alvogen closely tracks the distribution of its medicines as required by law and will take action in case of such diversions. Transparency across the supply chain is important to protect public health and the commercial interests of healthcare companies.

If you require further clarification regarding our opposition to the misuse of medicines in executions or have questions about specific products you have purchased from Alvogen, please do not hesitate to contact me; I would be glad to discuss these issues further.

Sincerely,

Andrea Sweet
Vice President, Legal Affairs

10 Bloomfield Avenue
Building B
Pine Brook, NJ 07058

Phone 973 796 3400
Fax 973 796 3459

info@alvogen.com
www.alvogen.com

EXHIBIT 4

State Governor
State Attorney General
Director of the State Department of Corrections

April 20, 2018

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I am writing to communicate in the clearest possible terms that Alvogen strongly objects to the use of its products in capital punishment. While Alvogen takes no position on the death penalty itself, our products were developed to save and improve patients' lives and their use in executions is fundamentally contrary to this purpose.

To ensure our products are not purchased for use in lethal injection executions, Alvogen does not accept orders from any state departments of corrections. Further, Alvogen has controls in place and directs its customers not to sell its medicines to correctional facilities or otherwise for use in connection with lethal injection executions. These controls reflect our company's policy of ensuring the appropriate use of our medicines.

The use of Alvogen products, such as midazolam or rocuronium, in executions clearly runs counter to the FDA-approved indication for these products. If your state has purchased products manufactured by Alvogen for use in capital punishment procedures – either directly or indirectly – we ask that you immediately return our products in exchange for a full refund.

Finally, I have been informe□hat some states have implemente□secrecy policies/laws" which they hope will enable them to bypass company control systems and purchase manufactured medicines for use in executions. Alvogen closely tracks the distribution of its medicines as required by law and will take action in case of such diversions. Transparency across the supply chain is important to protect public health and the commercial interests of healthcare companies.

If you require further clarification regarding our opposition to the misuse of medicines in executions or have questions about specific products you have purchased from Alvogen, please do not hesitate to contact me; I would be glad to discuss these issues further.

Sincerely,

Andrea Sweet
Vice President, Legal Affairs

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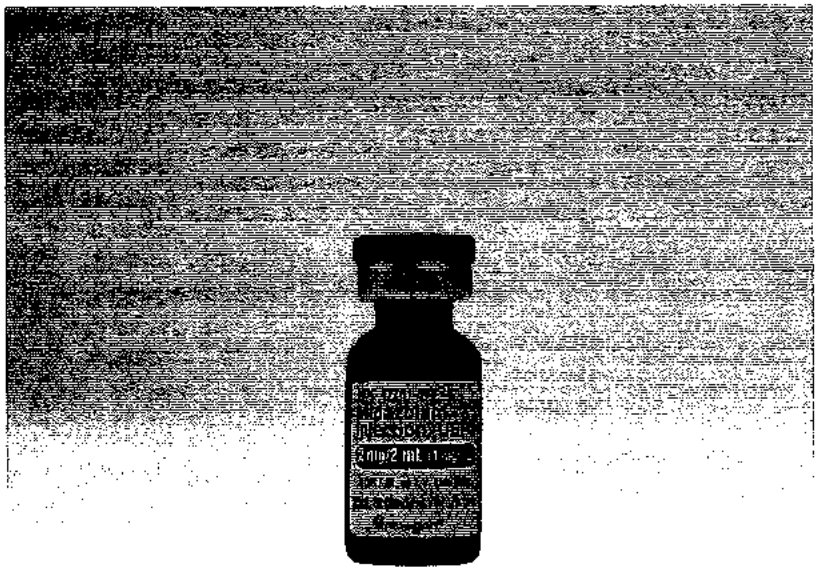
EXHIBIT 5

Midazolam Injection, USP C-IV Single Dose Vial

This product contains boxed warnings. See full prescribing information for this product.

Alvogen endorses the use of its products in accordance with FDA-approved indications. To this end, Alvogen has undertaken controls to avoid diversion of this product for use in execution protocols. In furtherance of this effort, Alvogen does not accept direct orders from prison systems or departments of correction. In addition, Alvogen is working to ensure that its distributors and wholesalers do not resell, either directly or indirectly this product, to prison systems or departments of correction.



MIDAZOLAM INJECTION, USP C-IV SINGLE DOSE VIAL

	NDC#	STRENGTH	PKG SIZE	GCN	GCN SEQ#	
	47781-588-88	2 mg/2 mL (1 mg/mL)	25			PRESCRIBING INFO **With Boxed Warnings**